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Growth and Quality Care Mark Exciting Future

BY BRAD PRECHTL, CEO, AND DR. WILLIAM HARWIN, FOUNDER & MANAGING PARTNER

BRAD PRECHTL: The sustained growth of FCS has been a hallmark of 2017. From new physicians joining our group throughout the year to new practice locations in Stuart and Fleming Island, FL, expansions in our Paylor administrative office (Lakewood Ranch), renovations in Port Charlotte and Leesburg, and the new 50,000 square foot Central Business Office (Fort Myers), as well as the new, 27,000-square-foot North Fort Myers Cancer Center, our practice continues to realize our mission of bringing world-class cancer care to local communities, large and small, across the state.

Cutting-edge technologies, such as next generation PET/CT scanners, on both fixed and mobile platforms, and state-of-the-art Linear Accelerators in our strategic locations for radiation oncology, also enhance our capabilities and bring more options to our patients. Our participation in the Oncology Care Model and expanding Care Management program ensures that we are able to maintain and deliver high quality care to our patients while reducing costs. It is truly an exciting time for Florida Cancer Specialists, despite the ongoing uncertainty about healthcare changes in the future.

DR. WILLIAM HARWIN: In addition to setting a benchmark for community oncology in Florida, this year, FCS has provided guidance on the national level through organizations such as the Community Oncology Alliance (COA) and the Florida chapter of the American Society of Clinical Oncology (FLASCO). FCS physicians and leaders presented clinical trials research and innovative thought leadership at the annual meeting of ASCO, where we also launched our program for seasonal patients, enabling medical oncologists from areas outside of Florida to refer patients who vacation or live seasonally in Florida, to FCS. With nearly 100 locations across the state, there is a very good chance that an FCS clinic will be only minutes away from a snowbird’s Florida home.

When I reflect on the progress we have made this year and consider the exciting plans that will be enacted in the coming months, I am excited about the future of FCS and extremely proud of all we have accomplished together. Advancing care and improving treatment for our patients truly requires our collective efforts. Thank you for your continued dedication and support.
In Hurricane Irma’s Wake, FCS Deland Helps One of the Helpers

The day after Hurricane Irma cleared Central Florida, Office Manager Jennifer Smith came in to the FCS Deland office to make sure everything was ready to reopen for patients. As she was leaving, she was approached by one of the electrical workers who had congregated in the parking lot next door to the office.

In the wake of Irma, thousands of good people from many states traveled to Florida to help with clean up and restoration. Taylor Frost, a lineman from Effingham, IL, is one of those good samaritans. He explained to Jennifer that he had been undergoing treatment for Hodgkin’s Lymphoma in his hometown, but when the call went out that Florida needed help, he didn’t hesitate to come and do his part. However, due to the storm’s interruptions of services and travel, he was worried that he might not make it back to Illinois in time to receive his final chemo treatment, which was scheduled for Friday, September 15.

Jennifer sprang into action and had Taylor come in to see Dr. Ernesto Bustinza the very next day. She coordinated with Taylor’s wife and made sure his medical records were sent to FCS and his oncologist in Illinois was contacted. He was then scheduled to come back on Friday and have his final chemo treatment at FCS.

However, when he showed up on Friday, an unforeseen circumstance occurred, as Jennifer explained: “Mr. Frost was not able to get his last treatment on Friday because he was neutropenic and his port was infected. Dr. Bustinza immediately contacted Interventional Radiology to get him in at Florida Hospital Deland to have it removed. Mr. Frost did not have a ride to get to the hospital, so Dr. Bustinza personally drove him to the hospital, where Taylor was immediately taken back to have his port removed.”

On Monday, September 18, Taylor returned to the FCS Deland office and received his final treatment among his newfound friends at Florida Cancer Specialists.

Taylor’s wife, Kelsey, was very grateful for the excellent care FCS provided to her husband; she posted this Facebook message:

Thank you SO MUCH, for everything you have done for my husband. His last treatment was scheduled for September 15th in our hometown, however when he got called out to do storm work in Florida last Thursday, we knew he wouldn’t be able to do his last treatment here. That’s when fate took over. The crews met in a parking lot next to the Deland office. Seeing the Florida Cancer Specialists sign, Taylor decided to go in and see if there was any possible way he could do his last treatment there on Friday. He was given information and then forwarded it to me. I then started making calls to your office and to his oncologist here in our hometown. Your staff was so friendly and helpful and it took no time to get Taylor scheduled for an appointment with Dr. Bustinza. Taylor recapped the appointment for me, but I had a few questions. I called and spoke with Amy, who was so helpful and answered all of my questions thoroughly. As an Advanced Nurse Practitioner, I know how important great, quality care is, and you all have gone above and beyond. I sincerely thank you from the bottom of my heart for taking care of my husband during a time that I cannot be with him. You will never know how much your hospitality and kindness means to this linewife and my lineman. God bless you and may God bless Florida!

Kelsey Frost
Liliana Bustamante, MD, Joins FCS in Lee County

Liliana Bustamante, MD, joined FCS on August 1, 2017, and is seeing patients at three FCS locations in Lee County: the Cay West office in Cape Coral, the Colonial office in Fort Myers, and at the North Fort Myers Cancer Center in Cape Coral.

After earning her medical degree from the University of Florida College of Medicine, Dr. Bustamante completed her Internship and Residency in Internal Medicine at the University of North Carolina in Chapel Hill, NC. In 2014, she was awarded a Fellowship in Hematology/Oncology at the University of South Florida/Moffitt Cancer Center in Tampa, FL. A native Spanish speaker, Dr. Bustamante has a keen interest in clinical research and has presented at various medical meetings.

Rayma Pinnamaneni, MD, Joins FCS in Pinellas County

On August 1, 2017, Dr. Pinnamaneni joined FCS as a Hospitalist in Pinellas County. Pinnamaneni attended medical school at Kasturba Medical College in Manipal India. She completed her Internal Medicine Residency and Fellowship in Oncology/Hematology at East Carolina University Brody School of Medicine in Greenville, NC. Pinnamaneni is board certified in Internal Medicine, and received the honor of “Best Oral Presentation” at the Annual GME Research Day at the Brody School of Medicine in June 2012.

FCS Foundation Board Welcomes Phipps and Shwiner

The FCS Foundation Board welcomed two new members in June: Jeffrey Phipps, Sr., AWMA, and John Shwiner.

Mr. Phipps, who is the senior member of the Phipps Group, earned his Accredited Wealth Management Advisor designation from The College for Financial Planning and has been working in the financial services industry since 1970. He has worked at Merrill Lynch since 2008. Mr. Phipps also serves on the boards of the Lake Worth Drainage District, Mounts Botanical Garden and as the Director of the Palm Beach County Historical Society.

Mr. Shwiner is a Vietnam veteran who worked for Gulf Oil/ Chevron for more than 40 years. He was president of Crime Stoppers of Palm Beach County’s “Student Crime Stoppers” program and was twice awarded “Civilian of the Year” recognition. He is lead volunteer at the FCS Clinic in Wellington, and holds many other volunteer positions in his community.

Lynn Rasys, Executive Director of the FCS Foundation said, “The Foundation is excited to welcome two new board members from the Palm Beach County area! Jeffrey Phipps, Sr., AWMA and John Shwiner have already contributed immensely by volunteering for the Foundation, and we are grateful for their additional involvement.”

Subaru and LLS Donate Blankets to Patients in Tampa, Ocala and Winter Park

In July, Reeves Subaru and the Leukemia & Lymphoma Society (LLS) delivered 80 blankets and 10 craft kits to patients at the Tampa Cancer Center in association with the “Subaru Loves to Care” program. The same month, Subaru and LLS teamed up again to deliver blankets and craft kits to patients at the Ocala and Winter Park locations.
“Love” Rocks Bring Hope to Local Cancer Patients in Wellington

The FCS Foundation, in conjunction with the Wellington clinic, received 200 “Go and Love” rocks from local congregation, Journey Church. The initiative recently launched by Journey Church’s student ministry aims to spread “rocks” of encouragement to the patients of FCS. The rocks have been decorated with heartfelt messages from local Palm Beach County high school and middle school students. The “love” rocks were distributed to FCS patients following treatment, as a token of hope and encouragement in their battle against cancer.

Port Charlotte Cancer Center Expands

FCS recently celebrated the expansion of the Port Charlotte location, which gained five exam rooms and accommodated an increase in chemotherapy chairs by almost 50 percent. Physicians practicing in Port Charlotte include Drs. Christopher Lobo MD, Eric T. Lubiner DO, Ivor Percent MD and Vance Wright-Browne MD.

Teens Establish “Coconuts for Cancer” and Raise Funds for FCS Foundation

Two impassioned young women, whose lives had been touched by cancer, wanted to make a difference in the lives of cancer patients. They considered how they could help and launched “Coconuts for Cancer,” an organization committed to raising money for cancer research and helping cancer patients. The young women personally make various products from coconuts and sell them; the proceeds benefit cancer research and patients. The FCS Foundation recently received a donation from Callie Goolgasian and Sabrina D’Agostino, the teenage Co-Founders of Coconuts for Cancer.

Brooksville Location Acquires VitalBeam™ Linear Accelerator

The FCS Brooksville location is the first community oncology clinic in its area to acquire a Varian VitalBeam™ linear accelerator (LINAC). It allows physicians to provide patients with cutting-edge radiation therapy that delivers high-energy x-rays or electrons to the region of the patient’s tumor. Radiation Oncologist Dr. Swasan Bishay added, “In addition to precisely targeting each tumor, the new VitalBeam™ enables us to customize radiation treatment for each individual treatment.” The device also allows doctors to visualize the subject tumor prior to each treatment and to treat superficial cancers to varying depths, among other various capabilities. FCS CEO, Brad Prechtl said, “Florida Cancer Specialists is committed to providing the highest quality care and latest therapies in the treatment of cancer, so that our patients do not have the additional burden of having to travel to larger academic centers.”
FCS Adds Expertise to 2017 Oncology Conference in D.C.

The 2017 Community Oncology Conference in Washington, D.C., drew more than 1,300 Oncologists, Administrators, Nurses, Pharmacists, industry leaders and patient advocates to the nation's capital in April to discuss some of the newest advancements in cancer care. This year's conference featured numerous physicians and leaders from FCS, including Dr. Michael Diaz, Dr. Craig Reynolds, FCS Founder and President Dr. William Harwin, FCS Director of Pharmacy Ray Bailey, FCS CEO Brad Prechtl and Dr. Lucio Gordan, who served as a national co-chair for the conference.

FCS CEO, Brad Prechtl participated in a panel discussion titled “Practice Vision for the Now & Future of Community Oncology.” He said, “As one of the practices selected to participate in the Oncology Care Model, FCS has been at the cutting-edge of developing new strategies, as we transition to a value-based care model.”

FCS Founder and President, Dr. Harwin addressed the conference during a panel discussion titled “How Community Oncology is Fueling the Cancer Moonshot.” He explained: “Our capacity to share big data and information from clinical research is greatly improving our understanding of cancer and our ability to treat it. This data is guiding physicians in tailoring and personalizing treatment strategies to each patient’s unique genetic makeup for maximum effectiveness.”

