SUMMER 2021

FCS THE MAGAZINE

Conquering Cancer

Personalized treatment leads to recovery and good health

Available Exclusively for **Florida Cancer Specialists** From **Oncology Supply**

octagam® 10%

Immune Globulin
Intravenous (Human) 10%
Liquid Preparation

Preserving Immunoglobulin Integrity

For the treatment of adults with chronic immune thrombocytopenic purpura (ITP)

Expanded Supply for the US Market

Enhancements to our FDA-approved manufacturing facilities have yielded substantial increases in the supply of octagam 10%

COPAY SUPPORT for patients with commercial insurance UP TO **$2,500** PER YEAR

Contact us today for pricing information.

JOSEPH CANNON
Vice President, National Accounts
Joseph.Cannon@octapharma.com | 201.604.1126

WARNING: THROMBOSIS, RENAL DYSFUNCTION and ACUTE RENAL FAILURE

Please see accompanying Highlights of full Prescribing Information for additional important information.

- Thrombosis may occur with immune globulin intravenous (IGIV) products, including Octagam® 10%. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.
- Renal dysfunction, acute renal failure, osmotic nephropathy, and death may occur with the administration of Immune Globulin Intravenous (Human) (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. Octagam 10% does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction or renal failure, administer Octagam 10% at the minimum infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Important Safety Information

Octagam® 10% is contraindicated in patients who have a history of severe systemic hypersensitivity reactions, such as anaphylaxis, to human immunoglobulin. Octagam 10% contains trace amounts of IgA (average 106 µg/mL in a 10% solution). It is contraindicated in IgA-deficient patients with antibodies against IgA and history of hypersensitivity. The most serious drug-related adverse event reported with Octagam 10% treatment was a headache (0.9% of subjects). The most common drug-related adverse reactions reported in >5% of the subjects during a clinical trial were headache, fever, and increased heart rate.

Please see accompanying Highlights of full Prescribing Information for additional important information.

Date of preparation: 5/2021. GAM10-0226-PAD

octapharma

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OCTAGAM 10% safely and effectively. See full prescribing information for OCTAGAM 10%.

OCTAGAM 10% [Immune Globulin Intravenous (Human)]
liquid solution for intravenous administration
Initial U.S. Approval: 2014

WARNING
THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE
See full prescribing information for complete boxed warning

- Thrombosis may occur with immune globulin intravenous (IGIV) products, including OCTAGAM 10%. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.
- Renal dysfunction, acute renal failure, osmotic nephropathy, and death may occur with the administration of Immune Globulin Intravenous (Human) (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products containing sucrose. OCTAGAM 10% does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction or renal failure, administer OCTAGAM 10% at the minimum infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

----------INDICATIONS AND USAGE ----------

- OCTAGAM 10% is an immune globulin intravenous (human) liquid preparation indicated for the treatment of chronic immune thrombocytopenic purpura (ITP) in adults.

---------- DOSAGE AND ADMINISTRATION ----------

For intravenous use only.

Indication	Dose	Initial Infusion rate	Maintenance Infusion Rate (if tolerated)
Chronic ITP	1 g/kg daily for 2 consecutive days	1.0 mg/kg/min (0.01 mL/kg/min)	Up to 12.0 mg/kg/min (Up to 0.12 mL/kg/min)

- Ensure that patients with pre-existing renal insufficiency are not volume depleted; discontinue OCTAGAM 10% if renal function deteriorates.
- For patients at risk of renal dysfunction or thrombotic events, administer OCTAGAM 10% at the minimum infusion rate practicable.

----------DOSAGE FORMS AND STRENGTHS----------

Solution containing 10% IgG (100 mg/mL)

---------- CONTRAINDICATIONS----------

- History of anaphylactic or severe systemic reactions to human immunoglobulin
- IgA deficient patients with antibodies against IgA and a history of hypersensitivity

---------- WARNINGS AND PRECAUTIONS ----------

- IgA-deficient patients with antibodies against IgA are at greater risk of developing severe hypersensitivity and anaphylactic reactions to OCTAGAM 10%. Epinephrine should be available immediately to treat any severe acute hypersensitivity reactions.
- Monitor renal function, including blood urea nitrogen and serum creatinine, and urine output in patients at risk of developing acute renal failure.
- Falsely elevated blood glucose readings may occur during and after the infusion of OCTAGAM 10% with testing by some glucometers and test strip systems.
- Hyperproteinemia, increased serum osmolarity and hyponatremia may occur in patients receiving OCTAGAM 10%.
- Hemolysis that is either intravascular or due to enhanced red blood cell sequestration can develop subsequent to OCTAGAM 10% treatments. Risk factors for hemolysis include high doses and non-O-blood group. Closely monitor patients for hemolysis and hemolytic anemia.
- Aseptic Meningitis Syndrome may occur in patients receiving OCTAGAM 10%, especially with high doses or rapid infusion.
- Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury (TRALI)).
- OCTAGAM 10% is made from human plasma and may contain infectious agents, e.g. viruses and, theoretically, the Creutzfeldt-Jakob disease agent.

