VALUE-BASED CARE:
Blue Cross Blue Shield recognizes FCS as a
BLUE DISTINCTION® CENTER FOR CANCER CARE

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A Notable Distinction

At Florida Cancer Specialists (FCS), providing high quality oncology care that promotes value has become one of our top strategic initiatives. While value-based care has been our focus for the past 35 years, we have recently put that initiative to paper with formal agreements with major payer partners such as Cigna, Florida Blue, Medicare, and United Healthcare. Additionally, we have partnered with many local Accountable Care Organizations and Physician Health Organizations to continue our partnership with referring physicians to enhance the patient experience.

This summer, we were recognized as a Blue Distinction® Center for Cancer Care with Florida Blue. FCS is the only community medical oncology and hematology practice in Florida to earn this distinction. More than just another award, this distinction clearly demonstrates our commitment to patient-centered, value-based care.

How did we earn it? Beyond meeting the strict criteria for quality and affordability of care, our dedicated team put in the work by taking more than 250,000 phone calls from patients last year, including over 4,000 after-hours calls by our Care Management Team of oncology nurses to assist in managing care in between physician visits.

At FCS, we are constantly seeking regular feedback from our patients. The latest results of our Patient Experience Survey show that we’re on the right track and that you, as a physician, can be confident in referring patients to FCS. From October 2016 through June 2017, our patients rated us with an overall net promoter score of 8.4 out of 10. This score is higher than the national average of 7.5 achieved by the most high-touch service providers, such as the Ritz-Carlton.

Another aspect of patient-centered care is helping our patients manage the financial aspect of their care. In 2017, FCS assisted over 5,000 patients to obtain financial aid for their medications. This service is provided as we approach our care in a holistic manner. FCS Director of Patient Financial Services Christy Banach has much more to say on that topic. Her comments can be found in this issue’s Q+A feature.

A recent report by the Community Oncology Alliance examines the troubling national trend of the closure or consolidation of community oncology practices, forcing patients into a less patient-centric, more expensive hospital environment. Our story is essential reading for anyone concerned about the future of community oncology and why our value-based care strategic focus is so critical to healthcare.

Also in this issue, you’ll find the inspiring story of cancer-survivor Roger Vergin, who is an award-winning senior track star, and an article on how FCS is connecting Florida’s first responders to the care they need.

We hope you enjoy this edition of Cancer360 Plus. ♦

Sarah Cevallos
Chief Revenue Cycle Officer
Florida Cancer Specialists
Over the last decade, there has been a troubling national and statewide trend towards the closure and/or consolidation of community oncology practices, according to a 2018 Community Oncology Alliance (COA) Practice Impact Report. Unfortunately, Florida has led the United States in every problematic category. The result of this development is that more and more cancer patients are being forced into a less patient-centric, more expensive hospital environment.

“Everybody believes that when people get cancer, they will travel to the moon and back to get care. Unfortunately, that’s not the case. Research is pretty extensive on this – when patients have to travel because there’s less local access to care, they don’t get treated,” according to Ted Okon, the Executive Director of COA, who sites seniors with limited transportation alternatives as an example. “And whether it’s a Medicare patient or private pay patient, they’re going to pay more when they’re in the hospital. Not to mention the fact that they have to wait longer. It’s just not as patient-centric as community care.”

The problem can be more acute in rural areas, Okon explains. “Typically, clinics operating in rural areas are, at best, breaking even or subsidizing the care they offer. A hospital that takes over a practice that has rural facilities is governed more by the financial concerns of big corporate health systems than by patient interests. Consequently, rural sites are the first to close, especially if they’re just breaking even.”

Bucking the Trend
Defying this trend is Florida Cancer Specialists (FCS) and their commitment to value-based care in a community setting.

“FCS is in a unique position, in that they have developed a model that allows independent practices to join them without losing their own regional and local autonomy. Rather than primarily being merged into
one central site like a hospital and having people come to their buildings, FCS has allowed independent practices to remain active in their communities. And they have done it by merging into a larger entity that is more financially viable, while keeping the FCS brand and keeping that local activity in the community,” Okon says.

“FCS embodies the whole hallmark of community care in general, which is to provide the highest quality care at the most affordable cost, accessible in your community. It’s novel that FCS is a large entity operating very much on a local basis.”

With nearly 100 offices throughout Florida, FCS is the nation’s largest independently owned oncology/hematology practice.

Study: Community Oncology Practices Have Lost $78 Million Due to Medicare Sequester

Community oncology practices nationwide have lost $78 million as a result of the ongoing Medicare sequester cut to reimbursement for Part B drugs. This amounts to practices losing an average of more than $847,000 each due to the sequester cut, which has driven an increase in closings of community oncology practices in the United States.

Beginning in 2013, the Centers for Medicare & Medicaid Services (CMS) began to apply a two percent budget sequester cut to all Medicare Part B reimbursement, including for drugs.

Sequestration is an automatic cut to Federal government spending triggered because Congress was unable to negotiate a balanced budget in 2011. The blunt budget-cutting gimmick has been extended multiple times, with the current sequester scheduled to continue through 2027.

Published in late August 2018, the study, The Financial Impact of the Sequester Cut to Medicare Part B Drug Reimbursement in Community Oncology by FCS Oncologist, Lucio Gordan, MD; Cass Schaedig; and Susan Weidner, MBA, MS, found that all community oncology practices experienced a significant impact from sequestration. Examining data and reimbursement over a 27-month study period from January 2016 to March 2018, the authors found that at the beginning of 2016, each practice, on average, experienced an approximate 28-31 percent loss due to sequestration. This remained steady for large practices, while the small and medium practices began to experience more impact (38.4 and 34.7 percent, respectively). The overall average loss was 32 percent in the first quarter of 2018.

Read the full study on the Evidence-Based Oncology website: Ajmc.com.

EDITOR’S NOTE:
Our feature in the Fall + Winter 2017 issue of Cancer 360+, “New Report Demonstrates The Value of Community Oncology,” describes the findings of The Value of Community Oncology Site of Care Cost Analysis report. The study, by Dr. Lucio Gordan, President & Managing Physician at FCS and Xcenda, a global health economics consultancy, details the cost differentials between cancer care delivered at independent community oncology practices as opposed to hospital outpatient settings.
Florida Cancer Specialists & Research Institute (FCS) has been recognized by Blue Cross Blue Shield (BCBS) as a Blue Distinction Center for Cancer Care.

What is a “Blue Distinction Center?” According to Blue Cross Blue Shield, this new national designation program recognizes physicians, physician practices, cancer centers and hospitals for their efforts in delivering all types of high quality cancer care. The program recognizes patient-centered and data-driven practices that coordinate care better and improve the quality of care and safety, as well as affordability. Providers are paid under an agreement with their local BCBS Plan that uses value-based reimbursement, rather than traditional fee-for-service. Providers must perform against quality and cost outcome targets to receive incentives and rewards for better outcomes.

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FCS is the only community-based hematology and oncology practice in the state of Florida that has met these exacting standards and been awarded this recognition.

**Moving to a New Care Model: Embracing Value-Based Care**

“We’re a large organization with some pretty cutting-edge thinkers,” FCS Director of Value-Based Care Sierra Tomlinson, RN, MBA, BSN, OCN, explains. “The traditional fee-for-service model seemed unsustainable as more and more people are diagnosed with life-threatening illnesses. We believe this is where healthcare is going, and we want to be part of the solution. That’s why it’s a good idea to be leading, making changes that will make health care better for everyone. It’s a culture change, and it’s the right thing to do.”

This forward-leaning approach to care is also why FCS participates in similar programs with Cigna and United Health Care and is in talks with other insurers. As an Accountable Care Organization (ACO), FCS was also chosen for the patient-centric Oncology Care Model (OCM), which was established by the Centers for Medicare and Medicaid Innovation. The Centers for Medicare and Medicaid Services defines an ACO as a group of doctors, hospitals and other healthcare providers who come together to give high quality, coordinated care to Medicare patients.

“All those measures [delivering high-quality care and spending health care dollars more wisely] are to drive better quality to the patient under the program. It means 14,701 Medicare Patients and 2,909 Florida Blue patients are benefiting from value-based care.”

Sarah Cevallos
Chief Revenue Cycle Officer
Florida Cancer Specialists

“One of the key components of an ACO is being accountable,” according to FCS Chief Revenue Cycle Officer, Sarah Cevallos. “To operate as an ACO, we have to meet certain criteria, both financially and regarding quality of care, to get this distinction. Part of this change requires us to take the risk along with the payer. So, in addition to adhering to specific quality measures to be eligible for this distinction award, we have to assume some financial risk along with Florida Blue.”
When an ACO succeeds, both in delivering high-quality care and spending health care dollars more wisely, the ACO will share in the savings it achieves for the Medicare program.

“All those measures are to drive better quality to the patient under the program,” Cevallos says. It means 14,701 Medicare Patients and 2,909 Florida Blue patients are benefiting from value-based care.

**Providing a Higher Level of Patient-Centric Care**

To earn its Blue Distinction Cancer Center status, specific quality criteria had to be met: Offering accessibility to timely, multi-disciplinary, coordinated care; providing safe, evidence-based patient-centered care; measuring and improving the quality of cancer care; focusing on the patient experience and engagement in shared decision making; and committing to a value-based payment model (see table on quality selection criteria).

For patients, it translates to services not traditionally offered. One of the most successful of these new patient-centric programs is the FCS Care Management Program, under the guidance of Director of Care Management Don Champlain, MHA, RN. The program provides each of our patients a dedicated oncology-certified care nurse manager who works with the patient throughout the course of their treatment.

“As soon as a patient is referred for treatment, we try to coordinate with them prior to their first visit with the doctor,” Tomlinson explains. “They receive a call from someone on the Care Management Team to go over their history and complete medication list.

Moreover, they have the opportunity to do this in the privacy and comfort of their own home, so patients don’t feel overwhelmed when they come in for their first visit.

“Each patient is informed about basic care therapy and introduced to some of the primary medical terms they’ll be hearing. They’ll have a care plan that outlines the treatments they will be getting and the medications they will receive. They will review all of this again when they meet their oncologist, who will also explain what they can expect and where treatment will go from there.

“We follow up with our patients during their treatment to see how they’re doing, see what side effects they may be experiencing and help them, if at all possible, with managing them. There will also be a Care Management Team member on call 24/7 to help them.” In 2017, more than 250,000 calls were received by the Care Management team, with 4,276 of them after hours.

“When it’s not medically necessary, patients don’t have to go to the ER or hospital,” Care Management Director Champlain says. “They want to be able to be treated locally, stay in their home, surrounded by their loving support system of family and friends. We help them achieve that.” This approach also helps keep in check one of healthcare’s main cost drivers – unnecessary visits to the ER and hospital. Additional supportive services are also available through the Care Management Program, such as social workers and nutritionists.

“When patients have finished their treatment, we don’t just say ‘good luck’,” Tomlinson continues. “We have survivorship care plans and survivorship nurses who are part of our Care Management Team. These nurses contact patients when active treatment is completed to ensure patients receive the appropriate follow-up. We try to keep them healthy once they are finished with active treatment.”

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Value-Based Care
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However, this is not a “one size fits all” approach to care. FCS recognizes that not every patient has the same needs, so a survivorship nurse will reach out and go over things with them, based on how frequently they require additional interaction.

While every plan is customized to meet individual needs, they all follow survivorship regimens and guidelines from the National Comprehensive Cancer Network, a non-profit alliance of leading cancer centers devoted to patient care, research and education, and dedicated to improving the quality, effectiveness and efficiency of care so that patients can lead better lives.

Through every phase of care, the patient’s referring physician is kept in the loop, so they can be assured that FCS is looking at all aspects of their patient’s treatment and care, inside and outside of the office. FCS offers an orientation with each patient about their treatment plans and FCS physicians and other clinical staff can follow their patients using an online portal through Electronic Medical Records.

Collaborating with Florida Blue
To earn the Blue Distinction recognition, FCS had to demonstrate that the practice is following nationally recognized guidelines for treatment by providing therapies in an appropriate setting with proven and effective specific cancer treatment regimens for patients. The practice is continuously monitoring, evaluating and reporting to Florida Blue on outcomes.

As soon as someone is identified as a Florida Blue member, FCS begins collecting the data the insurer requires, starting a regular exchange of information with them about the patient and the care they’re receiving.

Florida Blue sends claims data to FCS, so it can examine how the practice is performing against the program’s different quality measures, such as patient satisfaction, staging, frequency of ER and hospital visits, and pain management. Of course, the cost is also carefully monitored.

To make sure it is meeting BCBS benchmarks, FCS continually looks at how it delivers treatment and care. Its regimens are evaluated through a rigorous process with the practice’s quality team to ensure they follow the most up-to-date, clinically relevant guidelines. So, too, are the protocols used by Care Management to manage patient symptoms so they can remain at home, comfortable and out of an emergency room or hospital where they’re going to be using additional resources that negatively affect quality of care and costs.

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“We believe this is where healthcare is going, and we want to be part of the solution. That’s why it’s a good idea to be leading, making changes that will make health care better for everyone. It’s a culture change, and it’s the right thing to do.”

Sierra Tomlinson, RN, MBA, BSN, OCN
Director of Value-Based Care
Florida Cancer Specialists
### QUALITY SELECTION CRITERIA

#### DELIVERY
**DEFINITION:** Accessibility to timely, multi-disciplinary, coordinated cancer care

1. Delivers coordinated multidisciplinary care, including coordinated cancer care, facilitating timely access to quality medical and psychosocial care, from pre-diagnosis through all phases of the cancer experience.

2. Delivers efficient, appropriate, and effective flow of necessary patient care information to providers and patients (e.g., use of EHR and patient portal).

3. Delivers care planning by managing patients throughout all stages of treatment, survivorship, and end of life (e.g., use of patient app “My Care Plan,” ASCO care plan template).

4. Facilitates multidisciplinary care (either within an integrated delivery system or through coordination within a virtually organized delivery system of medical neighborhood), to ensure that the patient has access to all of the following disciplines:
   - Medical Oncology
   - Radiation Oncology
   - Relevant Surgical Specialties
   - Nursing/Oncology Nursing
   - Palliative Care
   - Diagnostic Radiology
   - Pathology
   - Genetic Counseling
   - Social Work/Psychosocial Support
   - Rehabilitation
   - Appropriate referral to Specialists/Centers with expertise in treating complex and rare cancers; and
   - Access to clinical trials (as appropriate)

5. Ensures enhanced care access (open access scheduling, expanded hours, and new options for communication between patient and practice) to support urgent patient needs, in lieu of ER use.

#### QUALITY
**DEFINITION:** Commitment to providing safe, evidence-based, patient-centered care

6. Implements evidence-based care aligned with established guidelines/clinical pathways, as appropriate.

7. Implements patient-centered care by including patient/family in planning and goal setting, as well as managing symptoms, with the goal to improve the quality of life for both the patient and the family.

8. Commits to standard practices and monitoring for safe administration of chemotherapy, radiation, and surgery.

**DEFINITION:** Commitment to measuring and improving quality of cancer care

9. Commits to system-wide monitoring and reporting of quality measures (e.g., Quality Oncology Practice Initiative [QOPI] measures, ASCO Choosing Wisely, evolving national oncology core measures).