Chosen to participate in panels post-conference were Don Champlain, Associate Director of Care Management and Sarah Cevallos, Chief Revenue Cycle Officer.

North Fort Myers Cancer Center Now Open

On July 31, 2017, the North Fort Myers Cancer Center started seeing patients at the brand new location in Cape Coral, Florida. The new Cancer Center is approximately 26,924 square feet and has 78 chairs in the treatment room.

Norman J. Brodsky, MD

On July 1, 2017, Dr. Norman J. Brodsky joined FCS as a part-time Radiation Oncologist. Brodsky attended medical school at the University of Minnesota in Minneapolis, MN. He completed his Residencies in Internal Medicine from Hennepin County General Hospital in Minneapolis, MN, and Radiation Oncology from Hahnemann University Hospital from Philadelphia, PA. He also completed his Fellowship in Rheumatology from Albert Einstein Medical Center in Philadelphia, PA. Brodsky is board certified from the American Board of Radiology - Therapeutic Radiology, and from the American Board of Internal Medicine.

Jennifer Byer, MD

On August 14, 2017, and is seeing patients at two FCS locations in Vero Beach & Sebastian, Florida.

Dr. Jennifer Byer earned her medical degree and completed her Internal Medicine Residency at the University of South Florida (USF) in Tampa, FL. In 2014, she was awarded a Fellowship in Hematology/Oncology at the Moffitt Cancer Center/USF. With a keen interest in clinical research, Dr. Byer has presented at various medical meetings, including the Gastrointestinal Cancers Symposium in California and Infectious Diseases Society of America in Philadelphia, PA. Also, she has written review articles and has been published in several peer-reviewed journals. Throughout her career, Dr. Byer has volunteered in her local community and beyond, including the USF BRIDGE Clinic and the Latin Medical Student Association (LMSA) Medical Mission Team.

Christopher A. Sequeira, MD

On August 28, 2017, Dr. Christopher A. Sequeira joined FCS as a Hospitalist in Orange County. Sequeira attended medical school at Ross University School of Medicine in Dominica, West Indies. He completed his Internal Medicine Residency at the University of Florida in Gainesville, FL, and his Fellowship in Hematology and Oncology at the University of Illinois in Chicago, IL. Sequeira is board certified from the American Board of Internal Medicine.
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Case Management
Help to get the health services you need

When you’re dealing with difficult health issues, you face some tough decisions. It can help to have your own personal case manager … a registered nurse who not only cares about what you’re going through, but can make sure you get the answers and services you need.

*About case management*

This free program connects you with a case manager who knows about your situation and health problems. Case managers are registered nurses, so they have insight and knowledge about a range of medical conditions. If you have questions about your condition and the treatments you are receiving, they can help you get answers. But patients often need information about other things as well. For example, as you deal with your illness or injury, you might need special equipment to help with a disability, transportation to medical appointments, groceries from a local food bank or assistance paying your utility bills. These are some of the needs your case manager can help you with.

*Is case management for you?*

Case management can be especially helpful for members who experience:

- Frequent hospitalization
- Long-term illness
- Extensive home health care
- Life-threatening illness
- Effects of traumatic injury

*An advocate who’s on your side*

When a person is dealing with serious illness or injury, it can be stressful for the whole family. Sometimes it’s hard to know the right questions to ask, let alone find all the answers. You might be uncertain about which health goals are realistic for you now, or how to make the most of your health insurance benefits. Your case manager can help you work through these issues. Your health is the case manager’s top priority. Case managers have experience at connecting patients with the resources and information they need.

*More about the case manager’s role*

Your case manager does not take the place of your doctor. But he or she can work with your health care providers and make sure your concerns are addressed. Sometimes getting the right services takes planning and coordination, and case managers help with that. You don’t have to worry about going through these challenging times alone. Also, as a medical professional, your case manager will respect your privacy by keeping details of your treatment confidential.
It’s your choice

This is a voluntary program. You can choose whether or not to have a case manager and you can withdraw from the program any time.

• **Signing up:** If you would like to try case management, just call the customer service number on the back of your insurance card and ask to speak to a case manager. You may opt out of the program at any time by notifying your case manager. If you have a problem or complaint, feel free to call the case management supervisor at 800-868-2500.

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**Patient Bill of Rights**

Case managers respect the wishes of patients and their families and recognize that all patients have the right to:

• Have information disclosed regarding why the service choices were chosen for their care.
• Offer input into the case management plan for their care.
• Refuse treatment or services, including case management.
• Have end-of-life and advance care directives honored by our case management organization.

• Be informed of the criteria used for closing cases.
• Be notified when case management services are changed or stopped and why.
• Receive a full case management assessment for services even if the patient or family cannot fully participate in the initial assessment process.

Case managers will tell patients about these rights at the beginning of a case and uphold them at all times during the management of the case. All patients will receive a written copy of these rights within five days of case opening.

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For more about your benefit plan, please log in to your account at [www.MyHealthToolkitFL.com](http://www.MyHealthToolkitFL.com).

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Inga Gonzalez may live in Orlando, but when she says, “It’s a rollercoaster,” she’s not talking about an amusement park ride in a nearby theme park; she’s referring to her work as the FCS Vice President of Operations for Central Florida, an area that covers clinics in Orange, Seminole, Volusia, Flagler, Lake, Sumter and Clay Counties.

With 23 clinics and approximately 350 staff members under her purview, Gonzalez is certainly busy — but she wouldn’t have it any other way. “My job never gets old,” she says. “It’s full of excitement, and I embrace every moment. I love what I do. I’m always on the go, always traveling throughout Central Florida, so even the landscape around me changes. But what’s really exciting to me are the challenges each day brings and the talented group of people I work with. It’s such a diverse group, and every person has taught me something. Who I am today is a reflection of the
Inga Gonzalez, Regional VP of Operations, and her family.

Regional Director of Operations. She became Senior Regional Director of Operations for FCS in 2015 and received her recent promotion to Vice President of Practice Operations in June 2017.

Since the 2011 merger that brought Gonzalez to FCS, she has led, supported or played an integral role in nine mergers.

“I’m a product of a merger,” she says, “They are near and dear to my heart. I can appreciate and understand the intricacies of the changes that surround a merger, as well as the highs and lows and the level of anxiety that comes with this kind of project. Some mergers are exciting because they’re new; some are exciting because they’re challenging. Each one is unique.”

In addition to the many mergers in which Gonzalez has been involved, she has also led several build-out and expansion projects, the largest of which was the Villages Cancer Center in October of 2016.

“That was a huge undertaking, literally,” she says. “It’s a 20,000-square-foot facility, and it provides both medical and radiation oncology.”

Gonzalez also led FCS into the Jacksonville market with a “dual transition” that involved merging with and building out an office. The new Fleming Island office opened this past July.

“From the growth in my area, I was privileged to have expanded my leadership team by two, with Annie Pigue and Laura Sperry coming on as Associate Regional Directors of Operations,” Gonzalez says. “We definitely stay busy; but even if there wasn’t a lot to do, I’m the kind of person who constantly wants to have a project in the pipeline. It’s important, though, that every project should serve our goal, which is to provide the best patient care possible. At FCS, everything we do is in the service of our patients.”

Gonzalez and other members of Senior Management developed new patient forms and a new patient guide, both of which became available last year. She also worked on the Operational Excellence Team, which developed standard operating procedures and devised improved workflows and processes.

“An effective team gets things done and in order to complete a project, it’s important to have good communication, Gonzalez says. “I believe that communication drives an organization. When you work with people who understand that, it makes all the difference in the world. Add to that the quality of physicians we have, and FCS is second to none.”

“I’ve worked in many medical specialties, but the reason I’ve stayed in oncology for so long is because I have a personal connection,” she says. “I know, through experience, that the way doctors treat their patients matters. I feel privileged to align myself with so many people who are giving their all in everything they do. I certainly wouldn’t be where I am, today, without them and the support of my wonderful family.”

team I work with, which includes members of Executive and Senior management, physicians and administrative and clinical team. I couldn’t tackle all the obstacles that arise without them. They’ve all made a difference in my career.”

Gonzalez’s career started when, as a 17-year-old, she took a job as a receptionist at a medical clinic in her home city of Brooklyn, New York. A marriage, a business, a birth and several years later, she, her husband, Peter, and son, Kevin, moved to Orlando, where she took a job as a manager at a pain management clinic and, subsequently, had another son, Matthew. In the ensuing years, as manager of patient services for cardiology, she developed physician protocols and optimized patient flow for another practice, which was served by 16 physicians and two nurse practitioners. In 2011, the businesses for which Gonzalez worked as Practice Manager merged with FCS, and she was made
For patients with multiple myeloma after 1 prior therapy

EXTEND EFFICACY.
EXTEND THE POSSIBILITIES.

The approval of the NINLARO® (ixazomib) regimen (NINLARO®+lenalidomide+dexamethasone) was based on a statistically significant ~6 month improvement in median PFS vs the placebo regimen (placebo+lenalidomide+dexamethasone).*

- Median PFS: 20.6 vs 14.7 months (95% CI, 17.0-NE and 95% CI, 12.9-17.6, respectively); HR=0.74 (95% CI, 0.587-0.939); P=0.012

**NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend ixazomib in combination with lenalidomide and dexamethasone as a category 1 treatment option for previously treated multiple myeloma.**¹

NINLARO is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

- **Thrombocytopenia** has been reported with NINLARO. During treatment, monitor platelet counts at least monthly, and consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines. Adjust dosing as needed. Platelet nadirs occurred between Days 14-21 of each 28-day cycle and typically recovered to baseline by the start of the next cycle.
- **Gastrointestinal Toxicities**, including diarrhea, constipation, nausea and vomiting, were reported with NINLARO and may occasionally require the use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea resulted in the discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for severe symptoms.
- **Peripheral Neuropathy** (predominantly sensory) was reported with NINLARO. The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimens, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (< 1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in both regimens. Monitor patients for symptoms of peripheral neuropathy and adjust dosing as needed.
- **Peripheral Edema** was reported with NINLARO. Monitor for fluid retention. Investigate for underlying causes when appropriate and provide supportive care as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.
- **Cutaneous Reactions**: Rash, most commonly maculo-papular and macular rash, was reported with NINLARO. Rash resulted in discontinuation of one or more of the three drugs in < 1% of patients in both regimens. Manage rash with supportive care or with dose modification.
- **Hepatotoxicity** has been reported with NINLARO. Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in < 1% of patients treated with NINLARO. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes regularly during treatment and adjust dosing as needed.

**THE FIRST AND ONLY ORAL PROTEASOME INHIBITOR**

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EXTEND THE POSSIBILITIES.

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- Thrombocytopenia

Warnings and Precautions

Important Safety Information

myeloma who have received at least one prior therapy.

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dexamethasone for the treatment of patients with multiple

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For patients with multiple myeloma after 1 prior therapy

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Peripheral Edema

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Hepatotoxicity

Events of liver impairment have been reported (6% in the

NINLARO regimen and 5% in the placebo regimen). Monitor

for symptoms of

Liver function tests should be monitored during

and if hepatic toxicity occurs.