---------- ADVERSE REACTIONS----------

The most common adverse reactions reported in greater than 5% of subjects during a clinical trial were headache, fever and increased heart rate.
To report SUSPECTED ADVERSE REACTIONS, contact Octapharma at 1-866-766-4860 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

The passive transfer of antibodies may:
Confound the results of serological testing.
Interfere with the immune response to live viral vaccines, such as measles, mumps, and rubella.

---------- USE IN SPECIFIC POPULATIONS----------

- Pregnancy: no human or animal data. Use only if clearly needed.
- Geriatric Use: In patients over age 65 or in any person at risk of developing renal insufficiency, do not exceed the recommended dose, and infuse OCTAGAM 10% at the minimum infusion rate practicable.

Revised: **August 2018**

Medical Affairs:
usmedicalaffairs@octapharma.com
Tel: 888-429-4535

Reimbursement:
usreimbursement@octapharma.com
Tel: 800-554-4440 | Fax: 800-554-6744

Drug Safety:
For all inquiries relating to drug safety, or to report adverse events, please contact our local Drug Safety Officer:
Tel: 201-604-1137 | Cell: 201-772-4546 | Fax: 201-604-1141 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

octapharma

IN THIS ISSUE

FEATURES

SPOTLIGHTS

DEPARTMENTS

We welcome your feedback, article suggestions and photos (high resolution please).

Email to FCSCommunications@FLCancer.com

On the cover: Vikas Malhotra, MD, with patient Peggy Moore; Photography by Blake Jones

NATHAN H. WALCKER, CHIEF EXECUTIVE OFFICER:

Our cover story in this issue of *FCS Magazine* is a touching example of the bonds that develop between our oncologists and their patients. With exceptional skill and knowledge and access to the most advanced treatments, they can replace shock and fear with hope and healing. Stories like these are told daily across our practice.

Information technology plays a key role in cancer treatment and research, as well. Be sure to read about how we are leveraging data intelligence initiatives in the Informatics feature.

As we continuously strive to enhance the patient experience, providing convenience and comfort as well as operational efficiencies is essential. In the first half of 2021, we began construction on several new clinic locations and celebrated the opening of others. (Details in People & Places.) These state-of-the-art facilities are equipped with the latest technologies as well as unique elements that foster well-being.

FCS continues to set the bar for community oncology. This is exciting work and it takes a skilled team. I acknowledge and thank all our FCS physicians and team members for their unwavering commitment to excellence and innovation, and a patient-first approach.

LUCIO GORDAN, MD, PRESIDENT & MANAGING PHYSICIAN:

At FCS we are making giant leaps forward for community oncology as we continue to implement advanced diagnostics, innovative therapies and treatments.

The expansion of genetic testing capabilities in our FCS Laboratory is a significant milestone. Next generation sequencing enables us to correlate a patient's diagnosis with any mutation that was identified. In turn, we can make better and faster decisions for our patients, which results in better outcomes. I thank and congratulate our skilled team members whose efforts and expertise are bringing us many steps closer to truly personalized medicine.

As physicians, our commitment to the wellbeing of our patients extends beyond our clinic walls. I am so proud of our leadership involvement in numerous advocacy initiatives at both the state and national levels. Two of our colleagues have gone above and beyond in this regard. They are actively engaged in legislative efforts to ensure that cancer patients can easily access care in their local communities that is affordable and of the highest quality. You'll learn more in our Advocacy Update.

We are proud of our ongoing successes as we strive to improve patient outcomes and work to conquer cancer. Thank you all for your support.

PHOTO BY BLAKE JONES

Time, Distance and Cancer: *A Love Story*

BY ELAINE GANICK

When Peggy Moore was diagnosed with pancreatic cancer early in 2020, she and her husband, Brian, had to prepare for a grueling fight to survive one of the most difficult cancers of all.

Relying on their faith and the expertise of Dr. Vikas Malhotra, a medical oncologist who practices at the FCS Brooksville and Spring Hill locations, they never lost hope.

This was not the first time Peggy and Brian had faced a cancer diagnosis, and they knew it would be a long battle. They also knew their love and marriage had already conquered time and distance, so they were prepared to persevere.

The couple first met almost 50 years ago, when Brian was a 26-year-old Peace Corps volunteer in Lima, Peru. Born in Hartford, Connecticut, Peggy had moved to Peru at the age of 5 with her Peruvian father and American mother, who was the Peace Corps office manager.