10. Incorporates measurement results into feedback and improvement of the cancer system of care.

#### UTILITY
**DEFINITION:** Focuses on patient experience and patient engagement in shared decision making

11. Engages patient (family) in shared decision-making process for goal setting and treatment planning that provides information on realistic expectations and impacts of treatment options, through use of appropriate tools, so that care delivers utility to the patient.

12. Participates in a standardized Patient Satisfaction and Experience Survey to evaluate and improve care delivery.
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**INDICATION AND USAGE**
CALQUENCE is a Bruton tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**IMPORTANT SAFETY INFORMATION**

**Hemorrhage**
Serious hemorrhagic events, including fatal events, have occurred in the combined safety database of 612 patients with hematologic malignancies treated with CALQUENCE monotherapy. Grade 3 or higher bleeding events, including gastrointestinal, intracranial, and epistaxis, have been reported in 2% of patients. Overall, bleeding events, including bruising and petechiae of any grade, occurred in approximately 50% of patients with hematological malignancies.

The mechanism for the bleeding events is not well understood. CALQUENCE may further increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant therapies, and patients should be monitored for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3 to 7 days pre- and post-surgery, depending upon the type of surgery and the risk of bleeding.

**Infection**
Serious infections (bacterial, viral, or fungal), including fatal events and opportunistic infections, have occurred in the combined safety database of 612 patients with hematologic malignancies treated with CALQUENCE monotherapy. Grade 3 or higher infections occurred in 18% of these patients. The most frequently reported Grade 3 or 4 infection was pneumonia. Infections due to hepatitis B virus (HBV) reactivation and progressive multifocal leukoencephalopathy (PML) have occurred.

Monitor patients for signs and symptoms of infection and treat as medically appropriate. Consider prophylaxis in patients who are at increased risk for opportunistic infections.

**Cytopenias**
In the combined safety database of 612 patients with hematologic malignancies, patients treated with CALQUENCE monotherapy experienced Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (11%), and thrombocytopenia (8%), based on laboratory measurements. Monitor complete blood counts monthly during treatment.

**Second Primary Malignancies**
Second primary malignancies, including non-skin carcinomas, have occurred in 11% of patients with hematologic malignancies treated with CALQUENCE monotherapy in the combined safety database of 612 patients. The most frequent second primary malignancy was skin cancer, reported in 7% of patients. Advise protection from sun exposure.

Please see Brief Summary of complete Prescribing Information on adjacent pages.
This indication is approved under accelerated approval for the treatment of adult patients with mantle cell lymphoma (MCL) and is contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

Serious hemorrhagic events, including fatal hemorrhages, have occurred in patients receiving CALQUENCE. Bleeding events, including hematomas, bruising and petechiae of any grade, occurred in 2% of patients. Overall, bleeding events, including post-surgery, have occurred in the combined safety database of 612 patients with hematologic malignancies treated with CALQUENCE.

Serious infections (bacterial, viral, or fungal), infection of surgery and the risk of bleeding.

Avoid co-administration with proton pump inhibitors. Due to the long-lasting effect of proton pump inhibitors, separation of doses may not eliminate the interaction with CALQUENCE.

SPECIFIC POPULATIONS

There is insufficient clinical data on CALQUENCE use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. Advise women of the potential risk to a fetus. It is not known if CALQUENCE is present in human milk. Advise lactating women not to breastfeed while taking CALQUENCE and for at least 2 weeks after the final dose.

Atrial Fibrillation and Flutter

In the combined safety database of 612 patients with hematologic malignancies treated with CALQUENCE monotherapy, atrial fibrillation and atrial flutter of any grade occurred in 3% of patients, and Grade 3 in 1% of patients. Monitor for atrial fibrillation and atrial flutter and manage as appropriate.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) of any grade were anemia, headache (39%), neutropenia, diarrhea (31%), fatigue (28%), myalgia (21%), and bruising (21%).

Atrial fibrillation and flutter of any grade occurred in 3% of patients, and Grade 3 in 1% of patients. Monitor for atrial fibrillation and atrial flutter and manage as appropriate.

*Treatment-emergent decreases (all grades) of hemoglobin (46%), platelets (44%), and neutrophils (36%) were based on laboratory measurements and adverse reactions.

The most common Grade ≥3 non-hematological adverse reaction (reported in at least 2% of patients) was diarrhea (3.2%). Dosage reductions or discontinuations due to any adverse reaction were reported in 1.6% and 6.5% of patients, respectively.

Increases in creatinine 1.5 to 3 times the upper limit of normal occurred in 4.8% of patients.

DRUG INTERACTIONS

Strong CYP3A Inhibitors: Avoid co-administration with a strong CYP3A inhibitor. If a strong CYP3A inhibitor will be used short-term, interrupt CALQUENCE.

Moderate CYP3A Inhibitors: When CALQUENCE is co-administered with a moderate CYP3A inhibitor, reduce CALQUENCE dose to 100 mg once daily.

Strong CYP3A Inducers: Avoid co-administration with a strong CYP3A inducer. If a strong CYP3A inducer cannot be avoided, increase the CALQUENCE dose to 200 mg twice daily.

Gastric Acid Reducing Agents: If treatment with a gastric acid reducing agent is required, consider using an H2-receptor antagonist or an antacid. Take CALQUENCE 2 hours before taking an H2-receptor antagonist. Separate dosing with an antacid by at least 2 hours.

Avoid co-administration with proton pump inhibitors. Due to the long-lasting effect of proton pump inhibitors, separation of doses may not eliminate the interaction with CALQUENCE.

Proven safety profile

Twice-daily dosing with a low pill burden

CALQUENCE®

(acalabrutinib) 100 mg capsules

VISIT CALQUENCE.COM
CALQUENCE® (acalabrutinib) capsules, for oral use
Initial U.S. Approval: 2017
Brief Summary of Prescribing Information. For full Prescribing Information consult official package insert.

INDICATIONS AND USAGE
CALQUENCE is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate [see Clinical Studies (14) in the full Prescribing Information]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSE AND ADMINISTRATION

Recommended Dosage
The recommended dose of CALQUENCE is 100 mg taken orally approximately every twelve hours until disease progression or unacceptable toxicity.

Advise patients to swallow capsule whole with water. Advise patients not to open, break or chew the capsules. CALQUENCE may be taken with or without food. If a dose of CALQUENCE is missed by more than 3 hours, it should be skipped and the next dose should be taken at its regularly scheduled time. Extra capsules of CALQUENCE should not be taken to make up for a missed dose.

Dose Modifications

Adverse Reactions
Recommended dose modifications of CALQUENCE for Grade 3 or greater adverse reactions are provided in Table 1.

Table 1: Recommended Dose Modifications for Adverse Reactions

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Occurrence</th>
<th>Dose Modification</th>
<th>(Starting dose = 100 mg twice daily)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 3 or greater non-hematologic toxicities, Grade 3 thrombocytopenia with bleeding, Grade 4 thrombocytopenia or Grade 4 neutropenia lasting longer than 7 days</td>
<td>First and Second</td>
<td>Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE therapy may be resumed at 100 mg twice daily.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Third</td>
<td>Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE therapy may be resumed at 100 mg daily.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fourth</td>
<td>Discontinue CALQUENCE.</td>
<td></td>
</tr>
</tbody>
</table>

Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.

Dose Modifications for Use with CY3PA Inhibitors or Inducers

Recommended dose modifications are described below [see Drug Interactions (7) in the full Prescribing Information].

CYP3A

<table>
<thead>
<tr>
<th>Inhibition</th>
<th>Co-administered Drug</th>
<th>Recommended CALQUENCE use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Induction</td>
<td>Strong CYP3A inhibitor</td>
<td>Avoid concomitant use. If these inhibitors will be used short-term (such as antiinfectives for up to seven days), interrupt CALQUENCE.</td>
</tr>
<tr>
<td></td>
<td>Moderate CYP3A inhibitor</td>
<td>100 mg once daily.</td>
</tr>
<tr>
<td>Induction</td>
<td>Strong CYP3A inducer</td>
<td>Avoid concomitant use. If these inducers cannot be avoided, increase CALQUENCE dose to 200 mg twice daily.</td>
</tr>
</tbody>
</table>

Concomitant Use with Gastric Acid Reducing Agents

Proton Pump Inhibitors: Avoid concomitant use [see Drug Interactions (7) in the full Prescribing Information].

H2-Receptor Antagonists: Take CALQUENCE 2 hours before taking a H2-receptor antagonist [see Drug Interactions (7) in the full Prescribing Information].

Antacids: Separate dosing by at least 2 hours [see Drug Interactions (7) in the full Prescribing Information].

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Hemorrhage

Serious hemorrhagic events, including fatal events, have occurred in the combined safety database of 612 patients with hematologic malignancies treated with CALQUENCE monotherapy.

Grade 3 or higher hemorrhages occurred in 1% of patients and Grade 3 or 4 hemorrhages occurred in 11% of patients. Hemorrhage has occurred most frequently as epistaxis, intracranial hemorrhage, and retroperitoneal hemorrhage.

In the CALQUENCE clinical Trial LY-004, patients’ complete blood counts were assessed monthly during treatment.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinomas, have occurred in 11% of patients with hematologic malignancies treated with CALQUENCE monotherapy in the combined safety database of 612 patients. The most frequent second primary malignancy was skin cancer, reported in 7% of patients. Advice protection from sun exposure.

Atrial Fibrillation and Flutter

In the combined safety database of 612 patients with hematologic malignancies treated with CALQUENCE monotherapy, atrial fibrillation and atrial flutter of any grade occurred in 3% of patients, and Grade 3 in 1% of patients. Monitor for atrial fibrillation and atrial flutter and manage as appropriate.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of this labeling:

- Hemorrhage [see Warnings and Precautions (5.5) in the full Prescribing Information]
- Infection [see Warnings and Precautions (5.2) in the full Prescribing Information]
- Cytopenias [see Warnings and Precautions (5.3) in the full Prescribing Information]
- Second Primary Malignancies [see Warnings and Precautions (5.4) in the full Prescribing Information]
- Atrial Fibrillation and Flutter [see Warnings and Precautions (5.5) in the full Prescribing Information]

Clinical Trials Experience

As clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the临床 trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety data described in this section reflect exposure to CALQUENCE (100 mg twice daily) in 124 patients with previously treated MCL in Trial LY-004 [see Clinical Studies (14) in the full Prescribing Information]. The median duration of treatment with CALQUENCE was 16.6 (range 0.1 to 26.6) months. A total of 91 (73.4%) patients were treated with CALQUENCE for ≥ 6 months and 74 (59.7%) patients were treated for ≥ 1 year.

The most common adverse reactions (≥ 20%) of any grade were anemia, thrombocytopenia, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising. Grade 1 severity for the non-hematologic, most common events were as follows: headache (25%), diarrhea (16%), fatigue (20%), myalgia (15%), and bruising (19%). The most common Grade 3 non-hematologic adverse reaction (reported in at least 2% of patients) was diarrhea.

Dose reductions or discontinuation due to any adverse reaction were reported in 1.6% and 6.6% of patients, respectively.

Tables 2 and 3 present the frequency category of adverse reactions observed in patients with MCL treated with CALQUENCE.

Table 2: Non-Hematologic Adverse Reactions* in ≥ 5% (All Grades) of Patients with MCL in Trial LY-004

<table>
<thead>
<tr>
<th>Body System</th>
<th>Adverse Reactions</th>
<th>CALQUENCE 100 mg twice daily</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades (%)</td>
<td>Grade ≥ 3 (%)</td>
</tr>
<tr>
<td>N=124</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Headache</td>
<td>39</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>Diarrhea</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>Nausea</td>
<td>19</td>
</tr>
<tr>
<td></td>
<td>Abdominal pain</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Constipation</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>Vomiting</td>
<td>13</td>
</tr>
<tr>
<td>General Disorders</td>
<td>Fatigue</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>Myalgia</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Skin &amp; subcutaneous tissue disorders</td>
<td>Bruising¹</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rash¹</td>
</tr>
<tr>
<td></td>
<td>Vascular disorders</td>
<td>Hemorrhage/Hematoma¹</td>
</tr>
<tr>
<td></td>
<td>Respiratory, thoracic &amp; mediastinal disorders</td>
<td>Epistaxis</td>
</tr>
</tbody>
</table>

* Per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03.

¹ Bruising: Includes all preferred terms (PTs) containing ‘bruise,’ ‘contusion,’ ‘petechiae,’ or ‘ecchymosis’

Rash: Includes all PTs containing ‘rash’

Hemorrhage/hematoma: Includes all PTs containing ‘hemorrhage’ or ‘hematoma’
CALQUENCE® (acalabrutinib) capsules, for oral use

Table 3: Hematologic Adverse Reactions Reported* in ≥ 20% of Patients with MCL in Trial LY-004

<table>
<thead>
<tr>
<th>Hematologic Adverse Reactions</th>
<th>CALQUENCE 100 mg twice daily</th>
<th>N=124</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades (%)</td>
<td>Grade ≥ 3 (%)</td>
</tr>
<tr>
<td>Hemoglobin decreased</td>
<td>46</td>
<td>10</td>
</tr>
<tr>
<td>Platelets decreased</td>
<td>44</td>
<td>12</td>
</tr>
<tr>
<td>Neutrophils decreased</td>
<td>36</td>
<td>15</td>
</tr>
</tbody>
</table>

*Per National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03; based on laboratory measurements and adverse reactions.

Increases in creatinine 1.5 to 3 times the upper limit of normal occurred in 4.8% of patients.

DRUG INTERACTIONS

Strong CYP3A Inhibitors

- **Clinical Impact**: Co-administration of CALQUENCE with a strong CYP3A inhibitor (itraconazole) increased acalabrutinib plasma concentrations [see Clinical Pharmacology (12.3) in the full Prescribing Information].
- **Prevention or Management**: Avoid co-administration of strong CYP3A inhibitors with CALQUENCE.
- **Prevention or Management**: Alternatively, if the inhibitor will be used short-term, interrupt CALQUENCE [see Dosage and Administration (2.2) in the full Prescribing Information].

Moderate CYP3A Inhibitors

- **Clinical Impact**: Co-administration of CALQUENCE with a moderate CYP3A inhibitor may increase acalabrutinib plasma concentrations [see Clinical Pharmacology (12.3) in the full Prescribing Information].
- **Prevention or Management**: When CALQUENCE is co-administered with moderate CYP3A inhibitors, reduce acalabrutinib dose to 100 mg once daily.

Strong CYP3A Inducers

- **Clinical Impact**: Co-administration of CALQUENCE with a strong CYP3A inducer (rifampin) decreased acalabrutinib plasma concentrations [see Clinical Pharmacology (12.3) in the full Prescribing Information].
- **Prevention or Management**: Avoid co-administration of strong CYP3A inducers with CALQUENCE.

Gastric Acid Reducing Agents

- **Clinical Impact**: Co-administration of CALQUENCE with a proton pump inhibitor, H2-receptor antagonist, or antacid may decrease acalabrutinib plasma concentrations [see Clinical Pharmacology (12.3) in the full Prescribing Information].
- **Prevention or Management**: Separate dosing by at least 2 hours [see Dosage and Administration (2.2) in the full Prescribing Information].