For patients with moderate or severe

Reduce the NINLARO starting dose

of NINLARO with strong CYP3A inducers.

Avoid concomitant administration

Hepatic Impairment:

Reduce the NINLARO starting
dose to 3 mg in patients with moderate or severe

hepatic impairment.

Renal Impairment:

Reduce the NINLARO starting
dose to 3 mg in patients with severe renal impairment or

end-stage renal disease requiring dialysis. NINLARO is not dialyzable.

Lactation:

Advise nursing women not to breastfeed during
treatment with NINLARO and for 90 days after the last dose.

Drug Interactions:

Avoid concomitant administration

NINLARO with strong CYP3A inducers.

TOURMALINE-MM1: a global, phase 3, randomized (1:1),
double-blind, placebo-controlled study that evaluated the safety

and efficacy of NINLARO (an oral proteasome inhibitor) vs

placebo, both in combination with lenalidomide and
dexamethasone, until disease progression or unacceptable
toxicity in 722 patients with relapsed and/or refractory multiple

myeloma who received 1-3 prior therapies.2

The NCCN Guidelines are a work in progress that may be refined as often as

new significant data becomes available. The NCCN Guidelines are a statement

of consensus of its authors regarding their views of currently accepted

approaches to treatment. Any clinician seeking to apply or consult any NCCN

Guidelines is expected to use independent medical judgment in the context of

individual clinical circumstances to determine any patient’s care or treatment.

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Available at Rx To Go.
Get more information at www.NINLAROhcp.com.

Embryo-Fetal Toxicity:

NINLARO can cause fetal harm. Women should be advised of the potential risk to a fetus, to avoid becoming pregnant, and to use contraception during treatment and for an additional 90 days after the final dose of NINLARO. Women using hormonal contraceptives should also use a barrier method of contraception.

Adverse Reactions

The most common adverse reactions (≥ 20%) in the NINLARO regimen and greater than the placebo regimen, respectively, were diarrhea (42%, 36%), constipation (34%, 25%), thrombocytopenia (78%, 54%; pooled from adverse events and laboratory data), peripheral neuropathy (28%, 21%), nausea (26%, 21%), peripheral edema (25%, 18%), vomiting (22%, 11%), and back pain (21%, 16%). Serious adverse reactions reported in ≥ 2% of patients included thrombocytopenia (2%) and diarrhea (2%).

Special Populations

Hepatic Impairment: Reduce the NINLARO starting dose to 3 mg in patients with moderate or severe hepatic impairment.

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Drug Interactions:

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approaches to treatment. Any clinician seeking to apply or consult any NCCN

Guidelines is expected to use independent medical judgment in the context of

individual clinical circumstances to determine any patient’s care or treatment.

The National Comprehensive Cancer Network makes no warranties of any

kind whatsoever regarding their content, use or application and disclaims

any responsibility for their application or use in any way.

Available at Rx To Go.
Get more information at www.NINLAROhcp.com.
BRIEF SUMMARY OF PRESCRIBING INFORMATION
NINLARO (ixazomib) capsules, for oral use

1 INDICATION

NINLARO (ixazomib) is indicated in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least one prior therapy.

5 WARNINGS AND PRECAUTIONS

5.1 Thrombocytopenia: Thrombocytopenia has been reported with NINLARO with rates typically occurring between Days 14-21 of each 28-day cycle and recovery to baseline by the start of the next cycle. Three percent of patients in the NINLARO regimen and 1% of patients in the placebo regimen had a platelet count ≤ 10,000/mm³ during treatment. Less than 1% of patients in both regimens had a platelet count ≤ 5000/mm³ during treatment. Discontinuations due to thrombocytopenia were similar in both regimens (< 1% of patients in the NINLARO regimen and 2% of patients in the placebo regimen discontinued one or more of the three drugs). The rate of platelet transfusions was 6% in the NINLARO regimen and 5% in the placebo regimen.

Monitor platelet counts at least monthly during treatment with NINLARO. Consider more frequent monitoring during the first three cycles. Manage thrombocytopenia with dose modifications and platelet transfusions as per standard medical guidelines.

5.2 Gastrointestinal Toxicities: Diarrhea, constipation, nausea, and vomiting, have been reported with NINLARO, occasionally requiring use of antidiarrheal and antiemetic medications, and supportive care. Diarrhea was reported in 42% of patients in the NINLARO regimen and 36% in the placebo regimen, constipation in 34% and 25%, respectively, nausea in 26% and 21%, respectively, and vomiting in 22% and 11%, respectively. Diarrhea resulted in discontinuation of one or more of the three drugs in 1% of patients in the NINLARO regimen and < 1% of patients in the placebo regimen. Adjust dosing for Grade 3 or 4 symptoms.

5.3 Peripheral Neuropathy: The majority of peripheral neuropathy adverse reactions were Grade 1 (18% in the NINLARO regimen and 14% in the placebo regimen) and Grade 2 (8% in the NINLARO regimen and 5% in the placebo regimen). Grade 3 adverse reactions of peripheral neuropathy were reported at 2% in both regimens; there were no Grade 4 or serious adverse reactions.

The most commonly reported reaction was peripheral sensory neuropathy (19% and 14% in the NINLARO and placebo regimen, respectively). Peripheral motor neuropathy was not commonly reported in either regimen (< 1%). Peripheral neuropathy resulted in discontinuation of one or more of the three drugs in 1% of patients in both regimens. Patients should be monitored for symptoms of neuropathy. Patients experiencing new or worsening peripheral neuropathy may require dose modification.

5.4 Peripheral Edema: Peripheral edema was reported in 25% and 18% of patients in the NINLARO and placebo regimens, respectively. The majority of peripheral edema adverse reactions were Grade 1 (16% in the NINLARO regimen and 13% in the placebo regimen) and Grade 2 (7% in the NINLARO regimen and 4% in the placebo regimen).

Grade 3 peripheral edema was reported in 2% and 1% of patients in the NINLARO and placebo regimens, respectively. There was no Grade 4 peripheral edema reported. There were no discontinuations reported due to peripheral edema. Evaluate for underlying causes and provide supportive care, as necessary. Adjust dosing of dexamethasone per its prescribing information or NINLARO for Grade 3 or 4 symptoms.

5.5 Cutaneous Reactions: Rash was reported in 19% of patients in the NINLARO regimen and 11% of patients in the placebo regimen. The majority of the rash adverse reactions were Grade 1 (10% in the NINLARO regimen and 7% in the placebo regimen) or Grade 2 (6% in the NINLARO regimen and 3% in the placebo regimen), Grade 3 rash was reported in 3% of patients in the NINLARO regimen and 1% of patients in the placebo regimen. There were no Grade 4 or serious adverse reactions of rash reported. The most common type of rash reported in both regimens included maculo-papular and macular rash. Rash resulted in discontinuation of one or more of the three drugs in < 1% of patients in both regimens. Manage rash with supportive care or with dose modification if Grade 2 or higher.

5.6 Hepatotoxicity: Drug-induced liver injury, hepatocellular injury, hepatic steatosis, hepatitis cholestatic and hepatotoxicity have each been reported in < 1% of patients treated with NINLARO. Events of liver impairment have been reported (6% in the NINLARO regimen and 5% in the placebo regimen). Monitor hepatic enzymes more frequently and adjust dosing for Grade 3 or 4 symptoms.

5.7 Embryo-Fetal Toxicity: NINLARO can cause fetal harm when administered to a pregnant woman based on the mechanism of action and findings in animals. There are no adequate and well-controlled studies in pregnant women using NINLARO. Ixazomib caused embryo-fetal toxicity in pregnant rats and rabbits at doses resulting in exposures that were slightly higher than those observed in patients receiving the recommended dose.

Females of reproductive potential should be advised to avoid becoming pregnant while being treated with NINLARO. If NINLARO is used during pregnancy or if the patient becomes pregnant while taking NINLARO, the patient should be apprised of the potential hazard to the fetus. Advise females of reproductive potential that they must use effective contraception during treatment with NINLARO and for 90 days following the final dose. Women using hormonal contraceptives should also use a barrier method of contraception.

6 ADVERSE REACTIONS

The following adverse reactions are described in detail in other sections of the prescribing information:

- Thrombocytopenia [see Warnings and Precautions (5.1)]
- Gastrointestinal Toxicities [see Warnings and Precautions (5.2)]
- Peripheral Neuropathy [see Warnings and Precautions (5.3)]
- Peripheral Edema [see Warnings and Precautions (5.4)]
- Cutaneous Reactions [see Warnings and Precautions (5.5)]
- Hepatotoxicity [see Warnings and Precautions (5.6)]

6.1 CLINICAL TRIALS 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.

The safety population from the randomized, double-blind, placebo-controlled clinical study included 720 patients with relapsed and/or refractory multiple myeloma, who received NINLARO in combination with lenalidomide and dexamethasone (NINLARO regimen; N=360) or placebo in combination with lenalidomide and dexamethasone (placebo regimen; N=360). The most frequently reported adverse reactions (> 20%) in the NINLARO regimen and greater than the placebo regimen were diarrhea, constipation, thrombocytopenia, peripheral neuropathy, nausea, peripheral edema, vomiting, and back pain. Serious adverse reactions reported in > 2% of patients included thrombocytopenia (2%) and diarrhea (2%). For each adverse reaction, one or more of the three drugs was discontinued in < 1% of patients in the NINLARO regimen.

Table 4: Non-Hematologic Adverse Reactions Occurring in ≥ 5% of Patients with a ≥ 5% Difference Between the NINLARO Regimen and the Placebo Regimen (All Grades, Grade 3 and Grade 4)

<table>
<thead>
<tr>
<th>System Organ Class / Preferred Term</th>
<th>NINLARO + Lenalidomide and Dexamethasone N=360</th>
<th>Placebo + Lenalidomide and Dexamethasone N=360</th>
<th>N (%)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infections and infestations</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>69 (19)</td>
<td>52 (14)</td>
<td>1 (%)</td>
<td>0</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peripheral neuropathies*</td>
<td>100 (28)</td>
<td>77 (21)</td>
<td>2 (%)</td>
<td>0</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>151 (42)</td>
<td>130 (36)</td>
<td>5 (%)</td>
<td>2 (%)</td>
</tr>
<tr>
<td>Constipation</td>
<td>122 (34)</td>
<td>90 (25)</td>
<td>4 (%)</td>
<td>1 (%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>92 (25)</td>
<td>74 (21)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>79 (22)</td>
<td>38 (11)</td>
<td>2 (%)</td>
<td>1 (%)</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>68 (19)</td>
<td>38 (11)</td>
<td>3 (%)</td>
<td>1 (%)</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>74 (21)</td>
<td>57 (16)</td>
<td>2 (%)</td>
<td>0</td>
</tr>
<tr>
<td>Back pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>91 (25)</td>
<td>66 (18)</td>
<td>4 (%)</td>
<td>0</td>
</tr>
</tbody>
</table>

Note: Adverse reactions included as preferred terms are based on MedDRA version 16.0.

*Represents a pooling of preferred terms

(Continued on next page)
Brief Summary (cont’d)

Table 5: Thrombocytopenia and Neutropenia (pooled adverse event and laboratory data)

<table>
<thead>
<tr>
<th></th>
<th>NINLARO + Lenalidomide and Dexamethasone N=360</th>
<th>Placebo + Lenalidomide and Dexamethasone N=360</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any Grade Grade 3-4</td>
<td>Any Grade Grade 3-4</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>281 (78) 93 (26)</td>
<td>196 (54) 39 (11)</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>240 (67) 93 (26)</td>
<td>238 (66) 107 (30)</td>
</tr>
</tbody>
</table>

Herpes Zoster

Herpes zoster was reported in 4% of patients in the NINLARO regimen and 2% of patients in the placebo regimen. Antiviral prophylaxis was allowed at the physician’s discretion. Patients treated in the NINLARO regimen who received antiviral prophylaxis had a lower incidence (<1%) of herpes zoster infection compared to patients who did not receive prophylaxis (6%).

Eye Disorders

Eye disorders were reported with many different preferred terms but in aggregate, the frequency was 26% in patients in the NINLARO regimen and 16% of patients in the placebo regimen. The most common adverse reactions were dry eye (5% in the NINLARO regimen and 1% in the placebo regimen), conjunctivitis (6% in the NINLARO regimen and 1% in the placebo regimen). Grade 3 adverse reactions were reported in 2% of patients in the NINLARO regimen and 1% in the placebo regimen.

The following serious adverse reactions have each been reported at a frequency of <1%: acute febrile neutrophilic dermatosis (Sweet’s syndrome), Stevens-Johnson syndrome, transverse myelitis, posterior reversible encephalopathy syndrome, tumor lysis syndrome, and thrombotic thrombocytopenic purpura.

7 DRUG INTERACTIONS

7.1 Strong CYP3A Inducers: Avoid concomitant administration of NINLARO with strong CYP3A inducers (such as rifampin, phenytoin, carbamazepine, and St. John’s Wort).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy:

Risk Summary: Based on its mechanism of action and data from animal reproduction studies, NINLARO can cause fetal harm when administered to a pregnant woman. There are no human data available regarding the potential effect of NINLARO on pregnancy or development of the embryo or fetus.

Ixazomib caused embryo-fetal toxicity in pregnant rats and rabbits at doses that were 1.9 times the clinical time averaged exposures at the recommended dose of 4 mg. In a rat dose range-finding embryo-fetal development study, at doses that were 2.5 times the clinical time averaged exposures at the recommended dose of 0.6 mg/kg. Exposures in rats at the dose of 0.6 mg/kg was 2.5 times the clinical time averaged exposures at the recommended dose of 4 mg. In a rat dose range-finding embryo-fetal development study, at doses that were 1.9 times the clinical time averaged exposures at the recommended dose of 4 mg. In a rat dose range-finding embryo-fetal development study, at doses that were 2.5 times the clinical time averaged exposures at the recommended dose of 0.6 mg/kg. Exposures in rats at the dose of 0.6 mg/kg was 2.5 times the clinical time averaged exposures at the recommended dose of 4 mg.

Hepatotoxicity: NINLARO is a registered trademark of Millennium Pharmaceuticals, Inc. Millennium Pharmaceuticals, Inc. is a wholly owned subsidiary of Takeda Pharmaceutical Company Limited.

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Please see full Prescribing Information for NINLARO at NINLARO-hcp.com.

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Focused on Total Care of the Patient

At the New Fleming Island Location, Oncologists Treat People, Not Just Conditions.

BY LAURA CASSELS

Patients diagnosed with cancer have much to learn in a short time — about their conditions, medications, radiation therapy, chemotherapy, surgical options, side effects, supportive therapies, and the roles of various physicians involved in the treatment program.

These seasoned oncologists have been practicing as a team for years, drawn together by similar outlooks on cancer, health, humanity and by mutual trust.

“We all believe in our group, the association we have made, and our commitment to provide the best possible care to our patients,” said Dr. Augusto Villegas.

Drs. Jeffrey Bubis and Villegas have practiced in the Jacksonville area since 2005 teaming up in 2011, with the addition of Dr. Elizabeth Kent in 2013. All three said they believe their new association with Florida Cancer Specialists allows them to deliver better care by giving them the freedom to provide resources that go beyond the essentials.

“It goes without saying that all practices provide the National Comprehensive Cancer Network (NCCN) guidelines for treatment. The differentiator is the intangibles that go with that,” said Dr. Bubis.

“It starts with the person who greets our patients at the front desk, and goes all the way to the clinical team who treats them.”

The Fleming Island physicians insist on providing services not uniformly provided in oncology practices. Those services include a Patient Navigator and an on-site Social Worker. The cost of certain “extras” may not be recouped through insurance, but these doctors believe the value to patients goes beyond price.

No Wait Time

Also priceless is the physicians’ commitment to immediately engage with newly diagnosed patients.

“Diagnosis to surgery in six days,” said Dr. Villegas, relating one experience that he says represents many.

“We got called about a patient with a diagnosis of breast cancer. We called her at 9:00 p.m. that night to arrange to see her the next morning. On the sixth day, she was post-surgical.”

A slower response in scheduling an appointment likely would not have affected the patient’s outcome, but by bringing the patient into the office the next day it allowed the patient to worry less and work with the physician to create a plan.

“If you have a cancer diagnosis, you shouldn’t have to wait a week to get in and be seen,” said Dr. Bubis. “We have you come right over.”

“It gives the patient a game plan. In the time between being given a diagnosis of cancer and starting an active plan of care, the worry and anxiety associated with the unknown can be overwhelming. Even if we do not have all of the information we need at the first visit to make all their treatment plans, we can give them the big picture, and that alone provides some relief,” says Dr Kent.

The office’s staff as a whole play important roles in expediting initiation of treatment, and they continue to serve over time in patients’ ongoing treatment and care.

The Navigator and the Social Worker handle logistics between medical sites, travel with patients to appointments, and help arrange financial assistance. They counsel patients and their loved ones on what to expect and how to cope.

These efforts help patients minimize their fears and cope with
physical and emotional side effects while navigating the intimidating terrain of cancer.

“A great example of how supportive care improves quality of life and thus can improve outcomes is in the area of long-term treatment and maintenance,” Dr. Kent said. “When patients face long-term treatment such as hormonal therapy for early stage breast cancer, compliance is essential to maximizing odds of cure. Left alone to contend with the side effects of various medications, some patients find the challenge too great, and stop the medication early.”

“We have to pay attention to the symptoms they’re having,” Dr. Kent continued. “We feel strongly that our job goes beyond just prescribing the medication and to care for their quality of life during and after therapy.”

Drs. Kent, Bubis and Villegas all agree that it is important to them as oncologists to provide patient-centered care above and beyond the standards of care provided at top cancer treatment centers, such as Moffitt Cancer Center, MD Anderson and Memorial Sloan-Kettering.

“It may be the same drug you’d get at the best facility, but the way you deliver that drug is what makes the difference,” said Dr. Villegas. “We are there 24/7 for our patients, and you don’t get that one-to-one at most large academic medical centers.

“Joining Florida Cancer Specialists gives us the freedom to continue to practice this way,” said Dr. Kent.

The Future of Cancer Treatment

Meanwhile, the FCS Fleming Island team is excited about research and development under way now, leading to new treatment options for tomorrow.

“We are strong believers in clinical trials as part of outstanding care,” said Villegas, who contributes to research and is a frequent presenter at research conferences. “We choose trials that fit our population.”

Breakthroughs in drug therapy promise brighter futures for cancer patients in the foreseeable future.

“The era of generic chemotherapy drugs is ending,” Dr. Villegas said. “We are going to have really targeted therapies that deal with the origins of a tumor to turn off the mutation. That’s how we treat CML (Chronic Myeloid Leukemia). That’s how we treat certain other types of cancers.”

He continued, “We’re learning that not all cancer is the same. With lung cancer, every patient previously received the same treatment. But now, we can ask: What subtype? What variations? What mutations?”

With each breakthrough, Dr. Villegas said, treatment options proliferate. “It’s almost like we have stagnant development, but then a discovery explodes. Once we developed immunotherapy, it wasn’t long until we had four! The development of these drugs continues to accelerate.”

Dr. Bubis said he is eager to see what develops in the area of genomic oncology, where researchers are striving to understand the biology of cancer cells so that “precision medicine” can be developed to target specifically profiled tumor cells while largely sparing normal cells.

“Finding a place for genomic oncology is the future of oncology,” he said. “For example, in breast cancer, you could have unique and individual treatments (based on genetic information),” he said. “This may not come in the next 10 years, but it will come in the span of my career.”

Oncology in the future will be different and more complex, more molecular and targeted; it will aim for the same goals now guiding Drs. Bubis, Villegas and Kent: to save as many lives as possible and, in all cases, even ones where cancer ends a life prematurely, to optimize each patient’s quality of life along the way.

“The research will lead to patients having a good quality of life for longer periods of time relative to what they could expect previously,” said Dr. Bubis.

“Not everything is about the length of survival,” added Dr. Kent. “It’s not just about cancer and treatment. It’s about a person’s whole life and helping him/her live it, despite having cancer.”

Ginger Moloney, Medical Assistant, Team Lead
Dr. Jeffrey A. Bubis, DO, FACOA, FACP

Dr. Bubis earned his medical degree and completed an Internship and Residency at Philadelphia College of Osteopathic Medicine. He was awarded a Fellowship in Hematology/Medical Oncology at Dartmouth-Hitchcock Medical Center and Dartmouth Medical School in Lebanon, New Hampshire. He is a Fellow of the American College of Physicians and of the American College of Osteopathic Internists. He has more than 10 years of clinical research experience, has been published in the Journal of Clinical Oncology, and has presented at national symposiums and conferences. He is a lecturer at the Orange Park Medical Center Internal Medicine Residency program.

Dr. Elizabeth C. Kent, MD

Dr. Kent earned her medical degree from Wayne State University School of Medicine in Detroit and completed her Internship and Residency at Mayo Graduate School of Medicine in Rochester, Minnesota. She was awarded a Fellowship in Hematology/Oncology at the University of Michigan in Ann Arbor. She is Chief of the Department of Medicine at St. Vincent’s Hospital Clay County and is Cancer Liaison for the Commission on Cancer at Orange Park Medical Center. She has participated in clinical research for more than 15 years, with multiple publications in peer-reviewed journals, and has presented at national meetings, including ASH. She is a faculty member and lecturer for Orange Park Medical Center Internal Medicine Residency program.

Dr. Augusto E. Villegas, MD

Dr. Villegas earned his medical degree from Ponce School of Medicine in Ponce, Puerto Rico. He completed his Fellowship training in Medical Oncology at the University of Florida Health Science Center, Jacksonville Campus. His research interests include breast cancer, lung cancer and immunotherapies. He has been published in peer-reviewed journals and has presented at symposiums and national scientific meetings, including the 2017 Annual Meeting of the American Society of Clinical Oncology (ASCO) and the 2015 World Conference on Lung Cancer. He is a faculty member and lecturer for the Orange Park Medical Center Internal Medicine Residency Program. He is fluent in Spanish.
Physician investigators continue to raise the research profile of Florida Cancer Specialists, most recently at the 2017 American Society of Clinical Oncology (ASCO) annual meeting, which brought more than 30,000 oncology professionals to Chicago in June.