H2-receptor antagonists

- **Prevention or Management**: Take CALQUENCE 2 hours before taking the H2-receptor antagonist [see Dosage and Administration (2.2) in the full Prescribing Information].

Proton pump inhibitors

- **Avoid co-administration**. Due to the long-lasting effect of proton pump inhibitors, separation of doses may not eliminate the interaction with CALQUENCE.

USE IN SPECIFIC POPULATIONS

Pregnancy

**Risk Summary**

Based on findings in animals, CALQUENCE may cause fetal harm when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. In animal reproduction studies, administration of acalabrutinib to pregnant rabbits during organogenesis resulted in reduced fetal body weights and delayed ossification. The AUC at 100 mg/kg/day in pregnant rabbits was approximately 4-times the AUC in patients at 100 mg twice daily. The presence of acalabrutinib and its active metabolite were confirmed in fetal rat plasma.

In an embryo-fetal development study in rabbits, pregnant animals were administered acalabrutinib orally at doses up to 200 mg/kg/day during the period of organogenesis (from GD 6-18). Administration of acalabrutinib at doses ≥ 100 mg/kg/day produced maternal toxicity and 100 mg/kg/day resulted in decreased fetal body weights and delayed skeletal ossification. The AUC at 100 mg/kg/day in pregnant rabbits was approximately 4-times the AUC in patients at 100 mg twice daily.

**Lactation**

**Risk Summary**

No data are available regarding the presence of acalabrutinib or its active metabolite in human milk, its effects on the breastfed child, or on milk production. Acalabrutinib and its active metabolite were present in the milk of lactating rats. Due to the potential for adverse reactions in a breastfed child from CALQUENCE, advise lactating women not to breastfeed while taking CALQUENCE and for at least 2 weeks after the final dose.

**Pediatric Use**

The safety and efficacy of CALQUENCE in pediatric patients have not been established.

**Geriatric Use**

Eighty (84.5%) of the 124 MCL patients in clinical trials of CALQUENCE were 65 years of age or older, and 32 patients (25.8%) were 75 years of age or older. No clinically relevant differences in safety or efficacy were observed between patients ≥ 65 years and younger.

**PATIENT COUNSELING INFORMATION**

Advise the patient to read the FDA-approved patient labeling (Patient Information).

**Hemorrhage**

Inform patients to report signs or symptoms of severe bleeding. Inform patients that CALQUENCE may need to be interrupted for major surgeries [see Warnings and Precautions (5.1) in the full Prescribing Information].

**Infections**

Inform patients to report signs or symptoms suggestive of infection [see Warnings and Precautions (5.2) in the full Prescribing Information].

**Cytopenias**

Inform patients that they will need periodic blood tests to check blood counts during treatment with CALQUENCE [see Warnings and Precautions (5.3) in the full Prescribing Information].

**Second Primary Malignancies**

Inform patients that other malignancies have been reported in patients who have been treated with CALQUENCE, including skin cancer. Advise patients to use sun protection [see Warnings and Precautions (5.4) in the full Prescribing Information].

**Atrial Fibrillation and Flutter**

Counsel patients to report any signs of palpitations, lightheadedness, dizziness, fainting, shortness of breath, and chest discomfort [see Warnings and Precautions (5.5) in the full Prescribing Information].

**Dosing Instructions**

Instruct patients to take CALQUENCE orally twice daily, about 12 hours apart. CALQUENCE may be taken with or without food. Advise patients that CALQUENCE capsules should be swallowed whole with a glass of water, without being opened, broken, or chewed [see Dosage and Administration (2.1) in the full Prescribing Information].

**Missed Dose**

Advise patients that if they miss a dose of CALQUENCE, they may still take it up to 3 hours after the time they were supposed to take it. If more than 3 hours have elapsed, they should be instructed to skip that dose and take their next dose of CALQUENCE at the usual time. Warn patients they should not take extra capsules to make up for the dose that they missed [see Dosage and Administration (2.1) in the full Prescribing Information].

**Drug Interactions**

Advise patients to inform their healthcare providers of all concomitant medications, including over-the-counter medications, vitamins and herbal products [see Drug Interactions (7) in the full Prescribing Information].

**Lactation**

Advise women not to breastfeed during treatment with CALQUENCE and for at least 2 weeks after the final dose [see Use in Specific Populations (8.2) in the full Prescribing Information].

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11/17 US-17859 2/18
“I love this job,” Christy Banach told her manager after just three days at Florida Cancer Specialists (FCS) in 2001. Though she’s held a number of positions within the Operations, Managed Care, and Patient Financial Services departments over the course of her 17-year career at FCS, it’s a feeling she says she’s never lost.

Now, as Director of Patient Financial Services, Christy oversees a team of nearly 250 Financial Counselors and support staff, all committed to a single purpose – mitigating the financial stress of patients by helping them take charge of the “business side” of their care, so they can concentrate on getting well.

FCS Financial Counselors serve as a single point of contact for patients, available to answer their questions about medical bills, insurance forms, benefits and deductibles, as well as patient assistance programs or payment options that may help provide financial support for out-of-pocket expenses.

We recently had the opportunity to talk with Christy about how FCS Financial Counselors work with patients and the difference they make in patients’ lives.

What qualities do you feel are essential for a Financial Counselor to possess?

When we’re hiring, we naturally look for someone with some healthcare billing and collections experience. Nevertheless, we’re looking for compassionate and professional people. It can be difficult to talk to a patient about the financial implications of their care, so it’s crucial that Counselors speak with a patient in a calm and reassuring manner. How the Counselor reacts under stress when a patient is upset is integral in keeping a patient positive during their interaction.

How are Financial Counselors trained to deal with the ever-changing landscape in insurance coverage among the many insurers with whom they work?

They go through a rigorous training program, because there are so many insurances and variables, guidelines and authorizations. Since healthcare is ever-changing, it’s an ongoing training and education process.
Many of the processes we have in place for financial counseling have been in place and helping patients for many years. I think it’s part of what makes us great. We have a terrific team and system, but we’re always striving for excellence and improvement.

**Do Financial Counselors get involved in helping patients resolve disputes or denials from their insurers?**

Of course, there are times, for whatever the reasons, that an insurance company won’t authorize the care our doctors feel is necessary. Patients should know that our Financial Counselors will fight with the insurance companies for them. For example, we’ll provide a special peer-to-peer review to try to help overturn the insurance company’s decision.

**Does every FCS office have a Financial Counselor available to patients, and how are relationships between patients and Counselors established?**

Virtually every office, depending on its size, will have anywhere from a single Financial Counselor to as many as seven. Every Counselor is assigned a specific group of patients to work with, so that a relationship can be established. We don’t shuffle patients around to different Counselors each time they have a question or an issue. If a patient is having financial difficulties, say they fall behind on their bill, their Counselor will meet with them privately to explore options for them. Because that one-to-one relationship has been established, it’s easier to reach a satisfactory resolution.

**What do you feel is the single most challenging financial issue patients - and by extension Financial Counselors - face when a patient is referred to FCS?**

A patient who has no insurance and no means to pay for their treatment is the scariest situation. Unfortunately, we encounter a lot of patients who delay seeing a doctor because they don’t have insurance and are afraid the expenses they’ll face will be overwhelming. We want patients to know that having insurance shouldn’t stop them from seeking the care they need. There are options for them, whether they have insurance or not. Anything we can do to help get them treatment, we’ll do. That’s our goal.

**What are some of those options?**

We have a dedicated support team that works with our Financial Counselors to help patients get the financial assistance they might need.

First, there’s the FCS Foundation, which can help with non-medical expenses, such as household expenses, during treatment. We have pharmaceutical vendors that have programs available that provide financial assistance for specific drugs, and we have relationships with all sorts of foundations and 501(c)(3) programs that can assist patients with their high deductibles and/or out-of-pocket costs.

We’re there to assist with everything the patient needs to apply for help from one of these programs, with everything from income verification to filling out applications for assistance.

When they receive a grant or pharmaceutical help, we set up a meeting to let them know just what and how much they’ve been approved for and how many treatments it will cover. It’s a huge relief for patients and very rewarding for the Financial Counselors.

**Is the work the Financial Counselors do concerned exclusively with financial matters or are there various other matters that come up?**

We have patients who need other kinds of help – for example, transportation or other personal needs. We put them in touch with community programs to help them get through a difficult time.

I’m also proud that some of our Financial Counselors sponsor families for Christmas. It’s a pretty neat thing we’ve been able to do. A couple of my managers and I have adopted a family in Tampa for Christmas. It was really rewarding to bring them gifts and be a part of some happiness in a difficult situation. I really do have a caring group of Financial Counselors who do try to help however and wherever they can.

**You’ve had quite a career at FCS. What’s kept you, as you say, in love with the job?**

The amount of growth over the years has been tremendous. I’ve participated in 17 merger transitions, and that’s been something I’m very proud of. It’s meant having to travel and leave my kids at home, but helping these other practices join FCS and integrate into our processes and bring care to so many people is one of my personal pride moments.

Our goal is to make sure that every patient gets the care they need, that their questions are answered, that their fears are put to rest, that they’re treated with respect, and that they’re comfortable coming to Florida Cancer Specialists, talking to us and asking for help. ♦
Meet Jeffrey Phipps Sr. and Dr. Michael Diaz, the new Florida Cancer Specialists (FCS) Foundation Co-Chairs. In addition to their work on the Foundation Board, both men have a long history of socially responsible activity in their respective communities.

**Michael Diaz, MD**

In multiple leadership roles, Dr. Michael Diaz has worked tirelessly to improve the quality of healthcare and to help make it available to those in need. He has a wealth of experience to bring into his new role as Co-Chair of the FCS Foundation.

In addition to serving on the Foundation board, Dr. Diaz serves FCS as a member of the Executive Board and as the Practice’s Director of Patient Advocacy. He is also active in the Community Oncology Alliance (COA), serving as Vice President of the Board of Directors, as Co-Medical Director for the COA Patient Advocacy Network, and as a leader in the COA Payment Reform Task Force, working to champion Medical Oncology Health Care Reform.

Dr. Diaz is also on the Florida Society of Clinical Oncology (FLASCO) board of directors, serving as Immediate Past President, and he is active with the American Society of Clinical Oncology (ASCO), serving as a member of their Clinical Practice Community and a contributor to multiple work groups.

With 10 years of experience in the academic environment, including a Fellowship in Oncology and Hematology at the University of South Florida/Moffitt Cancer Center in Tampa, Dr. Diaz truly appreciates the advantages of community-
based care, including improved cost-effectiveness, the more personal approach, and the benefit of proximity that patients find in the FCS community oncology settings.

Dr. Diaz practices at the FCS St. Petersburg-St. Anthony’s and St. Petersburg-Pasadena offices. His commitment to making health care services available to those in need extends to his volunteer work participating in many medical missions to Kingston, Jamaica.

Jeffrey Phipps Sr., AWMA

As part of their charitable work in Palm Beach County, Jeffrey and Linda Phipps have co-chaired several Florida Cancer Specialists Foundation fundraisers, including hosting one of the Foundation's major fundraising events, the Polo Brunch in Wellington, Florida, for the past two years.

This year, Jeffrey is taking on a new leadership role at the behest of several FCS physician friends who believe his background would make a significant contribution to the Foundation's work. Several of the fundraising activities that he has suggested have been implemented by the Foundation’s staff and are expected to be helpful in achieving the Foundation’s goals.

In addressing his new leadership role, Phipps said, “My objective for the coming year is to assist in the growth of the Foundation and further its mission to help those in need of financial assistance while being treated for their cancer.”

Phipps is the Senior Member of the Phipps Group Wealth Management practice with Merrill Lynch in Delray Beach, Florida. While attending the Wharton School of the University of Pennsylvania, he earned several advanced designations, including an Accredited Wealth Management Advisor degree and a bachelor of science degree from the University of Nebraska. He has been working in financial services since 1970 and with Merrill Lynch since 2008.

Phipps serves on the University of Nebraska College of Business Administration Advisory Council, and he is on the board of directors for the Palm Beach County Medical Society Planning Committee. He also serves on the board of directors for Mounts Botanical Gardens and Lake Worth Drainage District, and he is an Executive Committee Member of the Historical Society of Palm Beach County.

Phipps and Linda, their two children and five grandchildren all reside in Palm Beach County.

“I can think of no better, more highly qualified individuals than Michael Diaz and Jeffrey Phipps to provide inspired leadership as the FCS Foundation advances its mission. I’m confident the Foundation is in good hands.”

Brad Prechtl, MBA
Chair Emeritus, FCS Foundation
CEO, Florida Cancer Specialists
“When it’s not medically necessary, patients don’t have to go to the ER or hospital, they want to be able to be treated locally, stay in their home, surrounded by their loving support system of family and friends.”

Don Champlain, MHA, RN
Director of Care Management
Florida Cancer Specialists

Florida Blue census reports provide information on patients so that FCS can compare their reports to Florida Blue’s. This helps to determine who needs follow up and ensures that those patients who do are getting appropriate help with their discharge planning and tracking. After discharge from the hospital, FCS follows up with an office visit to monitor the patient’s progress and, hopefully, prevent the need for further hospitalization.

“Another thing that Blue Distinction does so well is to focus on the patient experience and engagement,” Tomlinson says. “We survey all our patients and the Care Management Team does a separate survey to learn about the patient’s experience.

“In fact,” she continues, “the involvement of the Care Management Team is critical to this process, and they have a lot of compassionate and clinically adept staff working with them. They’re the face of this process to the patient. What I do behind the scenes is the reporting and gathering of all this information. They’re the ones talking to the patients and getting things done.”

An Exciting Time

“It’s exciting to be part of this important initiative,” Tomlinson says. “I’m a nurse first, an oncology nurse. That’s my background and my training, and I’ve worked almost exclusively in oncology. To be able to be part of these programs, to steer care in a direction that is more patient-centric, is truly gratifying. To let patients know we’re looking at all these quality measures to make their outreach more effective and efficient, particularly at a time when their world has been turned upside down and they’re dealing with some pretty devastating circumstances - it’s a really exciting time, and so important to our patients!”

Value-Based Care
continued from page 5
Diarrhea occurred in 81% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 86% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 90% of patients receiving Verzenio alone in MONARCH 1. Grade 3 diarrhea occurred in 9% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 13% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and in 20% of patients receiving Verzenio alone in MONARCH 1. Episodes of diarrhea have been associated with dehydration and infection.

Diarrhea incidence was greatest during the first month of Verzenio dosing. In MONARCH 3, the median time to onset of the first diarrhea event was 8 days, and the median duration of diarrhea for Grades 2 and 3 were 9 days and 6 days, respectively. In MONARCH 3, 19% of patients with diarrhea required a dose omission and 13% required a dose reduction. In MONARCH 2, 22% of patients with diarrhea required a dose omission and 22% required a dose reduction. The time to onset and resolution for diarrhea were similar across MONARCH 3, MONARCH 2, and MONARCH 1.