FCS Investigators presented data on nearly 20 clinical trials, the result of the partnership between FCS and Sarah Cannon, one of the world’s leading clinical research organizations conducting community-based clinical trials. FCS is one of only six strategic oncology sites to partner with Sarah Cannon, headquartered in Nashville. FCS has partnered with Sarah Cannon for 11 years, though clinical trials have been performed at FCS since the start of the practice in 1984.

Katie Goodman, Director of Clinical Research at FCS, explained that the release of clinical trial data is typically timed to coincide with the ASCO Annual Meeting. “Leading up to ASCO, drug companies and researchers submit to ASCO some of their preliminary findings, and then ASCO determines which information is important to share.”

As research from clinical trials completed by FCS has gathered attention, the company’s program has begun to rival that of many academic medical centers. In 2016, 84 percent of all new cancer drugs were studied in clinical trials offered by FCS prior to FDA approval.

American Society of Clinical Oncology

“FCS is well-known to pharmaceutical companies as a place they can trust. When they’re selecting a research site, they need to be able to trust that those they’re allowing to manage their new drug will handle it with care and that we will provide quality and reliable care to the patients who are receiving it. Due to our many years of participating in trials, we have managed to become one of the premier research sites in the country,” Goodman said.

Dr. Manish Patel and Dr. Judy Wang, principal investigators of the Phase 1 Drug Development Unit (DDU) in Sarasota, Florida, had early and senior authorships on many of the FCS co-authored presentations. Research involving clinical trials focused on medications targeting specific genetic mutations, immunotherapy and antibody drug conjugates. Targeted therapies included ERK inhibitors, MNK 1/2 inhibitors, MDM2/MDMX inhibitors, and IDH2 inhibitors.
“Early phase trials are now much larger than they used to be and we are answering more questions earlier on in the process, and therefore the field is moving much more quickly,” Dr. Patel said of the presentations from the Phase 1 DDU, noting that advanced technologies also play a role. “It’s gratifying to see patient clinical responses this early in the life of these drugs.”

Shortening the timeline also means that oncologists and patients are able to obtain access to promising therapy earlier on. Patel believes that many of the new cancer drugs tested by the Phase 1 DDU may be approved in the near future.

In the meantime, commitment to research at FCS and the partnership with Sarah Cannon give FCS patients access to life-saving advances where they live. “The beauty of clinical trials, said Goodman, is that patients get additional therapies atop standard treatments. Clinical trial research at FCS means that if you’re living in the state of Florida, you have earlier access to new therapies that may prove to be successful.”

“Florida Cancer Specialists is dedicated to refining the science and the study of malignancies as well as sharing knowledge on new findings that will rapidly advance and improve cancer treatments for our patients,” said Brad Prechtl, CEO of FCS. “The fact that we had so many presentations accepted at ASCO is a reflection of the strong commitment to clinical research at FCS.”

FCS clinical trials changed the life of Pamela Klein, diagnosed with advanced adenocarcinoma lung cancer with the ROS1 gene mutation. She participated in a clinical trial at the Phase 1 DDU and she has achieved a complete response to treatment for over two years. “I knew that I had this really rare gene mutation. If I didn’t want to just receive chemo, killing cells all throughout my body, I needed to consider other forms of treatment. Florida Cancer Specialists had the trial that I needed. It was a trial specifically for my mutation,” Klein said.

She added, “I can definitively say that the actions of my doctor at Florida Cancer Specialists and the fact that they offer clinical trials for patients like me with rare gene mutations, is the reason I’m still here.”
Grab your girlfriends for an evening of wine, shopping, fashion & compassion!

**NOVEMBER 4, 2017**

5:30-9:30 PM • WESTIN, LAKE MARY

2974 International Pkwy, Lake Mary, FL 32746

Grab your girlfriends for an evening of wine, shopping, fashion & compassion!

**GENERAL ADMISSION $150 • VIP $200**

All tickets include wine tasting, savory bites and fashion show. VIP includes VIP seating with champagne and special dessert during program/fashion show and upgraded swag bag.

Proceeds help provide non-medical financial support to cancer patients and their families.

For tickets, visit: WineWomenAndShoes.com/LakeMary

-or- Foundation.FLCancer.com/WWS17
NOW APPROVED

Indication
ALIQOPA (copanlisib) is indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies.

Accelerated approval was granted for this indication based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Learn more at Aliqopa.com

Important Safety Information
Infections: Serious, including fatal, infections occurred in 19% of 317 patients treated with ALIQOPA monotherapy. The most common serious infection was pneumonia. Monitor patients for signs and symptoms of infection and withhold ALIQOPA for Grade 3 and higher infection.

Serious pneumocystis jiroveci pneumonia (PJP) infection occurred in 0.6% of 317 patients treated with ALIQOPA monotherapy. Before initiating treatment with ALIQOPA, consider PJP prophylaxis for populations at risk. Withhold ALIQOPA in patients with suspected PJP infection of any grade. If confirmed, treat infection until resolution, then resume ALIQOPA at previous dose with concomitant PJP prophylaxis.

Hyperglycemia: Grade 3 or 4 hyperglycemia (blood glucose 250 mg/dL or greater) occurred in 41% of 317 patients treated with ALIQOPA monotherapy. Serious hyperglycemic events occurred in 2.8% of patients. Treatment with ALIQOPA may result in infusion-related hyperglycemia. Blood glucose levels typically peaked 5 to 8 hours post-infusion and subsequently declined to baseline levels for a majority of patients; blood glucose levels remained elevated in 17.7% of patients one day after ALIQOPA infusion. Of 155 patients with baseline HbA1c <5.7%, 16 (10%) patients had HbA1c >6.5% at the end of treatment. Of the twenty patients with diabetes mellitus treated in CHRONOS-1, seven developed Grade 4 hyperglycemia and two discontinued treatment. Patients with diabetes mellitus should only be treated with ALIQOPA following adequate glucose control and should be monitored closely. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of hyperglycemia.

Please see additional Important Safety Information and Brief Summary of full Prescribing Information on the following pages.
Important Safety Information (cont’d)

**Hypertension:** Grade 3 hypertension (systolic 160 mmHg or greater or diastolic 100 mmHg or greater) occurred in 26% of 317 patients treated with ALIQOPA monotherapy. Serious hypertensive events occurred in 0.9% of 317 patients. Treatment with ALIQOPA may result in infusion-related hypertension. The mean change of systolic and diastolic BP from baseline to 2 hours post-infusion on Cycle 1 Day 1 was 16.8 mmHg and 7.8 mmHg, respectively. The mean BP started decreasing approximately 2 hours post-infusion; BP remained elevated for 6 to 8 hours after the start of the ALIQOPA infusion. Optimal BP control should be achieved before starting each ALIQOPA infusion. Monitor BP pre- and post-infusion. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of hypertension.

**Non-infectious Pneumonitis:** Non-infectious pneumonitis occurred in 5% of 317 patients treated with ALIQOPA monotherapy. Withhold ALIQOPA and conduct a diagnostic examination of a patient who is experiencing pulmonary symptoms such as cough, dyspnea, hypoxia, or interstitial infiltrates on radiologic exam. Patients with pneumonitis thought to be caused by ALIQOPA have been managed by withholding ALIQOPA and administration of systemic corticosteroids. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of non-infectious pneumonitis.

**Neutropenia:** Grade 3 or 4 neutropenia occurred in 24% of 317 patients treated with ALIQOPA monotherapy. Serious neutropenic events occurred in 1.3%. Monitor blood counts at least weekly during treatment with ALIQOPA. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of neutropenia.

**Severe Cutaneous Reaction:** Grade 3 and 4 cutaneous reactions occurred in 2.8% and 0.6% of 317 patients treated with ALIQOPA monotherapy respectively. Serious cutaneous reaction events were reported in 0.9%. The reported events included dermatitis exfoliative, exfoliative rash, pruritus, and rash (including maculo-papular rash). Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of severe cutaneous reactions.

**Embryo-Fetal Toxicity:** Based on findings in animals and its mechanism of action, ALIQOPA can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of copanlisib to pregnant rats during organogenesis caused embryo-fetal death and fetal abnormalities in rats at maternal doses as low as 0.75 mg/kg/day (4.5 mg/m²/day body surface area) corresponding to approximately 12% the recommended dose for patients. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for at least one month after the last dose.

**Lactation:** Advise women not to breastfeed. Advise a lactating woman not to breastfeed during treatment with ALIQOPA and for at least 1 month after the last dose.

**Adverse Drug Reactions:** Serious adverse reactions were reported in 44 (26%) patients. The most frequent serious adverse reactions that occurred were pneumonia (8%), pneumonitis (5%) and hyperglycemia (5%). Adverse reactions resulted in dose reduction in 36 (21%) and discontinuation in 27 (16%) patients. The most frequently observed adverse drug reactions (≥20%) in ALIQOPA-treated patients were: hyperglycemia (54%), leukopenia (36%), diarrhea (36%), decreased general strength and energy (36%), hypertension (35%), neutropenia (32%), nausea (26%), thrombocytopenia (22%), and lower respiratory tract infections (21%).

**Drug Interactions:** Avoid concomitant use with strong CYP3A inducers. Reduce the ALIQOPA dose to 45 mg when concomitantly administered with strong CYP3A inhibitors.

Please see additional Important Safety Information on the previous page and Brief Summary of full Prescribing Information on the following pages.
ALIQOPA™ (copanlisib) for injection, for intravenous use  
Initial U.S. Approval: 2017

BRIEF SUMMARY OF PRESCRIBING INFORMATION  
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE
ALIQOPA is indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies. Accelerated approval was granted for this indication based on overall response rate [see Clinical Studies (14.1)]. Continued approval for clinical benefit in a confirmatory trial.

5 WARNINGS AND PRECAUTIONS

5.1 Infections
Serious, including fatal, infections occurred in 19% of 317 patients treated with ALIQOPA monotherapy. The most common serious infection was pneumonia [see Adverse Reactions (6.1)]. Monitor patients for signs and symptoms of infection and withhold ALIQOPA for Grade 3 and higher infection [see Dosage and Administration (2.5)]. Serious pneumocystis jiroveci pneumonia (PJP) occurred in 0.6% of 317 patients treated with ALIQOPA monotherapy [see Adverse Reactions (6.1)]. Before initiating treatment with ALIQOPA, consider PJP prophylaxis for populations at risk. Withhold ALIQOPA in patients with suspected PJP infection of any grade. If confirmed, treat infection until resolution, then resume ALIQOPA at previous dose with concomitant PJP prophylaxis [see Dosage and Administration (2.5)].

5.2 Hyperglycemia
Grade 3 or 4 hyperglycemia (blood glucose 250 mg/dL or greater) occurred in 41% of 317 patients treated with ALIQOPA monotherapy [see Adverse Reactions (6.1)]. Serious hyperglycemic events occurred in 2.8% of patients. Treatment with ALIQOPA may result in infusion-related hyperglycemia. Blood glucose levels typically peaked 5 to 8 hours post-infusion and subsequently declined to baseline levels for a majority of patients; blood glucose levels remained elevated in 17.7% of patients one day after ALIQOPA infusion. Of 155 patients with baseline HbA1c <5.7%, 16 (10%) patients had HbA1c >6.5% at the end of treatment.

Of the twenty patients with diabetes mellitus treated in CHRONOS-1, seven developed Grade 4 hyperglycemia and two discontinued treatment. Patients with diabetes mellitus should only be treated with ALIQOPA following adequate glucose control and should be monitored closely. Achieve optimal blood glucose control before starting each ALIQOPA infusion. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of hyperglycemia [see Dosage and Administration (2.5)].

5.3 Hypertension
Grade 3 hypertension (systolic 160 mmHg or greater or diastolic 100 mmHg or greater) occurred in 26% of 317 patients treated with ALIQOPA monotherapy [see Adverse Reactions (6.1)]. Serious hypertensive events occurred in 0.9% of 317 patients. Treatment with ALIQOPA may result in infusion-related hypertension. The mean change of systolic and diastolic BP from baseline to 2 hours post-infusion on Cycle 1 Day 1 was 16.8 mmHg and 7.8 mmHg, respectively. The mean BP started decreasing approximately 2 hours post-infusion; BP remained elevated for 6 to 8 hours after the start of the ALIQOPA infusion. Optimal BP control should be achieved before starting each ALIQOPA infusion. Monitor BP pre- and post-infusion. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of hypertension [see Dosage and Administration (2.5)].

5.4 Non-Infectious Pneumonitis
Non-infectious pneumonitis occurred in 5% of 317 patients treated with ALIQOPA monotherapy [see Adverse Reactions (6.1)]. Withhold ALIQOPA and conduct a diagnostic examination of a patient who is experiencing pulmonary symptoms such as cough, dyspnea, hypoxia, or interstitial infiltrates on radiologic exam. Patients with pneumonitis thought to be caused by ALIQOPA have been managed by withholding ALIQOPA and administration of systemic corticosteroids. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of non-infectious pneumonitis [see Dosage and Administration (2.5)].

5.5 Neutropenia
Grade 3 or 4 neutropenia occurred in 24% of 317 patients treated with ALIQOPA monotherapy. Serious neutropenic events occurred in 1.3% [see Adverse Reactions (6.1)]. Monitor blood counts at least weekly during treatment with ALIQOPA. Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of neutropenia [see Dosage and Administration (2.5)].

5.6 Severe Cutaneous Reactions
Grade 3 and 4 cutaneous reactions occurred in 2.8% and 0.6% of 317 patients treated with ALIQOPA monotherapy, respectively [see Adverse Reactions (6.1)]. Serious cutaneous reaction events were reported in 0.9%. The reported events included dermatitis exfoliative, exfoliative rash, pruritus, and rash (including maculo-papular rash). Withhold, reduce dose, or discontinue ALIQOPA depending on the severity and persistence of severe cutaneous reactions [see Dosage and Administration (2.5)].

5.7 Embryo-Fetal Toxicity
Based on findings in animals and its mechanism of action, ALIQOPA can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of copanlisib to pregnant rats during organogenesis caused embryofetal death and fetal abnormalities in rats at maternal doses as low as 0.75 mg/kg/day (4.5 mg/m²/day body surface area) corresponding to approximately 12% the recommended dose for patients. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment and for at least one month after the last dose [see Use in Specific Populations (8.1, 8.3) and Clinical Pharmacology (12.1)].

6 ADVERSE REACTIONS
The following serious adverse reactions are described elsewhere in the labeling.

• Infections [see Warnings and Precautions (5.1)]
• Hyperglycemia [see Warnings and Precautions (5.2)]
• Hypertension [see Warnings and Precautions (5.3)]
• Non-infectious pneumonitis [see Warnings and Precautions (5.4)]
• Neutropenia [see Warnings and Precautions (5.5)]
• Severe cutaneous reactions [see Warnings and Precautions (5.6)]

6.1 Clinical Trials 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 the general patient population. The safety data reflect exposure to ALIQOPA in 168 adults with follicular lymphoma and other hematologic malignancies treated with ALIQOPA 60 mg or 0.8 mg/kg equivalent in clinical trials. The median duration of treatment was 22 weeks (range 1 to 206 weeks).

Serious adverse reactions were reported in 44 (26%) patients. The most frequent serious adverse reactions that occurred were pneumonia (8%), pneumonitis (5%) and hyperglycemia (5%). The most common adverse reactions (>20%) were hyperglycemia, diarrhea, decreased general strength and energy, hypotension, leukopenia, neutropenia, nausea, lower respiratory tract infections, and thrombocytopenia.
Adverse reactions resulted in dose reduction in 36 (21%) and discontinuation in 27 (16%) patients. The most common reasons for dose reduction were hyperglycemia (7%), neutropenia (5%), and hypertension (6%). The most common reasons for drug discontinuation were pneumonitis (2%) and hyperglycemia (2%).

Table 2 provides the adverse reactions occurring in at least 10% of patients receiving ALIQOPA monotherapy, and Table 3 provides the treatment-emergent laboratory abnormalities in ≥20% of patients and ≥4% of Grade ≥3 treated with ALIQOPA.

### Table 2: Adverse Reactions Reported in ≥10% of Patients with Follicular Lymphoma and Other Hematologic Malignancies Treated with ALIQOPA

<table>
<thead>
<tr>
<th>ADVERSE REACTIONS</th>
<th>Copanlisib N = 168</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metabolism and nutrition disorders</td>
<td></td>
</tr>
<tr>
<td>Hyperglycemia</td>
<td>90 (54%) 56 (33%) 10 (6%)</td>
</tr>
<tr>
<td>Blood and lymphatic system disorders</td>
<td></td>
</tr>
<tr>
<td>Leukopenia (including febrile neutropenia)</td>
<td>61 (36%) 20 (12%) 26 (15%)</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>53 (32%) 16 (10%) 26 (15%)</td>
</tr>
<tr>
<td>Thrombocytopenia</td>
<td>37 (22%) 12 (7%) 2 (1%)</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
</tr>
<tr>
<td>Decreased general strength and energy (includes fatigue and asthenia)</td>
<td>61 (36%) 6 (4%) 0</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>60 (36%) 8 (5%) 0</td>
</tr>
<tr>
<td>Nausea</td>
<td>43 (26%) 1 (&lt;1%) 0</td>
</tr>
<tr>
<td>Stomatitis (includes oropharyngeal erosion and ulcer, oral pain)</td>
<td>24 (14%) 3 (2%) 0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>21 (13%) 0 0</td>
</tr>
<tr>
<td>Vascular disorders</td>
<td></td>
</tr>
<tr>
<td>Hypertension (includes secondary hypertension)</td>
<td>59 (35%) 46 (27%) 0</td>
</tr>
<tr>
<td>Infections</td>
<td></td>
</tr>
<tr>
<td>Lower respiratory tract infections (includes pneumonia, pneumonia bacterial, pneumonia mucocellular, pneumonia fungal, pneumonia viral, pneumocystis jiroveci pneumonia, bronchopulmonary aspergillosis and lung infection)</td>
<td>35 (21%) 20 (12%) 3 (2%)</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
</tr>
<tr>
<td>Rash (includes exfoliative skin reactions)</td>
<td>26 (15%) 2 (1%) 1 (&lt;1%)</td>
</tr>
</tbody>
</table>

Additional adverse drug reactions reported at a frequency of <10% in patients with follicular lymphoma and other hematologic malignancies include pneumonitis (9%), mucosal inflammation (8%), and paresthesia and dysesthesia (7%).

### Table 3: Treatment-emergent Laboratory Abnormalities in ≥20% of Patients and ≥4% of Grade ≥3 Treated with ALIQOPA

<table>
<thead>
<tr>
<th>Laboratory Parameter</th>
<th>Copanlisib Monotherapy N = 168*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematology abnormalities</td>
<td></td>
</tr>
<tr>
<td>Decreased hemoglobin</td>
<td>130 (78%) 7 (4%) 0</td>
</tr>
<tr>
<td>Lymphocyte count decreased</td>
<td>126 (78%) 43 (27%) 4 (2%)</td>
</tr>
<tr>
<td>White blood cell decreased</td>
<td>118 (71%) 30 (18%) 3 (2%)</td>
</tr>
<tr>
<td>Platelet count decreased</td>
<td>109 (65%) 11 (7%) 3 (2%)</td>
</tr>
<tr>
<td>Neutrophil count decreased</td>
<td>104 (63%) 20 (12%) 25 (15%)</td>
</tr>
<tr>
<td>Serum chemistry abnormalities</td>
<td></td>
</tr>
<tr>
<td>Hyperglycemia</td>
<td>160 (95%) 72 (43%) 9 (5%)</td>
</tr>
<tr>
<td>Hypertriglyceridemia</td>
<td>74 (48%) 6 (5%) 0</td>
</tr>
<tr>
<td>Hyperphosphatemia</td>
<td>72 (44%) 24 (15%) 0</td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>42 (25%) 40 (24%) 2 (1%)</td>
</tr>
<tr>
<td>Serum lipase increased</td>
<td>34 (21%) 11 (7%) 2 (1%)</td>
</tr>
</tbody>
</table>

* Denominator for each laboratory parameter may vary based on number of patients with specific numeric laboratory values available.

**NCI-CTCAE v4.03

8 DRUG INTERACTIONS

8.1 Pregnancy

Risk Summary

Based on findings from animal studies and the mechanism of action, ALIQOPA can cause fetal harm when administered to a pregnant woman [see Clinical Pharmacology (12.1)]. There are no available data in pregnant women to inform the drug-associated risk. In animal reproduction studies, administration of copanlisib to pregnant rats during organogenesis resulted in embryofetal death and fetal abnormalities at maternal doses approximately 12% of the recommended dose for patients (see Data). Advise pregnant women of the potential risk to a fetus.

Additional adverse drug reactions reported at a frequency of <10% in patients with follicular lymphoma and other hematologic malignancies include pneumonitis (9%), mucosal inflammation (8%), and paresthesia and dysesthesia (7%).
Following administration of radiolabeled copanlisib to pregnant rats approximately 1.5% of the radioactivity (copanlisib and metabolites) reached the fetal compartment.

8.2 Lactation
Risk Summary
There are no data on the presence of copanlisib and/or metabolites in human milk, the effects on the breastfed child, or on milk production. Following administration of radiolabeled copanlisib to lactating rats, approximately 2% of the radioactivity was secreted into milk; the milk to plasma ratio of radioactivity was 25-fold. Because of the potential for serious adverse reactions in a breastfed child from copanlisib, advise a lactating woman not to breastfeed during treatment with ALIQOPA and for at least 1 month after the last dose.