Instruct patients that at the first sign of loose stools, they should start antidiarrheal therapy such as loperamide, increase oral fluids, and notify their healthcare provider for further instructions and appropriate follow-up. For Grade 3 or 4 diarrhea, or diarrhea that requires hospitalization, discontinue Verzenio until toxicity resolves to ≤ Grade 1, and then resume Verzenio at the next lower dose.

Select Important Safety Information

Diarrhea occurred in 81% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 86% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 90% of patients receiving Verzenio alone in MONARCH 1. Grade 3 diarrhea occurred in 9% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 13% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and in 20% of patients receiving Verzenio alone in MONARCH 1. Episodes of diarrhea have been associated with dehydration and infection.

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For patients with HR+, HER2– MBC, including those with concerning clinical characteristics1–14†

Verzenio is indicated for the treatment of hormone receptor- positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) advanced or metastatic breast cancer (MBC):

- In combination with fulvestrant for women with disease progression following endocrine therapy
- In combination with an aromatase inhibitor (AI) for postmenopausal women as initial endocrine-based therapy
- As a single agent for adult patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

† Patients who received prior therapy with a CDK4 & 6 inhibitor were excluded from the MONARCH trials. There are currently no data regarding the use of Verzenio following use of another CDK4 & 6 inhibitor.

Disease characteristics that typically confer a less favorable prognosis. Visceral disease and progression on ET and prior chemotherapy in the metastatic setting were concerning clinical characteristics in MONARCH 1. Primary resistance and visceral disease were concerning clinical characteristics in MONARCH 2. Liver metastases and treatment-free interval <36 months were concerning clinical characteristics in MONARCH 3. Exploratory subgroup analyses of PFS were performed for patients with liver metastases and for patients with a treatment-free interval <36 months. CDK4 & 6=cyclin-dependent kinases 4 and 6; ET=endocrine therapy; PFS=progression-free survival.

Select Important Safety Information

Diarrhea occurred in 81% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 86% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 90% of patients receiving Verzenio alone in MONARCH 1. Grade 3 diarrhea occurred in 9% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 13% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and in 20% of patients receiving Verzenio alone in MONARCH 1. Episodes of diarrhea have been associated with dehydration and infection.

Diarrhea incidence was greatest during the first month of Verzenio dosing. In MONARCH 3, the median time to onset of the first diarrhea event was 8 days, and the median duration of diarrhea for Grades 2 and 3 were 9 days and 6 days, respectively. In MONARCH 3, 19% of patients with diarrhea required a dose omission and 13% required a dose reduction. In MONARCH 2, 22% of patients with diarrhea required a dose omission and 22% required a dose reduction. The time to onset and resolution for diarrhea were similar across MONARCH 3, MONARCH 2, and MONARCH 1.

Instruct patients that at the first sign of loose stools, they should start antidiarrheal therapy such as loperamide, increase oral fluids, and notify their healthcare provider for further instructions and appropriate follow-up. For Grade 3 or 4 diarrhea, or diarrhea that requires hospitalization, discontinue Verzenio until toxicity resolves to ≤ Grade 1, and then resume Verzenio at the next lower dose.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information for Verzenio on the following pages.
For women with HR+, HER2− MBC
Verzenio + AI as first-line endocrine-based therapy

>28-month median PFS as initial endocrine-based therapy

ITT\(^1\)

\[\text{28.2 months} \quad \text{mPFS}\]

\[
\left(95\% \text{ CI: } 23.5-\text{NR}\right) \text{ vs } \left(95\% \text{ CI: } 11.2-19.2\right) \quad \text{P}<0.001\]

- The percentage of events at the time of analysis was 42.1\% (n=138) and 65.5\% (n=108) in the Verzenio + AI and AI alone arms, respectively\(^3\)
- At the time of the PFS analysis, 19\% of patients had died, and overall survival data were immature\(^1\)

Exploratory subgroup analyses

PFS results in women with concerning clinical characteristics were consistent with the ITT population\(^1,3,9-14\)$

Verzenio + AI as initial endocrine-based therapy\(^1\)

Exploratory subgroup analyses

PFS results in women with concerning clinical characteristics were consistent with the ITT population\(^1,3,9-14\)$

Liver metastases\(^13\)

\[\text{15.0 months} \quad \text{vs} \quad \text{7.2 months} \quad \text{median PFS}\]

\[\left(95\% \text{ CI: } 74-23.7\right) \text{ vs } \left(95\% \text{ CI: } 2.1-14.0\right) \quad \text{HR=0.477} \left(95\% \text{ CI: } 0.272-0.837\right)\]

- Exploratory subgroup analyses of PFS were performed for the subgroups of patients with liver metastases or with treatment-free interval $<$36 months who received prior ET.

Treatment-free interval $<$36 months\(^44\)

\[\text{29.5 months} \quad \text{vs} \quad \text{9.0 months} \quad \text{median PFS}\]

\[\left(95\% \text{ CI: } 11.6-\text{NR}\right) \text{ vs } \left(95\% \text{ CI: } 3.7-14.2\right) \quad \text{HR=0.441} \left(95\% \text{ CI: } 0.241-0.805\right)\]

MONARCH 3 was a multicenter trial that enrolled 493 patients with HR+, HER2− locoregionally recurrent or MBC in combination with a nonsteroidal AI as initial endocrine-based therapy. The median patient age was 63 years (range, 32 to 88 years). Forty-seven percent of patients had received prior ET and 39\% of patients had received chemotherapy in the adjuvant setting. Patients were randomized 2:1 to Verzenio + AI or placebo + AI. Patients received either letrozole (80\%) or anastrozole (20\%). Verzenio was dosed continuously until disease progression or unacceptable toxicity. The primary endpoint was PFS. Key secondary endpoints were ORR and DoR.\(^1\)

Select Important Safety Information (cont’d)

Neutropenia occurred in 41\% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 46\% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and 37\% of patients receiving Verzenio alone in MONARCH 1. A Grade ≥3 decrease in neutrophil count (based on laboratory findings) occurred in 22\% of patients receiving Verzenio plus an aromatase inhibitor in MONARCH 3, 32\% of patients receiving Verzenio plus fulvestrant in MONARCH 2 and in 27\% of patients receiving Verzenio alone in MONARCH 1. In MONARCH 1, the median time to first episode of Grade ≥3 neutropenia was 33 days, and in MONARCH 2 and MONARCH 1, was 29 days. In MONARCH 3, median duration of Grade ≥3 neutropenia was 11 days, and for MONARCH 2 and MONARCH 1 was 15 days.

Monitor complete blood counts prior to the start of Verzenio therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.

Febrile neutropenia has been reported in $<$1\% of patients exposed to Verzenio in the MONARCH studies. Two deaths due to neutropenic sepsis were observed in MONARCH 2. Inform patients to promptly report any episodes of fever to their healthcare provider.

Grade ≥3 increases in alanine aminotransferase (ALT) (6\% versus 2\%) and aspartate aminotransferase (AST) (3\% versus 1\%) were reported in the Verzenio and placebo arms, respectively, in MONARCH 3. Grade ≥3 increases in ALT (4\% versus 2\%) and AST (2\% versus 3\%) were reported in the Verzenio and placebo arms respectively, in MONARCH 2.

$^1$Disease characteristics that typically confer a less favorable prognosis. Liver metastases and treatment-free interval $<$36 months were concerning clinical characteristics in MONARCH 3.

$^2$PFS=progression-free survival; CR=complete response; DoR=duration of response; HR=hazard ratio; ITT=intent-to-treat; NR=not reached; ORR=objective response rate; PR=partial response.

$^3$MONARCH 3 was a multicenter trial that enrolled 493 patients with HR+, HER2− MBC in combination with a nonsteroidal AI as initial endocrine-based therapy. The median patient age was 63 years (range, 32 to 88 years). Forty-seven percent of patients had received prior ET and 39\% of patients had received chemotherapy in the adjuvant setting. Patients were randomized 2:1 to Verzenio + AI or placebo + AI. Patients received either letrozole (80\%) or anastrozole (20\%). Verzenio was dosed continuously until disease progression or unacceptable toxicity. The primary endpoint was PFS. Key secondary endpoints were ORR and DoR.\(^1\)

$^4$CRI=confidence interval; CR=complete response; DoR=duration of response; HR=hazard ratio; ITT=intent-to-treat; NR=not reached; ORR=objective response rate; PR=partial response; RECIST 1.1=Response Evaluation Criteria in Solid Tumors version 1.1.

$^5$In patients with measurable disease; N=267 for the Verzenio + AI arm, N=132 for the AI alone arm.\(^1\)

$^6$Based upon confirmed responses.\(^1\)

$^7$IPI defined as $>$30\% reduction in target lesion size per RECIST 1.1.\(^1\)

$^8$Disease characteristics that typically confer a less favorable prognosis. Liver metastases and treatment-free interval $<$36 months were concerning clinical characteristics in MONARCH 3.
Verzenio + fulvestrant in patients who recurred or progressed on or after ET

>16-month median PFS in women who recurred or progressed on or after ET

**ITT**

16.4 months mPFS

(95% CI: 14.4-19.3) vs 9.3 months with fulvestrant alone (95% CI: 7.4-12.7)

HR=0.553 (95% CI: 0.449-0.681)

P<0.0001

- The percentage of events at the time of analysis was 49.8% (n=222) and 70.4% (n=157) in the Verzenio + fulvestrant and fulvestrant alone arms, respectively.
- At the time of the primary analysis of PFS, overall survival data were not mature (20% of patients had died).

- ORR was defined as the proportion of patients with CR + PR, and does not include stable disease.

**Disease characteristics that** typically confer a less favorable prognosis. Primary resistance and visceral disease were concerning clinical characteristics in MONARCH 2.

**Primary resistance**

15.3 months

(95% CI: 12.4-24.1) (n=111) vs 7.9 months with fulvestrant alone (95% CI: 5.7-11.4) (n=58)

HR=0.494 (95% CI: 0.306-0.674)

- Primary resistance is defined as relapse while on the first 2 years of adjuvant endocrine therapy, or progressive disease within the first 6 months of first-line endocrine therapy for metastatic breast cancer.
- Preplanned subgroup analyses of PFS were performed for stratification factors of disease site, including visceral disease, and endocrine resistance, including primary resistance. The analyses were not adjusted for multiplicity and the study was not powered to test the effect of Verzenio + fulvestrant among subgroups.

**Visceral disease**

14.7 months

(95% CI: 13.0-17.4) (n=245) vs 6.5 months with fulvestrant alone (95% CI: 5.6-8.7) (n=128)

HR=0.481 (95% CI: 0.369-0.627)

- Visceral disease was defined as at least 1 lesion on an internal organ or in the third space and could have included lung, liver, pleural, or peritoneal metastatic involvement.

MONARCH 2 was a phase III, randomized, double-blind, placebo-controlled trial that enrolled 669 patients with HR+, HER2– MBC who progressed on ET. Patients were randomized 2:1 to Verzenio + fulvestrant or placebo + fulvestrant. Verzenio was dosed on a continuous dosing schedule until disease progression or unacceptable toxicity. The primary endpoint was PFS. Key secondary endpoints were ORR, overall survival, and DoR.

**Select Important Safety Information (cont’d)**

Venous thromboembolic events were reported in 5% of patients treated with Verzenio plus an aromatase inhibitor plus placebo in MONARCH 3. Venous thromboembolic events were reported in 5% of patients treated with Verzenio plus fulvestrant in MONARCH 2 as compared to 0.9% of patients treated with fulvestrant plus placebo. Venous thromboembolic events included deep vein thrombosis, pulmonary embolism, pelvic venous thrombosis, cerebral venous sinus thrombosis, subclavian and axillary vein thrombosis, and inferior vena cava thrombosis. Across the clinical development program, deaths due to venous thromboembolism have been reported.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information for Verzenio on the following pages.
For heavily pretreated women with HR+, HER2− MBC

The only CDK4 & 6 inhibitor approved as a single agent

**ORR1**

19.7%

**95% CI: 13.3-27.5**

per investigator assessment

ORR was defined as the proportion of patients with CR + PR, and does not include stable disease.

- 17.4% ORR (95% CI: 11.4-25.0), per independent review

**Median duration of response (mDoR)**

8.6 months

**95% CI: 5.6-11.2**

- 3.7-month median time to response (range: 1.1-14.2 months)
- 7.2-month mDoR (95% CI: 5.6-NR), per independent review

### Select Important Safety Information (cont’d)

**MONARCH 1** was a single-arm, open-label, multicenter study in 132 women with measurable HR+, HER2− MBC whose disease progressed during or after ET, received taxane in any setting, and who received 1 or 2 prior chemotherapy regimens in the metastatic setting. Patients had an Eastern Cooperative Oncology Group Performance Status of 0 (55% of patients) or 1 (45% of patients). Patients took 200 mg of Verzenio orally twice daily on a continuous schedule unless disease progression or unacceptable toxicity occurred. The primary endpoint was ORR. A key secondary endpoint was DoR.

**Most common adverse reactions (all grades, ≥10%)** observed in MONARCH 1 with Verzenio were diarrhea (90%), fatigue (65%), nausea (64%), decreased appetite (45%), abdominal pain (39%), vomiting (39%), anemia (25%), leukopenia (24%), leukocytopenia (21%), neutropenia (19%), constipation (15%), dysgeusia (14%), stomatitis (12%), peripheral edema (12%), pruritus (11%), rash (11%), flatulence (10%), and weight decreased (10%).

**The most common adverse reactions (all grades, ≥10%)** observed in MONARCH 3 for Verzenio plus fulvestrant were diarrhea (86% vs 25%), neutropenia (46% vs 4%), fatigue (46% vs 32%), anemia (45% vs 23%), infections (43% vs 25%), abdominal pain (35% vs 16%), nausea (29% vs 4%), leukopenia (28% vs 2%), decreased appetite (27% vs 12%), vomiting (26% vs 10%), headache (20% vs 15%), dysgeusia (18% vs 3%), thrombocytopenia (16% vs 3%), alopecia (16% vs 2%), stomatitis (15% vs 10%), ALT increased (13% vs 5%), pruritus (13% vs 6%), cough (13% vs 11%), dizziness (12% vs 6%), AST increased (12% vs 7%), peripheral edema (12% vs 7%), creatinine increased (12% vs <1%), rash (11% vs 4%), pyrexia (11% vs 6%), and weight decreased (10% vs 2%).

**The most frequently reported ≥5% Grade 3 or 4 adverse reactions** that occurred in the Verzenio arm were neutropenia (22% vs 2%), diarrhea (9% vs 1%), leukopenia (8% vs <1%), ALT increased (7% vs 2%), and anemia (6% vs 1%).

**The most frequently reported ≥5% Grade 3 or 4 adverse reactions** that occurred in the Verzenio arm were neutropenia (27% vs 2%), diarrhea (13% vs <1%), leukopenia (9% vs 0%), anemia (7% vs 1%), and infections (6% vs 3%).