8.3 Females and Males of Reproductive Potential
Pregnancy Testing
ALIQOPA can cause fetal harm when administered to a pregnant woman [see Use in Specific Populations (8.1)]. Conduct pregnancy testing prior to initiation of ALIQOPA treatment.

Contraception
Females
Advise female patients of reproductive potential to use highly effective contraception (contraception with a failure rate <1% per year) during treatment with ALIQOPA and for at least one month after the last dose.

Males
Advise male patients with female partners of reproductive potential to use highly effective contraception during treatment with ALIQOPA and for at least one month after the last dose.

Infertility
There are no data on the effect of ALIQOPA on human fertility. Due to the mechanism of action of copanlisib, and findings in animal studies, adverse effects on reproduction, including fertility, are expected [see Nonclinical Toxicology (13.1)].

8.4 Pediatric Use
Safety and effectiveness have not been established in pediatric patients.

8.5 Geriatric Use
No dose adjustment is necessary in patients ≥65 years of age. Of 168 patients with follicular lymphoma and other hematologic malignancies treated with ALIQOPA, 48% were age 65 or older while 16% were age 75 or older. No clinically relevant differences in efficacy were observed between elderly and younger patients. In patients ≥65 years of age, 30% experienced serious adverse reactions and 21% experienced adverse reactions leading to discontinuation. In the patients <65 years of age, 23% experienced serious adverse reactions and 11% experienced adverse reactions leading to discontinuation.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenicity studies have not been conducted with copanlisib. Copanlisib did not cause genetic damage in in vitro or in vivo assays.

Fertility studies with copanlisib were not conducted; however, adverse findings in male and female reproductive systems were observed in the repeat dose toxicity studies. Findings in the male rats and/or dogs included effects on the testes (germinal epithelial degeneration, decreased weight, and/or tubular atrophy), epididymides (spermatid debris, decreased weight, and/or oligospermia/aspermia), and prostate (reduced secretion and/or decreased weight). Findings in female rats included effects on ovaries (hemorrhage, hemorrhagic cysts, and decreased weight), uterus (atrophy, decreased weight), vagina (mononuclear infiltration), and a dose-related reduction in the numbers of female rats in estrus.

17 PATIENT COUNSELING INFORMATION
Advise the patient to read the FDA-approved patient labeling (Patient Information).

- Infections – Advise patients that ALIQOPA can cause serious infections that may be fatal. Advise patients to immediately report symptoms of infection [see Warnings and Precautions (5.1)].
- Hyperglycemia – Advise patients that an infusion-related increase in blood glucose may occur, and to notify their healthcare provider of any symptoms such as pronounced hunger, excessive thirst, headaches, or frequently urinating. Blood glucose levels should be well controlled prior to infusion [see Warnings and Precautions (5.2)].
- Hypertension – Advise patients that an infusion-related increase in blood pressure may occur, and to notify their healthcare provider of any symptoms such as dizziness, passing out, headache, and/or a pounding heart. Blood pressure should be normal or well controlled prior to infusion [see Warnings and Precautions (5.3)].
- Non-infectious pneumonitis – Advise patients of the possibility of pneumonitis, and to report any new or worsening respiratory symptoms including cough or difficulty breathing [see Warnings and Precautions (5.4)].
- Neutropenia – Advise patients of the need for periodic monitoring of blood counts and to notify their healthcare provider if they develop a fever or any signs of infection [see Warnings and Precautions (5.5)].
- Severe cutaneous reactions – Advise patients that a severe cutaneous reaction may occur, and to notify their healthcare provider if they develop skin reactions (rash, redness, swelling, itching or peeling of the skin) [see Warnings and Precautions (5.6)].
- Pregnancy – Advise females of reproductive potential to use effective contraceptive methods and to avoid becoming pregnant during treatment with ALIQOPA and for at least one month after the last dose. Advise patients to notify their healthcare provider immediately in the event of a pregnancy if pregnancy is suspected during ALIQOPA treatment. Advise males with female partners of reproductive potential to use effective contraception during treatment with ALIQOPA and for at least one month after the last dose [see Warnings and Precautions (5.7)].
- Lactation – Advise women not to breastfeed during treatment with ALIQOPA and for at least 1 month after the last dose [see Use in Specific Populations (8.2)].
Florida is a haven for sun seekers, leading many from northern climes to make annual migrations away from snow-covered conifers to a land of palm trees. Some of these winter residents, in addition to dodging chilling conditions, find relief while in Florida from diseases including cancer.

“When winter visitors become cancer patients, we know they’re concerned about quality — and continuity — of care and are sometimes conflicted about where to receive the care they need, or even if they can continue coming to Florida during the winter,” said Shelly Glenn, Chief Marketing Officer at Florida Cancer Specialists.

That’s why FCS has partnered with physicians across the country to ensure that any cancer patient who lives in Florida can receive quality healthcare, regardless of that person’s residency status. It’s all part of the Seasonal Patient Referral Program.

The program, which was launched at the annual meeting of the American Society of Clinical Oncology (ASCO) in June 2017, enables medical oncologists from areas outside of Florida to refer patients who vacation or live seasonally in Florida, to FCS. With nearly 100 locations across the state, there is a very good chance that an FCS clinic will be only minutes away from a winter resident’s Florida home.

Think of the referral program as a collaborative effort. The referring oncologist works with the patient’s FCS Care Management Team to establish a plan for the patient’s care while the patient resides in Florida. The referring oncologist is able to follow the patient’s progress and receive updates and lab results. The patient’s FCS Care Manager (who is a member of the Care Management Team) guides the patient through cancer treatment with FCS, provides counsel and emotional support throughout the treatment process and introduces the patient to the many services provided by FCS that go beyond traditional cancer treatment.

At FCS, cancer patients benefit from integrative oncology, or an evidence-based approach to cancer care that addresses a patient’s mental and physical well-being. So in addition to receiving treatments such as surgery, radiation and chemotherapy, patients can explore acupressure and/or acupuncture, exercise training, massage therapy, meditation instruction, meal preparation training and nutrition counseling through FCS and affiliate organizations.

“Our mission is to provide world-class care in a community setting,” said Glenn. “Referring physicians both near and far play an important role in helping us to accomplish that mission.”

“Receiving a cancer diagnosis is a life-altering experience that marks the beginning of even more change,” said FCS CEO Brad Prechtl. “At Florida Cancer Specialists, we understand that cancer patients need to maintain as much stability in their lives as possible, including when it comes to their treatment routines. We want every cancer patient who walks through the door of an FCS clinic to rest assured that they will receive exceptional care, whether they’re full-time residents of the state or are only here for part of the year.”

Oncologists in the northeastern or midwestern United States can refer patients to a Florida Cancer Specialists physician or clinic location by calling (855) 327-9952, sending an email to Refer@FLCancer.com or visiting FLCancer.com/Refer.

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**A Sampling of FCS Services**

(Courtesy of the FCS Referral Program brochure)

- **Effective management of patients**, ensured by FCS providers who fully understand value-based care.
- **Access to more national clinical trials** (including early phase) than any other practice in FL. In 2016, 84 percent of all new cancer drugs approved for use in the U.S. were studied in FCS clinical trials, prior to approval.
- **Rx To Go**, the FCS in-house specialty pharmacy for oral oncology, offers superior service and delivers prescriptions to patients’ addresses in Florida and when they return to their home outside of Florida.
- **In-house hematopathology lab** provides comprehensive tests and analysis, including histology, IHC, ISH, flow cytometry, FISH and cytogenetics, with turnaround times generally under 48 hours.
- **FCS Financial Counselors** at every location offer expert financial assistance to patients.
- **The entire FCS team** is committed to providing the highest quality treatment and a seamless continuity of care for seasonal patients referred to us when they are in Florida.
1. **DAY OF CHAMPIONS | DAYTONA INTERNATIONAL SPEEDWAY**

On June 4, 2017, around 500 cancer survivors and their guests gathered at the Daytona International Speedway in honor of National Cancer Survivors Day.

Left to right | Guests of the Day of Champions Event, Dr. Padmaja Sai and Dr. Ernesto Bustinza speaking on stage.

2. **GAINESVILLE PATIENT APPRECIATION BBQ | NATIONAL CANCER SURVIVORS DAY**

On June 4, 2017, the Gainesville Cancer Center hosted a western themed BBQ in honor of National Cancer Survivors Day. During the event guests enjoyed music, games and bbq food.

Left to right | Dr. Vijay Patel, Walt Behnert, Dr. Allison Grow, Brett Hipsley FCS Physician Liaison, Dr. Laurel Warwicke and Dr. Christopher Balamucki.

3. **PINK DAY**

On October 13, FCS celebrated Pink Day 2017! Look for a recap and photos in the Winter edition of FCS Magazine.

4. **JOYCE DAVIS RETIRES**

Joyce Davis is a Pharmacy Coordinator who has worked in research pharmacy for over 15 years and during that time has supported the care of 4,801 patients who participated in clinical trials.
5. **DR. DUNN RETIRES**

After 36 years practicing medicine in the Orlando area, the treatment room at the FCS Winter Park location was named in honor of Dr. Philip H. Dunn's retirement on July 31, 2017.

Pictured in photo left to right | Sonalee K. Shroff MD, David C. Molthrop MD, Philip H. Dunn MD, Lee M. Zehngebot MD, CMSO Shelly Glenn and William B. Grow MD.

6. **PAINTING WITH A TWIST**

On July 14, 2017, the Revenue Cycle Management Team hosted a team building event at Painting with a Twist in Tampa, FL.

7. **SARASOTA DOWNTOWN | LUZ RAMIREZ**

Chemotherapy nurse, Luz Ramirez, at the Sarasota Downtown location is all smiles while passing out breakfast to patients.

8. **FCS DINNER AT RIVERHORSE ON MAIN**

FCS Physicians and Executive Team gathered for a networking dinner at Riverhorse on Main in Park City, Utah.

9. **PEGGY HINMAN AWARDED BY HEALTHCARE HEROES**

On August 11, 2017, Peggy Hinman, was awarded the Nursing of Excellence Award by Healthcare Heroes in Citrus County.
10. TEDDY BEAR DRIVE FOR VALERIE’S HOUSE | NAPLES
Staff at the Naples Napa Ridge office truly go above and beyond for the Naples community. They recently donated stuffed animals to the Children of Hospice patients at Valerie’s House.

11. PHYSICIAN OF THE QUARTER | DR. PADMAJA SAI
In August, Florida Hospital Flagler named Dr. Sai the Physician of the Quarter!

12. LAKEWOOD RANCH CONTINUES TO GROW
The Lakewood Ranch location is excited to have new staff members and multiple employees who have received their one year certificate. The clinic continues to grow and create the need for additional staff, including nurses, lab techs, and MA’s.
Left to right | Kathleen McAninch, Tiarra Patrick, Chelsea Enright, Victoria Moore, and Candace Uppgard.

Submit your recent event photos to FCS Marketing at marketing@FLCancer.com.
FCS Foundation Dazzles with Fall Fundraising Events

50 SHADES OF ROARING PINK
 realized by 50 SHADES OF ROARING PINK

**>> OCT. 7**
Dr. Christopher George and Dr. Julio Lautersztain dressed up at the Grand Hyatt Tampa Bay for an evening of decadence in the roaring style of The Great Gatsby. The 4th annual 50 Shades of Pink gala, with flappers, casino games, live jazz and swing dancing transported guests to a laid back time long before smartphones and the Internet.