**The most frequently reported ≥5% Grade 3 or 4 adverse reactions** from MONARCH 1 with Verzenio were neutropenia (24%), diarrhea (20%), fatigue (13%), infections (7%), leukopenia (6%), anemia (5%), and nausea (5%).
Abemaciclib (Verzenio®): recommended by the National Comprehensive Cancer Network® (NCCN®)\(^{19}\)

**Abemaciclib (Verzenio): the only CDK4 & 6 inhibitor recommended by NCCN in combination with fulvestrant or an AI and as a single agent\(^{19}\)**

**CATEGORY 1\(^\ast\)**

**Abemaciclib (Verzenio) + fulvestrant\(^{19}\)**

Recommended option for the treatment of postmenopausal women with HR+, HER2– MBC after disease progression on prior ET

**Abemaciclib (Verzenio) + an AI\(^{19}\)**

Recommended option for the treatment of postmenopausal women with HR+, HER2– MBC as initial endocrine-based therapy

**CATEGORY 2A\(^{1}\)**

**Abemaciclib (Verzenio) as a single agent\(^{19}\)**

Recommended option for the treatment of postmenopausal women with HR+, HER2– MBC after disease progression on prior ET and prior chemotherapy in the metastatic setting

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**Select Important Safety Information (cont’d)**

**Lab abnormalities (all grades; Grade 3 or 4) for MONARCH 3 in ≥10% for Verzenio plus anastrozole or letrozole and ≥2% higher than placebo plus anastrozole or letrozole vs placebo plus anastrozole or letrozole**

- Increased serum creatinine (98% vs 84%; 2% vs 0%), decreased white blood cells (82% vs 27%; 13% vs <1%), anemia (82% vs 28%; 2% vs 0%), decreased neutrophil count (80% vs 21%; 22% vs 3%), decreased lymphocyte count (53% vs 26%; 8% vs 2%), decreased platelet count (36% vs 12%; 2% vs <1%), increased ALT (48% vs 25%; 7% vs 2%), and increased AST (37% vs 23%; 4% vs <1%).

**Lab abnormalities (all grades; Grade 3 or 4) for MONARCH 2 in ≥10% for Verzenio plus fulvestrant and ≥2% higher than placebo plus fulvestrant**

- Increased serum creatinine (98% vs 74%; 1% vs 0%), decreased white blood cells (90% vs 33%; 23% vs 1%), decreased neutrophil count (87% vs 30%; 33% vs 4%), anemia (84% vs 33%; 3% vs <1%), decreased lymphocyte count (63% vs 32%; 12% vs 2%), decreased platelet count (53% vs 15%; 2% vs 0%), increased ALT (41% vs 32%; 5% vs 1%), and increased AST (37% vs 25%; 4% vs 4%).

**Lab abnormalities (all grades; Grade 3 or 4) for MONARCH 1 with Verzenio**

- Increased serum creatinine (98%; <1%), decreased white blood cells (91%; 28%), decreased neutrophil count (88%; 27%), anemia (68%; 0%), decreased lymphocyte count (42%; 14%), decreased platelet count (41%; 2%), increased ALT (31%; 3%), and increased AST (30%; 4%).

**Strong CYP3A inhibitors**

increased the exposure of abemaciclib plus its active metabolites to a clinically meaningful extent and may lead to increased toxicity. Avoid concomitant use of ketoconazole. Ketoconazole is predicted to increase the AUC of abemaciclib by up to 16-fold. In patients with recommended starting doses of 200 mg twice daily or 150 mg twice daily, reduce the Verzenio dose to 100 mg twice daily with concomitant use of other strong CYP3A inhibitors. In patients who have had a dose reduction to 100 mg twice daily due to adverse reactions, further reduce the Verzenio dose to 50 mg twice daily with concomitant use of other strong CYP3A inhibitors. If a patient taking Verzenio discontinues a strong CYP3A inhibitor, increase the Verzenio dose (after 3 to 5 half-lives of the inhibitor) to the dose that was used before starting the strong inhibitor. Patients should avoid grapefruit products.

**Avoid concomitant use of strong CYP3A inducers and consider alternative agents.**

Coadministration of Verzenio with rifampin, a strong CYP3A inducer, decreased the plasma concentrations of abemaciclib plus its active metabolites and may lead to reduced activity.

**With severe hepatic impairment (Child-Pugh Class C), reduce the Verzenio dosing frequency to once daily.**

The pharmacokinetics of Verzenio in patients with severe renal impairment (CLcr <30 mL/min), end stage renal disease, or in patients on dialysis is unknown. No dosage adjustments are necessary in patients with mild or moderate hepatic (Child-Pugh A or B) and/or renal impairment (CLcr ≥30-89 mL/min).

AL HCP ISI 26FEB2018

Please see Brief Summary of full Prescribing Information for Verzenio on the following pages.
Please see Brief Summary of full Prescribing Information for Verzenio on the following pages.

VERZENIO™ (abemaciclib) tablets, for oral use

**INITIAL U.S. APPROVAL: 2017**

**BRIEF SUMMARY:** Consult the package insert for complete prescribing information.

**INDICATIONS AND USAGE**

VERZENIO™ (abemaciclib) is indicated:

- in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
- in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy.
- as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

**CONTRAINDICATIONS:** None

**WARNINGS AND PRECAUTIONS**

**Diarrhea**

Diarrhea occurred in 81% of patients receiving VERZENIO plus an aromatase inhibitor in MONARCH 3, 86% of patients receiving VERZENIO plus fulvestrant in MONARCH 2, and 90% of patients receiving VERZENIO alone in MONARCH 1. Grade 3 diarrhea occurred in 9% of patients receiving VERZENIO plus an aromatase inhibitor in MONARCH 3, 13% of patients receiving VERZENIO plus fulvestrant in MONARCH 2, and in 20% of patients receiving VERZENIO alone in MONARCH 1. Episodes of diarrhea have been associated with dehydration and infection.

Diarrhea incidence was greatest during the first month of VERZENIO dosing. In MONARCH 3, the median time to onset of the first diarrhea event was 8 days, and the median duration of diarrhea for Grades 2 and 3 were 11 and 8 days, respectively. In MONARCH 2, the median time to onset of the first diarrhea event was 6 days, and the median duration of diarrhea for Grades 2 and 3 were 9 days and 6 days, respectively. In MONARCH 3, 19% of patients with diarrhea required a dose omission and 13% required a dose reduction. In MONARCH 2, 22% of patients with diarrhea required a dose omission and 22% required a dose reduction. The time to onset and resolution for diarrhea were similar across MONARCH 3, MONARCH 2, and MONARCH 1.

Instruct patients that at the first sign of loose stools, they should start antidiarrheal therapy such as loperamide, increase oral fluids, and notify their healthcare provider for further instructions and appropriate follow up. For Grade 3 or 4 diarrhea, or diarrhea that requires hospitalization, discontinue VERZENIO until toxicity resolves to ≤ Grade 1, and then resume VERZENIO at the next lower dose.

**Neutropenia**

Neutropenia occurred in 41% of patients receiving VERZENIO plus an aromatase inhibitor in MONARCH 3, 46% of patients receiving VERZENIO plus fulvestrant in MONARCH 2, and 37% of patients receiving VERZENIO alone in MONARCH 1. A Grade 3 decrease in neutrophil count (based on laboratory findings) occurred in 22% of patients receiving VERZENIO plus an aromatase inhibitor in MONARCH 3, 32% of patients receiving VERZENIO plus fulvestrant in MONARCH 2, and in 27% of patients receiving VERZENIO in MONARCH 1. In MONARCH 3, the median time to first episode of Grade ≥ 3 neutropenia was 33 days, and in MONARCH 2 and MONARCH 1 was 29 days. In MONARCH 3, median duration of Grade ≥ 3 neutropenia was 11 days, and for MONARCH 2 and MONARCH 1 was 15 days.

Monitor complete blood counts prior to the start of VERZENIO therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia.

Febrile neutropenia has been reported in <1% of patients exposed to VERZENIO in the MONARCH studies. Two deaths due to neutropenic sepsis were observed in MONARCH 2. Inform patients to promptly report any episodes of fever to their healthcare provider.

**Hepatotoxicity**

In MONARCH 3, Grade ≥ 3 increases in ALT (6% versus 2%) and AST (3% versus 1%) were reported in the VERZENIO and placebo arms, respectively. In MONARCH 2, Grade ≥ 3 increases in ALT (4% versus 2%) and AST (2% versus 3%) were reported in the VERZENIO and placebo arms, respectively.

In MONARCH 3, for patients receiving VERZENIO plus an aromatase inhibitor with Grade ≥ 3 ALT increased, median time to onset was 61 days, and median time to resolution to Grade < 3 was 14 days. In MONARCH 2, for patients receiving VERZENIO plus fulvestrant with Grade ≥ 3 ALT increased, median time to onset was 57 days, and median time to resolution to Grade < 3 was 14 days. In MONARCH 3, for patients receiving VERZENIO plus an aromatase inhibitor with Grade ≥ 3 AST increased, median time to onset was 71 days, and median time to resolution was 15 days. In MONARCH 2, for patients receiving VERZENIO plus fulvestrant with Grade ≥ 3 AST increased, median time to onset was 185 days, and median time to resolution was 13 days.

Monitor liver function tests (LFTs) prior to the start of VERZENIO therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. Dose interruption, dose reduction, dose discontinuation, or delay in starting treatment cycles is recommended for patients who develop persistent or recurrent Grade 2, or Grade 3 or 4, hepatic transaminase elevation.

**Venous Thromboembolism**

In MONARCH 3, venous thromboembolic events were reported in 5% of patients treated with VERZENIO plus an aromatase inhibitor as compared to 0.6% of patients treated with an aromatase inhibitor plus placebo. In MONARCH 2, venous thromboembolic events were reported in 5% of patients treated with VERZENIO plus fulvestrant as compared to 0.9% of patients treated with fulvestrant plus placebo. Venous thromboembolic events included deep vein thrombosis, pulmonary embolism, pelvic venous thrombosis, cerebral venous sinus thrombosis, subclavian and axillary vein thrombosis, and inferior vena cava thrombosis. Across the clinical development program, deaths due to venous thromboembolism have been reported.

Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism and treat as medically appropriate.

**Embryo-Fetal Toxicity**

Based on findings from animal studies and the mechanism of action, VERZENIO can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of abemaciclib to pregnant rats during the period of organogenesis caused teratogenicity and decreased fetal weight at maternal exposures that were similar to the human clinical exposure based on area under the curve (AUC) at the maximum recommended human dose.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with VERZENIO and for at least 3 weeks after the last dose.

**ADVERSE REACTIONS**

**Clinical Studies Experience**

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

**MONARCH 3: VERZENIO in Combination with an Aromatase Inhibitor (Anastrozole or Letrozole) as Initial Endocrine-Based Therapy**

Postmenopausal Women with HR-positive, HER2-negative locoregionally recurrent or metastatic breast cancer with no prior systemic therapy in this disease setting

MONARCH 3 was a study of 488 women receiving VERZENIO plus an aromatase inhibitor or placebo plus an aromatase inhibitor. Patients were randomly assigned to receive 150 mg of VERZENIO or placebo orally twice daily, plus physician’s choice of anastrozole or letrozole once daily. Median duration of treatment was 15.1 months for the VERZENIO arm and 13.9 months for the placebo arm. Median dose compliance was 98% for the VERZENIO arm and 99% for the placebo arm.

Dose reductions due to an adverse reaction occurred in 43% of patients receiving VERZENIO plus anastrozole or letrozole. Adverse reactions leading to dose reductions in ≥ 5% of patients were diarrhea and neutropenia. VERZENIO dose reductions due to diarrhea of any grade occurred in 13% of patients receiving VERZENIO plus an aromatase inhibitor compared to 2% of patients receiving placebo plus an aromatase inhibitor. VERZENIO dose reductions due to neutropenia of any grade occurred in 11% of patients receiving VERZENIO plus an aromatase inhibitor compared to 0.6% of patients receiving placebo plus an aromatase inhibitor.

**Permanent treatment discontinuation due to an adverse event was reported in 13% of patients receiving VERZENIO plus an aromatase inhibitor and in 3% placebo plus an aromatase inhibitor. Adverse reactions leading to permanent discontinuation for patients receiving VERZENIO plus an aromatase inhibitor were diarrhea (2%), ALT increased (2%), infection (1%), venous thromboembolic events (VTE) (1%), neutropenia (0.9%), renal impairment (0.9%), AST increased (0.5%), dyspnea (0.6%), pulmonary fibrosis (0.6%) and anemia, rash, weight decreased and thrombocytopenia (each 0.3%).
Deaths during treatment or during the 30-day follow up, regardless of causality, were reported in 11 cases (3%) of VERZENIO plus an aromatase inhibitor treated patients versus 3 cases (2%) of placebo plus an aromatase inhibitor treated patients. Causes of death for patients receiving VERZENIO plus an aromatase inhibitor included: 3 (1%) patient deaths due to underlying disease, 3 (0.9%) due to lung infection, 3 (0.9%) due to VTE event, 1 (0.3%) due to pneumonitis, and 1 (0.3%) due to cerebral infarction.

The most common adverse reactions reported (≥20%) in the VERZENIO arm and ≥2% than the placebo arm were diarrhea, neutropenia, fatigue, infections, nausea, abdominal pain, anemia, vomiting, alopecia, decreased appetite, and leukopenia (Table 6). The most frequently reported (≥5%) Grade 3 or 4 adverse reactions were neutropenia, diarrhea, leukopenia, increased ALT, and anemia. Diarrhea incidence was greatest during the first month of VERZENIO dosing. The median time to onset of the first diarrhea event was 8 days, and the median durations of diarrhea for Grades 2 and for Grade 3 were 11 days and 8 days, respectively. Most diarrhea events recovered or resolved (88%) with supportive treatment and/or dose reductions. Nineteen percent of patients with diarrhea required a dose omission and 13% required a dose reduction. The median time to the first dose reduction due to diarrhea was 38 days.

### Table 6: Adverse Reactions ≥10% of Patients Receiving VERZENIO Plus Anastrozole or Letrozole and ≥2% Higher Than Placebo

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo plus Anastrozole or Letrozole</th>
<th>VERZENIO plus Anastrozole or Letrozole</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=327</td>
<td>N=161</td>
</tr>
<tr>
<td><strong>Gastrointestinal Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>81</td>
<td>9</td>
</tr>
<tr>
<td>Nausea</td>
<td>39</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>29</td>
<td>1</td>
</tr>
<tr>
<td>Vomiting</td>
<td>28</td>
<td>1</td>
</tr>
<tr>
<td>Constipation</td>
<td>16</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Infections and Infestations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infectionsa</td>
<td>39</td>
<td>4</td>
</tr>
<tr>
<td><strong>Blood and Lymphatic System Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutropenia</td>
<td>41</td>
<td>20</td>
</tr>
<tr>
<td>Anemia</td>
<td>28</td>
<td>6</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>21</td>
<td>7</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td><strong>General Disorders and Administration Site Conditions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>40</td>
<td>2</td>
</tr>
<tr>
<td>Influenza like illness</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td><strong>Skin and Subcutaneous Tissue Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alopecia</td>
<td>27</td>
<td>0</td>
</tr>
<tr>
<td>Rash</td>
<td>14</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Pruritis</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td><strong>Metabolism and Nutrition Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>24</td>
<td>1</td>
</tr>
<tr>
<td><strong>Investigations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood creatinine increased</td>
<td>19</td>
<td>2</td>
</tr>
<tr>
<td>Alanine aminotransferase increased</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>Aspartate aminotransferase increased</td>
<td>15</td>
<td>3</td>
</tr>
<tr>
<td>Weight decreased</td>
<td>10</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Respiratory, Thoracic, and Mediastinal Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>12</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Nervous System Disorders</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>11</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

a Includes all reported preferred terms that are part of the Infections and Infestations system organ class. Most common infections (≥1%) include upper respiratory tract infection, lung infection, and pharyngitis.