KENDRA SCOTT WINTER LAUNCH EVENTS – TAMPA AND ORLANDO
 realized by KENDRA SCOTT WINTER LAUNCH EVENTS – TAMPA AND ORLANDO

**>> OCT. 11.**
Sips, sweets and jewels were enjoyed while checking out Kendra Scott’s new winter collection! Kendra Scott donated 20% of the proceeds to the FCS Foundation.

HERBS FOR THE CURE
 realized by HERBS FOR THE CURE

**>> OCT. 19**
Lasting Looks of Sarasota hosted the 5th Annual Herbs for the Cure fundraising event, featuring a silent auction, raffles, fresh herbs for healthy cooking, and celebrity bartenders. Proceeds benefited the FCS Foundation to help cancer patients with their essential living expenses so they can concentrate on fighting cancer.

WINE, WOMEN & SHOES
 realized by WINE, WOMEN & SHOES

**>> NOV. 4 • 5:30 – 9:30 p.m.**
Join the FCS Foundation at the Westin Lake Mary/Orlando North, for a night of sipping, shopping, fashion and compassion. The evening begins with a boutique marketplace with something for everyone – jewelry, accessories, shoes, fragrance, clothing and more. Guests can bid on silent auction items and participate in a chance drawing for a “closetful” of amazing items valued at over $10,000. The evening winds down with a live auction and a fashion show featuring styles from Bloomingdale’s. Tickets for this fabulous fundraiser are $150 per person for general admission and $200 for VIP.

All tickets include wine tasting, savory bites and a swag bag. VIP tickets also include premier seating during the fashion show with champagne and special dessert and an upgraded swag bag. Proceeds benefit the FCS Foundation and help cancer patients with their essential, non-medical living expenses. A block of rooms is available at Westin Lake Mary the night of Nov. 4. Breakfast the next morning is included with hotel room.

Foundation.FLCancer.com/WWS17

LYRICS FOR LIFE
 realized by LYRICS FOR LIFE

**>> NOV. 5 • 6-10 p.m.**
Save this date! Join the FCS Foundation at a unique fundraising event featuring special performances by Gainesville alt-rockers Sister Hazel (“All For You”), Edwin McCain and Emerson Hart. The event will be held at the Fine Arts Hall of Santa Fe College, in Gainesville, FL. A block of rooms is available at the Best Western Gateway Grand Hotel. Watch for details and updates to be posted online.

Foundation.FLCancer.com/Gainesville

PARTY UNDER THE STARS CITY LIGHTS
 realized by PARTY UNDER THE STARS CITY LIGHTS

**>> January 27, 2018 • 6-10 p.m.**
Fete Ballroom at Polo Grill
10670 Boardwalk Loop, Lakewood Ranch, FL 34202

Picture yourself at a rooftop party in Manhattan. This festive evening “under the stars,” will feature music, dancing, dining and a silent auction with fabulous prizes.

This year, we are honoring FCS Foundation Chair and CEO of Florida Cancer Specialists, Brad Prechtl and his wife Terri Prechtl, Lead Patient Support Volunteer at Florida Cancer Specialists, Lakewood Ranch.

All event proceeds provide non-medical, financial assistance to cancer patients.

Foundation.FLCancer.com/Gainesville

Benefiting Florida Cancer Specialists Foundation
Jeanie Harris, RN, OCN, at Gainesville Cancer Center
Jeanie Harris is one of the lucky few who came into this world knowing exactly what they want to do and how they’re going to do it.

As a girl, the Gainesville native developed a penchant for people and became enamored with the idea of devoting her life to improving the lives of others. When her stepfather received a job opportunity in Saudi Arabia, young Jeanie was thrilled with the prospect of expanding her horizons and meeting people outside of her Floridian bubble.

After spending four years in Saudi Arabia and attending boarding school in Cyprus during her teenage years, Harris returned to her roots and enrolled at Santa Fe College in Gainesville, Florida.

“It came down to choosing whether I should be a physician or a nurse,” Harris says. “I made the decision to go directly into nursing school and became an RN at age 21. Since then, I haven’t looked back. I knew it was the right decision.”

That fervor has sustained Harris for 25 years of nursing, 12 of which have been spent with Florida Cancer Specialists. She currently works in the Gainesville Cancer Center that opened one year ago.

“The new facility is nice, because everything is bright and sparkly; but it also really seems to be geared toward the patient,” Harris says. “We have a fantastic nourishment room and waiting room for the patient and their family. Our nurse’s station is especially great, because we’re right in the center of the action and we can observe everyone and we can help other nurses as needed.”

Harris specializes as an infusion nurse within the chemo room, with the primary duties of administering medication, observing patients and assisting with their needs during their visit.

Last October, she found herself on the other side of treatment. Upon finding a lump in her breast tissue, Harris scheduled a mammogram and ultrasound. The wife and mother of three quickly learned that the lump was a malignant tumor. News of cancer was delivered while she was on duty, prompting her to immediately schedule a double mastectomy three weeks later. Due to the aggressive nature of Harris’ tumor, chemotherapy started just three weeks after her surgery.

“I was fortunate to be able to work throughout my chemo,” Harris says. “Cancer is tough, but being at the office made the whole thing a positive experience. Having my patients tell me how encouraging it was to see me coming to work — bald, but still smiling — was so uplifting, because I had always seen them as my source of inspiration. Suddenly, we had this bond.”

Now fully recovered, Harris doesn’t speak about her journey as a tale of woe. Instead, she counts her blessings and focuses on the positive opportunities cancer afforded her, such as marching across Washington D.C.’s Capitol Hill as a patient advocate and appearing on Gainesville’s local news while participating in the Pink Heals tour. Cancer has never slowed her down. She describes herself running the Divas 5K marathon in St. Augustine as “bald, with a crown, and a smile on my face.”

Today, she is a grandmother to a six-month-old baby boy. With the burden of illness behind her, Harris’ thoughts mostly drift to visions of her and her husband loading the Jeep to go camping and kayaking, which now occurs several times a month. Sometimes, their 18-year-old daughter accompanies them.

“I live life with a whole different perspective, both for myself and the patients I care for, because I know how they’re feeling,” Harris explains. “I always said to myself: ‘If I was sitting in that chair, I’d want somebody to be nice to me.’ I had that care and I want to give that to every patient who comes in here.”
When you think about “coastal living,” a gem like Stuart, Florida, might come to mind. It’s a small-town dream on the Treasure Coast where visitors stay in seaside cottages, splash around Bathtub Reef, stroll along Riverwalk and through the historic shopping district.

As a community, Stuart’s standards of quality and care are as clear as the waters that surround it. Florida Cancer Specialists opened the new Stuart location on March 6, 2017, and it is the first FCS site in Martin County.

The Stuart Office is located on Southeast Ocean Boulevard, near the area’s largest hospital and several other medical facilities. The beachy blue and sea-glass green color-scheme lends an atmosphere of warmth and serenity to the office, which hosts four medical exam rooms, a laboratory, a chemotherapy treatment room and a pharmacy. With a staff of 15, the Stuart location is living proof that good things come in small packages.

Overseeing everything is Senior Office Manager, Diane Mann, who has been with FCS since 2014. Her duties are split, as she also manages operations at the Palm Beach Gardens location and travels between
the two. Although the Stuart location isn’t as sizable as her other office, Mann is confident that the tight-knit Stuart team has no problem providing the utmost in compassion and care for patients.

“The staff is great at working as a team,” Mann says. “Everybody has a really nice personality. They all take an interest in learning as much as they can about all the areas in the office so they can assist with whatever needs to be done, and that helps each day run smoothly.”

Among the office staff are Medical Assistants who work closely with each doctor. Some of these Medical Assistants are cross-trained to process lab results. The Head Nurse oversees the daily operation of the Chemotherapy Room, Pharmacy, Clinical Operations and administers chemo treatments for the patients. The Head Nurse works closely with another full time RN and a per diem RN to fill in the gaps where needed. One nurse currently supervises patient processing and staff communications, while a Pharmacy Technician is responsible for the behind-the-scenes operations. Along with receiving care from three Patient Service Specialists, patients may also wish to seek counsel from the on-site Financial Counselor.

“We are settled now, and our patients tell us that they’re very happy here.”

“Dr. Guillermo Abesada-Terk and Dr. Alpana Desai are two leading physicians who are committed to serving the patients in the community,” Mann explains. “They have worked together for many years and have an excellent reputation throughout the county.”

Dr. Abesada-Terk currently sees all types of oncology patients, but he focuses on the treatment of lymphoma and on lung, colorectal and skin cancers. He is also heavily engaged in clinical research and has investigated trials on cancer vaccines and assorted types of immunotherapies. He currently operates as an Associate Investigator at H. Lee Moffitt Cancer Center and as an Assistant Clinical Professor at Florida State University.

Like her colleague, Dr. Desai actively participates in the investigation of clinical trials. With her current practice, Dr. Desai treats multiple types of malignancies, but most of her patients are those with breast cancer. Outside of FCS, she functions as the Chair of the Martin Health Cancer Committee, a community-based organization devoted to the research and application of the latest cancer treatments.

In addition to the commitment and consideration they receive from physicians and other staff members, what patients seem to enjoy most about the Stuart location is the intimate setting. During the stressful process of chemotherapy administration, comfort and accommodation is essential for the well being of the patient. The 11-chair chemo room is cozy without being overfull, so nurses are able to watch over each patient and provide quick, efficient assistance should a need arise.

“Between our two physicians, we’re currently seeing about 30 or more patients a day,” Mann says. “It was a lot for patients to get used to at first, because they were coming to us from other, non-FCS clinics, and at FCS, we do things a little bit differently. We are settled now, and our patients tell us that they’re very happy here.”
The FCS Foundation fulfills a unique purpose for cancer patients who are struggling to pay their everyday living expenses. Imagine cancer patients who can’t make car payments leaving them without transportation to their physician’s office; or patients who can’t pay mortgage or rent and are facing eviction while they are fighting for their lives. The Foundation pays for non-medical expenses such as mortgage, rent, utilities and car payments, so that patients can concentrate on recovering from cancer.

What Separates the FCS Foundation from Other Charities?

Florida Cancer Specialists pays the overhead, which means that **100% of all donations go directly to help cancer patients in need!** The FCS Foundation provides help for the entire family, as well, by relieving some of the stress cancer patients and their family members face on a daily basis.

You Can Make a Difference. Volunteer.

The Florida Cancer Specialists Foundation is seeking volunteers to provide non-medical support and comfort to patients undergoing treatment for cancer at Florida Cancer Specialists clinics. Duties include offering a pillow, warm blanket, snack or beverage to the patient, sharing a magazine and providing companionship.

Applications are available at Foundation.FLCancer.com/Volunteer or send email inquiries to: VolunteerProgram@FLCancer.com

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**FLORIDA CANCER SPECIALISTS FOUNDATION**

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