Additional adverse reactions in MONARCH 3 include venous thromboembolic events (deep vein thrombosis, pulmonary embolism, and pelvic venous thrombosis), which were reported in 5% of patients treated with VERZENIO plus anastrozole or letrozole as compared to 0.6% of patients treated with anastrozole or letrozole plus placebo.

### Table 7: Laboratory Abnormalities ≥10% in Patients Receiving VERZENIO Plus Anastrozole or Letrozole and ≥2% Higher Than Placebo

<table>
<thead>
<tr>
<th>Laboratory Abnormality</th>
<th>Placebo plus Anastrozole or Letrozole</th>
<th>VERZENIO plus Anastrozole or Letrozole</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Grades %</td>
<td>Grade 3 %</td>
</tr>
<tr>
<td>Creatinine increased</td>
<td>98</td>
<td>2</td>
</tr>
<tr>
<td>White blood cell decreased</td>
<td>82</td>
<td>13</td>
</tr>
<tr>
<td>Anemia</td>
<td>82</td>
<td>2</td>
</tr>
<tr>
<td>Neutrophil count decreased</td>
<td>80</td>
<td>19</td>
</tr>
<tr>
<td>Lymphocyte count decreased</td>
<td>53</td>
<td>7</td>
</tr>
<tr>
<td>Platelet count decreased</td>
<td>36</td>
<td>1</td>
</tr>
<tr>
<td>Alanine aminotransferase increased</td>
<td>48</td>
<td>6</td>
</tr>
<tr>
<td>Aspartate aminotransferase increased</td>
<td>37</td>
<td>4</td>
</tr>
</tbody>
</table>

**Creatine Increased**

Abemaciclib has been shown to increase serum creatinine due to inhibition of renal tubular secretion transporters, without affecting glomerular function. Across the clinical studies, increases in serum creatinine (mean increase, 0.2-0.3 mg/dL) occurred within the first 28-day cycle of VERZENIO dosing, remained elevated but stable through the treatment period, and were reversible upon treatment discontinuation. Alternative markers such as BUN, cystatin C, or calculated GFR, which are not based on creatinine, may be considered to determine whether renal function is impaired.

**MONARCH 2: VERZENIO in Combination with Fulvestrant**

Women with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression on or after prior adjuvant or metastatic endocrine therapy

The safety of VERZENIO (150 mg twice daily plus fulvestrant (500 mg) versus placebo plus fulvestrant was evaluated in MONARCH 2. The data described below reflect exposure to VERZENIO in 441 patients with HR-positive, HER2-negative advanced breast cancer who received at least one dose of VERZENIO plus fulvestrant in MONARCH 2.

Median duration of treatment was 12 months for patients receiving VERZENIO plus fulvestrant and 8 months for patients receiving placebo plus fulvestrant.

Dose reductions due to an adverse reaction occurred in 43% of patients receiving VERZENIO plus fulvestrant. Adverse reactions leading to dose reductions in ≥5% of patients were diarrhea and neutropenia. VERZENIO dose reductions due to diarrhea of any grade occurred in 19% of patients receiving VERZENIO plus fulvestrant compared to 0.4% of patients receiving placebo plus fulvestrant. VERZENIO dose reductions due to neutropenia of any grade occurred in 10% of patients receiving VERZENIO plus fulvestrant compared to no patients receiving placebo plus fulvestrant.

Permanent study treatment discontinuation due to an adverse event was reported in 9% of patients receiving VERZENIO plus fulvestrant and in 3% of patients receiving placebo plus fulvestrant. Adverse reactions leading to permanent discontinuation for patients receiving VERZENIO plus fulvestrant were infection (2%), diarrhea (1%), hepatotoxicity (1%), fatigue (0.7%), nausea (0.2%), abdominal pain (0.2%), acute kidney injury (0.2%), and cerebral infarction (0.2%).

Deaths during treatment or during the 30-day follow up, regardless of causality, were reported in 18 cases (4%) of VERZENIO plus fulvestrant treated patients versus 10 cases (5%) of placebo plus fulvestrant treated patients. Causes of death for patients receiving VERZENIO plus fulvestrant included: 7 (2%) patient deaths due to underlying disease, 4 (0.9%) due to sepsis, 2 (0.5%) due to pneumonitis, 2 (0.5%) due to hepatotoxicity, and one (0.2%) due to cerebral infarction.
Table 8: Adverse Reactions ≥10% in Patients Receiving VERZENIO Plus Fulvestrant and ≥2% Higher Than Placebo Plus Fulvestrant in MONARCH 2

<table>
<thead>
<tr>
<th></th>
<th>All Grades %</th>
<th>Grade 3 %</th>
<th>Grade 4 %</th>
<th>Placebo All Grades %</th>
<th>Grade 3 %</th>
<th>Grade 4 %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gastrointestinal Disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>86</td>
<td>13</td>
<td>0</td>
<td>25</td>
<td>&lt;1</td>
<td>0</td>
</tr>
<tr>
<td>Nausea</td>
<td>45</td>
<td>3</td>
<td>0</td>
<td>23</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Abdominal Pain**</td>
<td>35</td>
<td>2</td>
<td>0</td>
<td>16</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>26</td>
<td>&lt;1</td>
<td>0</td>
<td>10</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Stomatitis</td>
<td>15</td>
<td>&lt;1</td>
<td>0</td>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Infections and Infestations</strong></td>
<td></td>
<td></td>
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<td>24</td>
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<td>4</td>
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<td>Anemia*</td>
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<td><strong>General Disorders and Administration Site Conditions</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Fatigue**</td>
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<td>3</td>
<td>0</td>
<td>32</td>
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<td>0</td>
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<tr>
<td>Edema peripheral</td>
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<td>Pyrexia</td>
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<td>&lt;1</td>
<td>&lt;1</td>
<td>6</td>
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<tr>
<td><strong>Metabolism and Nutrition Disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>27</td>
<td>1</td>
<td>0</td>
<td>12</td>
<td>&lt;1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Respiratory, Thoracic and Mediastinal Disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Cough</td>
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<td>11</td>
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<td>0</td>
</tr>
<tr>
<td><strong>Skin and Subcutaneous Tissue Disorders</strong></td>
<td></td>
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<td>Pruritus</td>
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<td>Rash</td>
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<td>1</td>
<td>0</td>
<td>4</td>
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<td>0</td>
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<tr>
<td><strong>Nervous System Disorders</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>20</td>
<td>1</td>
<td>0</td>
<td>15</td>
<td>&lt;1</td>
<td>0</td>
</tr>
<tr>
<td>Dysgeusia</td>
<td>18</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>12</td>
<td>1</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Investigations</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alanine aminotransferase increased</td>
<td>13</td>
<td>4</td>
<td>&lt;1</td>
<td>5</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Aspartate aminotransferase increased</td>
<td>12</td>
<td>2</td>
<td>0</td>
<td>7</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Creatinine increased</td>
<td>12</td>
<td>&lt;1</td>
<td>0</td>
<td>&lt;1</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Weight decreased</td>
<td>10</td>
<td>&lt;1</td>
<td>0</td>
<td>2</td>
<td>&lt;1</td>
<td>0</td>
</tr>
</tbody>
</table>

* Includes abdominal pain, abdominal pain upper, abdominal pain lower, abdominal discomfort, abdominal tenderness.
** Includes upper respiratory tract infection, urinary tract infection, lung infection, pharyngitis, conjunctivitis, sinusitis, vaginal infection, sepsis.
* Includes neutropenia, neutrophil count decreased.
* Includes anemia, hematocrit decreased, hemoglobin decreased, red blood cell count decreased.
* Includes leukopenia, white blood cell count decreased.
* Includes platelet count decreased, thrombocytopenia.
* Includes asthenia, fatigue.

Additional adverse reactions in MONARCH 2 include venous thromboembolic events (deep vein thrombosis, pulmonary embolism, cerebral venous sinus thrombosis, subclavian vein thrombosis, axillary vein thrombosis, and DVT inferior vena cava), which were reported in 5% of patients treated with VERZENIO plus fulvestrant as compared to 0.9% of patients treated with fulvestrant plus placebo.

Table 9: Laboratory Abnormalities ≥10% in Patients Receiving VERZENIO Plus Fulvestrant and ≥2% Higher Than Placebo Plus Fulvestrant in MONARCH 2

<table>
<thead>
<tr>
<th></th>
<th>VERZENIO plus Fulvestrant N=441</th>
<th>Placebo plus Fulvestrant N=223</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Grades</strong></td>
<td><strong>Grade 3</strong></td>
<td><strong>Grade 4</strong></td>
</tr>
<tr>
<td>Creatinine increased</td>
<td>98 %</td>
<td>1 %</td>
</tr>
<tr>
<td>White blood cell decreased</td>
<td>90 %</td>
<td>23 %</td>
</tr>
<tr>
<td>Neutrophil count decreased</td>
<td>87 %</td>
<td>29 %</td>
</tr>
<tr>
<td>Anemia</td>
<td>84 %</td>
<td>3 %</td>
</tr>
<tr>
<td>Lymphocyte count decreased</td>
<td>63 %</td>
<td>12 %</td>
</tr>
<tr>
<td>Platelet count decreased</td>
<td>53 %</td>
<td>&lt;1 %</td>
</tr>
<tr>
<td>Alanine aminotransferase increased</td>
<td>41 %</td>
<td>4 %</td>
</tr>
<tr>
<td>Aspartate aminotransferase increased</td>
<td>37 %</td>
<td>4 %</td>
</tr>
</tbody>
</table>

**Creatinine Increased**
Abemaciclib has been shown to increase serum creatinine due to inhibition of renal tubular secretion transporters, without affecting glomerular function. In clinical studies, increases in serum creatinine (mean increase, 0.2 mg/dL) occurred within the first 28-day cycle of VERZENIO dosing, remained elevated but stable through the treatment period, and were reversible upon treatment discontinuation. Alternative markers such as iBUN, cystatin C, or calculated glomerular filtration rate (GFR), which are not based on creatinine, may be considered to determine whether renal function is impaired.

**VERZENIO Administered as a Monotherapy in Metastatic Breast Cancer (MONARCH 1)**
Patients with HR-positive, HER2-negative breast cancer who received prior endocrine therapy and 1-2 chemotherapy regimens in the metastatic setting.

Safety data below are based on MONARCH 1, a single-arm, open-label, multicenter study in 132 women with measurable HR+, HER2- metastatic breast cancer. Patients received 200 mg VERZENIO orally twice daily until development of progressive disease or unacceptable toxicity. Median duration of treatment was 4.5 months.

Ten patients (8%) discontinued study treatment from adverse reactions due to (1 patient each) abdominal pain, arterial thrombosis, aspartate aminotransferase (AST) increased, blood creatinine increased, chronic kidney disease, diarrhea, ECG QT prolonged, fatigue, hip fracture, and lymphopenia. Forty-nine percent of patients had dose reductions due to an adverse reaction. The most frequent adverse reactions that led to dose reductions were diarrhea (20%), neutropenia (11%), and fatigue (9%).

Deaths during treatment or during the 30-day follow-up were reported in 2% of patients. Cause of death in these patients was due to infection.

The most common reported adverse reactions (≥20%) were diarrhea, fatigue, nausea, decreased appetite, abdominal pain, neutropenia, vomiting, infections, anemia, headache, and thrombocytopenia (Table 10). Severe (Grade 3 and 4) neutropenia was observed in patients receiving abemaciclib.

Table 10: Adverse Reactions (≥10% of Patients) in MONARCH 1

<table>
<thead>
<tr>
<th></th>
<th>VERZENIO N=132</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Grades</strong></td>
<td><strong>Grade 3</strong></td>
</tr>
<tr>
<td><strong>Gastrointestinal Disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>90 %</td>
</tr>
<tr>
<td>Nausea</td>
<td>64 %</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>39 %</td>
</tr>
<tr>
<td>Vomiting</td>
<td>35 %</td>
</tr>
<tr>
<td>Constipation</td>
<td>17 %</td>
</tr>
<tr>
<td>Dry mouth</td>
<td>14 %</td>
</tr>
<tr>
<td>Stomatitis</td>
<td>14 %</td>
</tr>
</tbody>
</table>
**Drug Interactions**

**Effect of Other Drugs on VERZENIO**

**Strong CYP3A inhibitors**

Strong CYP3A inhibitors increased the exposure of abemaciclib plus its active metabolites to a clinically meaningful extent and may lead to increased toxicity.

Ketoconazole

Avoid concomitant use of ketoconazole. Ketoconazole is predicted to increase the AUC of abemaciclib by up to 16-fold.

**Other Strong CYP3A inhibitors**

In patients with recommended starting doses of 200 mg twice daily or 150 mg twice daily, reduce the VERZENIO dose to 100 mg twice daily with concomitant use of other strong CYP3A inhibitors. In patients who have had a dose reduction to 100 mg twice daily due to adverse reactions, further reduce the VERZENIO dose to 50 mg twice daily with concomitant use of other strong CYP3A inhibitors. If a patient taking VERZENIO discontinues a strong CYP3A inhibitor, increase the VERZENIO dose (after 3-5 half-lives of the inhibitor) to the dose that was used before starting the strong inhibitor. Patients should avoid grapefruit products.

**Strong CYP3A Inducers**

Concomitant use of VERZENIO with rifampin, a strong CYP3A inducer, decreased the plasma concentrations of abemaciclib plus its active metabolites and may lead to reduced activity. Avoid concomitant use of strong CYP3A inducers and consider alternative agents.

**Use in Specific Populations**

**Pregnancy**

**Risk Summary**

Based on findings in animals and its mechanism of action, VERZENIO can cause fetal harm when administered to a pregnant woman. There are no available human data informing the drug-associated risk. Advise pregnant women of the potential risk to a fetus. In animal reproduction studies, administration of abemaciclib during organogenesis was teratogenic and caused decreased fetal weight at maternal exposures that were similar to human clinical exposure based on AUC at the maximum recommended human dose (see Data). Advise pregnant women of the potential risk to a fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown. However, the background risk in the U.S. general population of major birth defects is 2 to 4% and of miscarriage is 15 to 20% of clinically recognized pregnancies.

**Data**

**Animal Data**

In an embryo-fetal development study, pregnant rats received oral doses of abemaciclib up to 15 mg/kg/day during the period of organogenesis. Doses >4 mg/kg/day caused decreased fetal body weights and increased incidence of cardiovascular and skeletal malformations and variations. These findings included absent innominate artery and aortic arch, malpositioned subclavian artery, unossified sternum, bipartite ossification of thoracic centrum, and rudimentary or nodulated ribs. At 4 mg/kg/day in rats, the maternal systemic exposures were approximately equal to the human exposure (AUC) at the recommended dose.

**Lactation**

**Risk Summary**

There are no data on the presence of abemaciclib in human milk, or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed infants from VERZENIO, advise lactating women not to breastfeed during VERZENIO treatment and for at least 3 weeks after the last dose.

**Females and Males of Reproductive Potential**

**Pregnancy Testing**

Based on animal studies, VERZENIO can cause fetal harm when administered to a pregnant woman. Pregnancy testing is recommended for females of reproductive potential prior to initiating treatment with VERZENIO.

**Contraception**

**Females**

VERZENIO can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during VERZENIO treatment and for at least 3 weeks after the last dose.

**Infertility**

**Males**

Based on findings in animals, VERZENIO may impair fertility in males of reproductive potential.

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**Table 10: Adverse Reactions (>10% of Patients) in MONARCH 1 (Cont.)**

<table>
<thead>
<tr>
<th>Category</th>
<th>All Grades</th>
<th>Grade 3</th>
<th>Grade 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infections</td>
<td>31</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>General Disorders and Administration Site Conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue*</td>
<td>65</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>11</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Blood and Lymphatic System Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neutropenia**</td>
<td>37</td>
<td>19</td>
<td>5</td>
</tr>
<tr>
<td>Anemia**</td>
<td>25</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>Thrombocytopenia**</td>
<td>20</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Leukopenia**</td>
<td>17</td>
<td>5</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Metabolism and Nutrition Disorders</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>45</td>
<td>3</td>
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<tr>
<td>Dehydration</td>
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<td>0</td>
</tr>
<tr>
<td>Respiratory, Thoracic and Mediastinal Disorders</td>
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<td></td>
</tr>
<tr>
<td>Cough</td>
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</tr>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
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<tr>
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<td>0</td>
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<tr>
<td>Nervous System Disorders</td>
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</tr>
<tr>
<td>Headache</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dysesthesia</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>11</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Skin and Subcutaneous Tissue Disorders</td>
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<td>Investigations</td>
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</tr>
<tr>
<td>Creatinine increased</td>
<td>13</td>
<td>&lt;1</td>
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<tr>
<td>Weight decreased</td>
<td>14</td>
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</tr>
</tbody>
</table>

* Includes anemia, fatigue.  
** Includes neutropenia, neutrophil count decreased.

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**Table 11: Laboratory Abnormalities for Patients Receiving VERZENIO in MONARCH 1**

<table>
<thead>
<tr>
<th>Category</th>
<th>All Grades %</th>
<th>Grade 3 %</th>
<th>Grade 4 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine increased</td>
<td>98</td>
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<td>0</td>
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<tr>
<td>White blood cell decreased</td>
<td>91</td>
<td>28</td>
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</tr>
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<td>Neutrophil count decreased</td>
<td>88</td>
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<td>Anemia</td>
<td>68</td>
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</tr>
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<td>Lymphocyte count decreased</td>
<td>42</td>
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<td>&lt;1</td>
</tr>
<tr>
<td>Platelet count decreased</td>
<td>41</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>ALT increased</td>
<td>31</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>AST increased</td>
<td>30</td>
<td>4</td>
<td>0</td>
</tr>
</tbody>
</table>

---

**Creatinine Increased**

Abemaciclib has been shown to increase serum creatinine due to inhibition of renal tubular secretion transporters, without affecting glomerular function. In clinical studies, increases in serum creatinine (mean increase, 0.3 mg/dL) occurred within the first 28-day cycle of VERZENIO dosing, remained elevated but stable through the treatment period, and were reversible upon treatment discontinuation. Alternative markers such as Bun, cystatin C, or calculated GFR, which are not based on creatinine, may be considered to determine whether renal function is impaired.
Pediatric Use
The safety and effectiveness of VERZENIO have not been established in pediatric patients.

Geriatric Use
Of the 900 patients who received VERZENIO in MONARCH 1, MONARCH 2, and MONARCH 3, 38% were 65 years of age or older and 10% were 75 years of age or older. The most common adverse reactions (≥5%) were neutropenia, diarrhea, fatigue, nausea, dehydration, leukopenia, anemia, infections, and ALT increased. No overall differences in safety or effectiveness of VERZENIO were observed between these patients and younger patients.

Renal Impairment
No dosage adjustment is required for patients with mild or moderate renal impairment (CLcr ≥30-89 mL/min, estimated by Cockcroft-Gault [C-G]). The pharmacokinetics of abemaciclib in patients with severe renal impairment (CLcr <30 mL/min, C-G), end stage renal disease, or in patients on dialysis is unknown.

Hepatic Impairment
No dosage adjustments are necessary in patients with mild or moderate hepatic impairment (Child-Pugh A or B). Reduce the dosing frequency when administering VERZENIO to patients with severe hepatic impairment (Child-Pugh C).

OVERDOSAGE
There is no known antidote for VERZENIO. The treatment of overdose of VERZENIO should consist of general supportive measures.

Rx only.

Additional information can be found at www.verzenio.com.
Responding First

When a First Responder Needed Immediate Attention, His Insurer Turned to Florida Cancer Specialists

When a law enforcement First Responder with stage 4 lung cancer with metastasis to bone, including his spine, began experiencing extreme pain, he called his oncologist for help, only to discover the doctor had retired. The physician who had taken over the practice understandably wouldn’t prescribe pain medication without first seeing the patient. Unfortunately, he told the patient (whose name is being withheld for privacy concerns) that he wouldn’t be able to fit him into his schedule for several weeks.

Suffering, the First Responder called his insurance representative at the Florida Sheriffs Multiple Employers Trust who contacted Tamara Volkert, Senior Vice President at the Hunt Insurance Group, the Trust’s Administrator. She immediately called her contact at Florida Cancer Specialists, Chief Marketing & Sales Officer, Shelly Glenn.

“Anytime we’ve reached out to them, they’ve been very responsive. Like Johnny on the spot,” Volkert says. “This time was no different.”

Ms. Glenn contacted FCS Senior Physician Liaison, Rhonda Webster and Dr. Ralph Gousse, an FCS oncologist who sees patients in the Greater Orlando area at FCS offices in Tavares, Altamonte Springs, and Apopka. The doctor made sure that the First Responder was seen that very afternoon. And while he was the first First Responder the doctor treated, he hasn’t been the last.

“I try to see every patient as soon as possible. For someone diagnosed with cancer, there’s always anxiety,” Dr. Gousse explained. “I don’t want them to suffer more from anxiety than their cancer.”

“People call me when they’re not getting the attention and care they need. We’re able to reach out to FCS and know that our client will see a doctor within one or two days. There’s nothing like getting in and being treated. It’s another one of the reasons FCS is renowned in the state.”

Tamara Volkert
Sr. Vice President, Hunt Insurance Group

Not a surprising attitude from a doctor who has led a medical mission every three months, for nearly 25 years, to his native Haiti to treat the island’s sick. The doctor explains that his extraordinary efforts are largely inspired by an aunt with stage 4 colon cancer who was like a second mother to him.

“Coming from a country like Haiti has made me sensitive to human suffering,” he says. “I believe that whatever we can do now to help, we should do, because we won’t be here forever.”

FCS has been extremely supportive of the doctor’s efforts in Haiti, donating a mobile PET/CT unit to a
nonprofit the doctor founded in the island country. He plans to use it at a hospital he supports there. (For more on this, see our People + Places section.)

Patient-centric, community-based care is the essence of the FCS culture and the reason that the Hunt Group had chosen FCS as one of their providers. “They treat people like people, not like a number,” Volkert says, “which happens all too often at large facilities or crowded practices. You need that personal care that FCS provides, particularly if you’re someone with a stage 4 cancer.

“People call me when they’re not getting the attention and care they need,” she continues. “We’re able to reach out to FCS and know that our client will see a doctor within one or two days. There’s nothing like getting in and being treated. It’s another one of the reasons FCS is renowned in the state.”

For the Hunt Insurance Group, that quick response is critical. In business since 1945, Hunt has been working with sheriff offices throughout the state since 1962. According to Volkert, they chose FCS first because, as a community-based provider, they are spread across the state, just as the group’s members are.

“The FCS commitment is not just to law enforcement and our First Responders, but to every citizen of Florida,” she says. “That’s what sets them apart from other practices.”

Volkert’s confidence in FCS is clear, as she pronounced, “If I had cancer, I’d want someone who’d treat me like that, which is why if I or someone in my family had cancer, FCS is who I would call.”

Ralph Gousse, MD
Florida Cancer Specialists

The New York Times article, *Good News for Women With Breast Cancer: Many Don’t Need Chemo*, was published on June 3, 2018 and can be found online at Nytimes.com.
Sparing Breast Cancer Patients From Chemotherapy

The recent TAILORx study provides the information women and their oncologists need to make better informed decisions and get more personalized treatment for their breast cancer.

Nearly 70 percent of the women with early stage breast cancer, and an intermediate risk of recurrence, who are currently receiving chemotherapy after surgery do not need it, according to a major international research study called the Trial Assigning Individualized Options for Treatment (TAILORx).

Recently published in the New England Journal of Medicine and presented at a meeting of the American Society of Clinical Oncology (ASCO), the study is good news for the nearly 260,000 women in the United States expected to be diagnosed with the disease this year.

The groundbreaking study determined that for a specific group of women with hormone receptor-positive, HER2-negative, axillary lymph node-negative breast cancer, who have an intermediate risk recurrence score, being treated with both chemotherapy and hormone therapy is not more beneficial than treatment with hormone therapy alone.

“We can spare thousands and thousands of women from getting toxic chemotherapy treatment that really wouldn’t benefit them,” Dr. Ingrid Mayer of Vanderbilt University Medical Center, one of the study’s authors, told the New York Times. “This is very powerful. It really changes the standard of care.”

The trial, in which Florida Cancer Specialists (FCS) was proud to participate, involved 10,273 women at 1,182 sites in the United States, Australia, Canada, Ireland, New Zealand and Peru.

Conducting the Trial
For the past several years, patient breast tumors have been analyzed using a molecular test, the Oncotype DX Breast Recurrence Score, which assess the 21 genes associated with breast cancer. Each tumor is assigned a recurrence risk score on a scale of 0-100. Women in the low-risk range of 0-10 were only treated with hormone therapy, while those with scores of 26 and above were considered high-risk and treated with a combination of hormone and chemotherapy, as traditional protocol required. Traditionally, there has been no chemotherapy treatment protocol advised for women in the intermediate risk category, with a recurrence risk score between 11 and 25.

In the recent Oncotype DX trial, of the 9,719 eligible patients with follow-up information, 6,711 (69 percent) had a midrange recurrence score of 11 to 25. There was no definitive treatment protocol regarding chemotherapy. The study randomly assigned participants to either chemoendocrine therapy or endocrine therapy alone to discover the efficacy of chemotherapy for these women.

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“The trial was designed to address this question, and it provides a very definitive answer,” said the study’s lead author, Joseph A. Sparano, MD, Associate Director for Clinical Research at the Albert Einstein Cancer Center and Montefiore Health System in New York City and Vice Chair of the ECOG-ACRIN Cancer Research Group. “Any woman with early-stage breast cancer 75 years or younger should have the test and discuss the results of TAILORx with her doctor to guide her decision regarding chemotherapy after surgery to prevent recurrence. “The new results from TAILORx give clinicians high-quality data to inform personalized treatment recommendations for women,” said Dr. Sparano.

Dr. Jeffrey Abrams, Associate Director of NCI’s Cancer Therapy Evaluation Program, agrees. “Until now, we’ve been able to recommend treatment for women with these cancers at high and low risk of recurrence, but women at intermediate risk have been uncertain about the appropriate strategy to take. These findings, showing no benefit from receiving chemotherapy plus hormone therapy for most patients in this intermediate-risk group, will go a long way to support oncologists and patients in decisions about the best course of treatment.”

Following Up
The study met its pre-specified endpoint at a follow-up after 7.5 years, demonstrating that in women with a recurrence score of 11-25, hormone treatment alone was as effective as chemotherapy and hormone therapy together.

Nine-year rates were virtually identical: Disease free survival was 83.3 percent vs. 84.3 percent; distant recurrence was 94.5 percent vs. 95 percent; and overall survival was 93.9 percent vs. 93.8 percent.

The conclusion of the study’s authors is that chemotherapy need not be used in all women 50 and older with hormone receptor-positive, HER2 negative, node negative breast cancer who have a Recurrence Score of 0-25, which translates to about 85 percent of women in this age group. For women 50 or younger, about 40 percent of women with the disease fit this description.

Helping FCS Patients to Make the Most Informed Decisions
Florida Cancer Specialists (FCS) has taken a lead in educating the public and encouraging conversations between patients and their doctors. A number of FCS oncologists have begun a campaign to inform the public about the importance of this research and the benefits it offers, and to encourage patients to ask about available clinical trials.

Among them are Dr. Caryn Silver in Sarasota, Dr. Scott Tetreault in Tallahassee, Dr. Marilyn Raymond in West Palm Beach, and Drs. Joel Grossman and Jay Wang in Naples.

In their Naples Daily News guest commentary about the study (See p. 35), Drs. Grossman and Wang wrote, “Its findings provide more certainty for oncologists about which patients need chemotherapy and which do not.”

“While this study provides useful information for a specific scenario within one cancer type, the results might benefit thousands of patients in the future. This is just one example of the incredible benefit of clinical research. In our practice, we encourage clinical trial participation when available and appropriate.”

The study received its primary funding from the National Cancer Institute. Funds from The Breast Cancer Research Foundation, Komen Foundation, and the U.S. Postal Service Breast Cancer Stamp provided additional support. The ECOG-ACRIN Cancer Research Group designed and conducted the study.
Following is the complete text of the Naples Daily News (June 18, 2018) guest commentary co-authored by FCS physicians Dr. Joel Grossman and Dr. Jay Wang. Dr. Grossman is the division chief of oncology and hematology for the NCH Healthcare System. Dr. Wang is the chief of hematology/oncology for the Physicians Regional Healthcare System.

**Commentary: New Breast Cancer Study Helps Clarify Who Can Skip Chemotherapy**

We have been receiving numerous inquiries about the recent media articles concerning a large study of chemotherapy for early-stage breast cancer.

Florida Cancer Specialists & Research Institute participated in this trial, and we’d like to help clarify what it means.

When we see patients with early-stage breast cancer, we know there is a chance they will be cured by surgery. But we also know that, unfortunately for some patients, despite surgery, their cancer will spread and become life-threatening.

What we really need in oncology is a test that perfectly predicts who those patients are, but all we can do currently is estimate the risks and make decisions on additional treatment accordingly. There are traditional risk factors that are still useful: whether or not lymph nodes were involved with cancer, the tumor size, how fast growing/dividing the cancer cells are under the microscope (the “grade”), whether or not there is expression of hormonal receptors, and whether there is overexpression of the HER2 protein.

Now, we also have genomic studies in which the DNA profile of the patient’s tumor is tested.

There are different genomic tests on the market, and one of them is OncoType DX. That test is useful in patients whose breast cancer is hormone-receptor positive and HER2 negative. The results come back in a “recurrence score” which falls in either a low-, intermediate- or high-risk category. We have known for years that for those in the low-risk category, there is essentially no increase in cure rate with chemotherapy. Similarly, chemotherapy offers a significant potential benefit for patients whose recurrence score falls in the high-risk category.

The problem has been what to do with those who fall in the intermediate range. The thinking among experts has been that chemotherapy probably offers them a small potential benefit – meaning that only a few out of every 100 patients would likely be cured because of chemotherapy.

The best way to answer these questions, of course, is with clinical trial evidence, and now we have that. According to the study recently reported at the annual American Society of Clinical Oncology meeting and published in the New England Journal of Medicine, the outcomes for postmenopausal women with intermediate-range recurrence scores were very similar whether or not they received chemotherapy. For premenopausal women, there was a small difference with chemotherapy.

Florida Cancer Specialists (FCS), the largest independent oncology/hematology practice in the U.S., is proud to have participated in this clinical study. Its findings provide more certainty for oncologists about which patients need chemotherapy and which do not.

While this study provides useful information for a specific scenario within one cancer type, the results might benefit thousands of patients in the future. This is just one example of the incredible benefit of clinical research. In our practice, we encourage clinical trial participation when available and appropriate.

Joel S. Grossman, MD  
Jay Wang, MD
Getting Back on Track
Roger Vergin is busy running around the country, competing in National Senior Games and U.S.A. Track and Field Master Championships, not only winning, but also setting new records. Indeed, through July of this year, he’s already won 17 national championships. No small triumph for an 81-year-old man.

Nor was his victory over an extremely rare blood disease that affects less than 100,000 people in the United States. Getting an accurate diagnosis proved every bit as challenging, hard fought, and ultimately sweet, as any of Roger’s competitive achievements.

Before discovering his passion for track and field, Roger taught Business Administration at some of the nation’s top universities, including the University of California Berkeley, the University of Washington and Penn State. Between teaching assignments, he took time off to work with Oscar-winner Marlon Brando as his financial manager, an experience he’s written about in a book titled “Brando: With his Guard Down.”

His equally dynamic wife, Rosemary, who earned a PhD in History at Carnegie Mellon and established herself as an expert in Family Research, has been with Roger through every challenge, just as he supported her when she faced a breast cancer diagnosis. Helping them both prevail was Florida Cancer Specialists (FCS) President and Managing Partner Dr. William Harwin.

Solving Roger’s Medical Mystery
Roger began competing at age 70. At 74, his extraordinary athletic career was almost sidelined. While doing weight training, he experienced pain in his abdomen he initially thought was a muscle sprain.

When the pain worsened over the next few days, he and Rosemary decided a trip to the emergency room, near their Ft. Myers winter home, was necessary. There, physicians diagnosed him with a gall bladder issue and advised that he have it removed. It was a misdiagnosis that, had Roger undergone an operation, could have cost his life.

Fortunately, Rosemary sensed something wasn’t right. After an extensive Internet search, she found Dr. Brent Myers, a Ft. Myers Internist. He performed a number of lab tests, a sonogram and an MRI, which revealed a number of unusual blood clots in his spleen and liver. As soon as the doctor saw the results, he had his nurse call Dr. William Harwin at FCS.

“His presenting complaint was abdominal pain, and he was found to have portal and mesenteric vein thrombosis and a very high platelet count,” Dr. Harwin explained.

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“My diagnosis was essential thrombocythemia, one of the myeloproliferative disorders.”

For a second opinion, Dr. Harwin reached out to his old friend and colleague at the University of Florida, nationally recognized hematologist Dr. Craig Kitchens, author of the definitive work on bleeding and clot disorders. Roger was placed on a pharmaceutical treatment regimen that he still maintains, and in about a month he was back on track running circles around his competition.

Rosemary Faces Her Own Challenge
But the Vergins hadn’t quite crossed the finish line. In December 2014, Rosemary noticed a hard lump in her left breast. Though she’d recently had a mammogram, extremely dense breast tissue had kept the lump hidden.

A biopsy was performed and the lump was confirmed as cancerous. “The first thing a woman thinks when she finds out she has breast cancer is ‘Get it out, get it out,’” Rosemary said.

Fortunately, this time, no Internet searches for a doctor were necessary. The couple returned to FCS and Dr. Harwin for his expertise. The doctor diagnosed a virulent triple negative breast cancer, so the doctor’s treatment plan began with chemo to shrink the tumor before surgery.

The chemo lasted from Christmas 2014 until April 2015. It was a grueling experience, but successful. Rosemary had a bi-lateral mastectomy in May 2015. The sentinel lymph node revealed that the cancer was successfully removed.

Rosemary’s voice understandably fills with emotion when she recalls Dr. Harwin running down the hallway to greet her after surgery shouting, “Rosemary, you’ve had a complete pathological response. It’s the best response possible.”

“It’s a thrilling moment that will live in my memory forever,” she says.

Back on Track
Now, Roger gets quarterly checkups and continues to compete. When we spoke with him, he was on his way back from the Spokane Track and Field Master Championships near their summer home in Poulsbo, Washington, where he captured eight Gold Medals, two Silver and two Bronze Medals.

Rosemary, who joins Roger and films his achievements whenever possible, has been cancer-free for three plus years and waits to pass the all-important five-years-free threshold. You can find them on YouTube by searching Roger Vergin. Some of the clips have appeared on HBO.

Thanks to Dr. Harwin and the FCS team, the couple grows more hopeful every day. Their determination helps make any victory seem possible.
When Debra Dolby returned to her job as a Corrections Nurse for the Hernando County Sheriff’s Department after surgery and chemotherapy for Stage 4 ovarian cancer, her co-workers had a surprise for her. She asked another nurse, Terri Johnson, to take her picture. Bald and beautiful, she wanted the image to inspire others. Inspiration is often contagious. Debra’s co-workers were so inspired that they shaved their heads and took the group photo that you see here. Semper Fidelis.

Spend any time talking to this former Marine Staff Sergeant and you soon understand this act of solidarity and why she takes so much pride in it.

Debra’s war with cancer began in 2012 when a blood test revealed a slightly elevated CA125 level. For the next five years, she continued to be monitored. In October 2017, experiencing acute abdominal pain, she had a neighbor drive her to the emergency room. An MRI revealed a mass.

Her surgeon, Dr. Hector Arango, a Gynecologic Oncologist, referred her to Dr. Jorge Ayub at Florida Cancer Specialists (FCS) for follow-up chemotherapy. Dr. Ayub practices at FCS locations in Hudson, Land O’ Lakes and New Port Richey.

“He’s awesome and so is FCS,” Debra says.

The feeling, according to Dr. Ayub, is mutual. “From the moment we met Debra, she demonstrated such courage and a willingness to do whatever was necessary to win her battle with cancer; she was inspirational. She never uttered any word that was negative towards her goal of being cured. Her attitude and humor always brought smiles to all our staff and even to the patients who were being treated at the same time. She’d always dress in cheerful colors. That was uplifting to her and was a point of conversation. Patients such as Debra, with that kind of attitude, teach us all that we can face major adversities and overcome them. I am sure that her spirits are instrumental in her recovery and, hopefully, a cure.”

“Every time you go in, the staff is smiling and laughing, motivating you to get your treatment. Everything is explained to you. It’s a pick-me-up. You actually look forward to going. You’re just not afraid,” Debra says. “You’ve got to put on your big girl pants and keep moving forward.”

Though chemo is finished, this mother of four and grandmother of six (two of whom she’s raising) is now getting the anti-blood vessel growth factor drug (Avastin®) for a mass on her aorta. No complaints though. In fact, she’s pleased that this isn’t nearly as hard on her as chemo was. And just to prove that you can’t beat a Marine, she’s keeping up her spirits and moving on by paying it forward.

“When I was getting chemo, I bought a pair of pink glitter sneakers to give the other folks getting infused with me something to laugh about. Something I hoped would start a conversation. It worked. And when my chemotherapy was finished, I gave them to one of the other women. I never even asked her name. Chemo can rob you of your energy, but not your soul.”

Debra Dolby Knows Chemo Can Rob You of Your Energy, but Not Your Soul

Jorge Ayub, MD
Executive Board Member
Florida Cancer Specialists
People + Places

FCS donates a mobile PET/CT unit to non-profit in Haiti

Florida Cancer Specialists (FCS) Brooksville location recently upgraded its PET/CT scanner technology and decided to donate one of the practice’s mobile PET/CT units to a non-profit organization in Haiti, founded by Dr. Ralph Gousse, who practices at several FCS locations in Central Florida. Dr. Gousse has been providing humanitarian aid to his native Haiti for more than two decades. FCS Director of Radiology, Levester Jones, facilitated the donation and physicians Dr. Vikas Malhotra and Dr. Mary Li presented Dr. Gousse with an honorary key and official title to the mobile PET/CT scanner.

Happy Hats Project Brings Smiles to Patients at FCS Lakewood Ranch

Patients at the FCS Lakewood Ranch office are sporting colorful, hand-knitted hats, thanks to the daughters of two FCS oncologists. Abigail Eakle, daughter of FCS physician Janice Eakle, MD, and Margaret Buck, daughter of FCS physician Richard Buck, MD, started the Happy Hats Project to provide hats for patients that have lost their hair due to chemotherapy.

Presenting “Happy Hats” to the FCS Lakewood Ranch office on August 10, 2018 (L-R): Office Manager Amy Morrow; Tiffany Kovalsky, PSS; Abby Eakle; Tiarra Patrick, MA; Mary Ellen Woska, PL; Margaret Buck; and Candace Uppgard, MA.
The FCS management team and physicians gathered recently to break ground for several new cancer centers in Lakewood Ranch, Ocala and Brownwood.

The new $16 million FCS Lakewood Ranch Cancer Center will be built in the rapidly growing master-planned community of Lakewood Ranch. Conveniently located to serve patients in the Sarasota-Bradenton area, the Center will feature 38 chemotherapy chairs, 10 examination rooms and a fixed imaging suite, including a Siemens PET/CT unit. A summer 2019 completion is planned.

In Ocala, FCS and Marion County physicians, Drs. Patrick Acevedo, Shilpa Oberoi, Vipul Patel, Craig Reynolds, Sachin Kamath and Mohammad Kamal, have broken ground for a new $10 million state-of-the-art comprehensive center located on SW 48th Avenue off SR 200. Scheduled to open in fall 2019, the Ocala Cancer Center will be approximately 21,009 square feet with 17 exam rooms and 47 chairs in the infusion room. This will be the region’s first and only comprehensive cancer center where a patient can receive a variety of services and treatments under one roof, including chemotherapy, radiation oncology, national clinical trials, radiology (PET/CT imaging), physician visits and laboratory services, to provide unsurpassed convenience for cancer patients in Marion County.

The Villages, Anchor Health and AHC Hospitality have broken ground on the 10,820-square-foot Center of Advanced Healthcare at Brownwood. In attendance were local dignitaries, executives from The Villages Health, Florida Cancer Specialists physicians and staff, and guest speaker Governor Rick Scott. Florida Cancer Specialists’ new Brownwood office will be located at 2925 Traverse Trail, The Villages.

All three facilities are being designed and built by St. Petersburg-based Optimal Outcomes, with processes and principals that will integrate Evidence-Based Design (EBD) to achieve functional and aesthetic outcomes that increase operational efficiencies for providers, while creating environments that enhance patient experiences and reduce stress.
People + Places

FCS Senior Physician Liaison Rhonda Webster is Leukemia & Lymphoma Society Chapter’s Woman of the Year

FCS is pleased to announce that Central Florida Senior Physician Liaison Rhonda Webster has been named Woman of the Year by the North and Central Florida chapter of the Leukemia & Lymphoma Society (LLS). To earn this recognition, Rhonda raised more than $130,000 for the chapter.

“Cancer has touched my life like so many others,” Rhonda said. “When I see patients in infusion suites daily fighting for their lives, I want to do anything I can to assist in providing funding for patient services and research to benefit these brave men and women.”

LLS is the world’s largest voluntary health agency dedicated to blood cancer. The LLS mission: Cure leukemia, lymphoma, Hodgkin’s disease and myeloma, and improve the quality of life for patients and their families. LLS funds lifesaving blood cancer research around the world, provides free information and support services, and is the voice for all blood cancer patients seeking access to quality, affordable, coordinated care.

Lara Stachow loves a challenge. When diagnosed with a Stage 3 tumor in her breast, her fight against cancer required surgery, chemotherapy, radiation and the strength of a soldier. See Lara’s story of Hope & Science on our website.

Blue Cross Blue Shield has recognized Florida Cancer Specialists as a Blue Distinction® Center for Cancer Care. FCS is the only community hematology and oncology practice in Florida to earn this distinction. For more information about the Blue Distinction Specialty Care Program, visit bcbs.com/bluedistinction.

Florida Cancer Specialists & Research Institute (FCS), founded in 1984, is the largest independent medical oncology/hematology practice in the United States, with nearly 100 locations. FCS delivers world-class cancer care in community-based settings, providing innovative clinical research and cutting-edge technologies that help advance targeted treatments and genetically-based immunotherapies.

FCS serves patients on the Gulf coast from Naples to Tallahassee, in central Florida communities, and on the east coast from Palm Coast to Palm Beach County.

For a listing of locations, helpful information about your first visit, and other patient resources, visit FLCancer.com
New Doctors + Updates

Medical Oncologist, **Simon Abi Aad, MD** has joined FCS at the Naples Napa Ridge office, 6360 Pine Ridge Road, Suite 201, Naples.

Medical Oncologist, **Elizabeth Guancial, MD** is now practicing at the FCS Sarasota Downtown office, 1970 Golf Street, Sarasota.

Medical Oncologist, **Amy Nance, MD** has joined FCS and practices at the Gainesville Cancer Center, 6420 W. Newberry Rd., East Wing, Suite 100, Gainesville.

Hospitalist, **Adewale Fawole, MD** has joined FCS and will be seeing patients in Lake and Sumter counties who require hospitalization.

Expanded news releases and complete physician bios can be found on the FCS website: FLCancer.com.

FCS Pathologist, **Dr. Gina Elhammady**, Climbs Mount Kilimanjaro

FCS reached new heights (19,341 feet, to be exact) this March when Pathologist, **Dr. Gina Elhammady**, climbed Mount Kilimanjaro in Tanzania. Always eager to fly the FCS flag, Dr. Elhammady had the forethought to take the FCS logo with her so she could take her picture with it at the summit. Dr. Elhammady is always looking for new adventures, and this one will surely be hard to “top” by her FCS colleagues.

FCS Physicians Featured on “The Weekly Check-Up” Radio Show

Physicians from Florida Cancer Specialists can be heard on a new weekly radio program dedicated to health. The Weekly Check-Up with JoJo Petrella is brought to you by Florida Cancer Specialists.

**JoJo Petrella** is the high-energy host of The Weekly Check-Up in Tampa-St. Pete, offering listeners a go-to resource for the latest healthcare news, views, and tips for better living. She ensures that listeners are not only educated but also entertained. Each week, JoJo brings listeners live interviews with the community’s top physicians and medical specialists – with a woman-on-the-street perspective and direct access to the experts that can help listeners stay healthy and feel their best.

Listen live every Saturday from 10-11 a.m. on 102.5 The Bone, or stream online at TheBoneOnline.com
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