Brian recalls, "Peggy's mother would occasionally invite some of us volunteers for a home-cooked meal, and I remember Peggy as a bright and attractive 14-year-old girl. I spent several years in South America in the Corps, and I became friends with the family. We kept in touch after we moved back to the U.S."

Life went on and Peggy grew up, married and started a family in Florida. Brian remained a bachelor.

After Peggy's husband passed away in 1998, their ongoing friendship blossomed into a romantic relationship. The couple dated for almost five years before then 60-year-old Brian asked Peggy to be his bride in 2003 — 34 years and an entire continent away from where and when they had first met.

In 2012, Peggy was diagnosed with stage 3 breast cancer

Brian and Peggy Moore's wedding day, Nov. 13, 2003.

and was referred to FCS and Dr. Malhotra. She wanted to be treated close to home. Unsure whether a community oncology practice would have the most advanced treatments, she sought a second opinion from a large academic medical center over an hour's drive away. That second opinion concurred with everything Dr. Malhotra had told her, and so she began treatment at FCS.

Brian accompanied her on every visit, treatment and follow-up appointment. By 2018, Peggy's cancer was in remission.

Then, early in 2020, Peggy noticed a discoloration in her urine. When it did not clear up, Brian convinced her to see a doctor, who referred her to a local hospital ER. There, she underwent several tests and scans before the ER doctor told her, "You have a tumor on your pancreas. Get your affairs in order, you have three months to live."

Peggy remembers the shock and fear. She and Brian immediately called Dr. Malhotra. "Dr. Malhotra was outraged when I told him what the ER doctor said to me," Peggy says. "He pointed out that the ER physician did not know my medical history and likely was not aware of some of the most recent breakthroughs in treating pancreatic cancer."

Dr. Malhotra gave the couple some much-needed reassurance and hope. He explained that because Peggy's tumor was located on the head of her pancreas, she had a much better chance for survival than most patients. He proposed aggressive chemotherapy treatment followed by a complex surgery known as a Whipple procedure.

"We trusted him implicitly," Peggy says. "Dr. Malhotra was honest and direct with us. He explained the risks and the survival rates and that he had had some success with this kind of approach … so we put my life in his hands." Brian adds, "I put my life in his hands too. I waited over 30 years for Peggy, and I wasn't ready to lose her."

Following chemotherapy, Peggy underwent the Whipple surgery, which typically removes the head of the pancreas, the first part of the small intestine, the gallbladder and the bile duct. It is a difficult operation and can have serious risks; however, the surgery can be lifesaving.

When the tumor was removed and biopsied, there was no sign of cancer. Peggy's surgeon credits the good outcome to Dr. Malhotra's use of a personalized chemotherapy regimen for Peggy that reduced the cancer prior to the surgery. Brian agrees and says, "We think his treatment plan was responsible for Peggy's recovery and good health."

Today, almost a year later, Peggy is cancer-free. She gets follow-up blood work every two weeks and goes in every six months for a check-up to make sure everything is going well. The couple is eager to share the advice that has helped them navigate time, distance and cancer as they look toward the future together. "Take it one day at a time … and don't believe everything you read on the internet or you'll drive yourself crazy," she said. "Keep your faith, and don't give up hope."

"Dr. Malhotra was honest and direct with us. He explained the risks and the survival rates and that he had had some success with this kind of approach … so we put my life in his hands."

PHOTO BY BLAKE JONES


FLORIDA CANCER SPECIALISTS
& Research Institute

Executive Leadership Team Welcomes New Additions

As a former U.S. Navy officer, Rich MacClary has always valued service and excellence. In Florida Cancer Specialists & Research Institute (FCS), he found both. "I was certainly aware of FCS as a highly respected and well-branded company. It's always rewarding to work for a company that has a broader mission of serving the community."

Prior to joining the company in February 2021, MacClary held various leadership positions establishing strategic direction and driving financial growth for public and private equity-backed companies. His healthcare experience spans multi-site services, information technology and electronic payments.

He held senior financial leadership roles with Alliance Oncology, a division of Alliance Healthcare Services, Healthcare Holdings of America, Comdata Inc. and Emdeon (now Change Healthcare). When working for the U.S. Navy, he began his career as an officer on the staff of the U.S. Naval Nuclear Propulsion Program in Washington, D.C.

MacClary graduated cum laude from Duke University with an undergraduate degree in economics and later earned an accounting certificate from the University of Virginia. He received an MBA from Duke University's Fuqua School of Business, where he was named a Fuqua Scholar.

Having grown up in the Fort Lauderdale area, MacClary says he was eager to return to Florida, and he is excited to help guide FCS through continued growth and its next chapter.

"I am excited to be here," he said. "We are maturing as a company and as a financial organization, and we are ensuring that our foundation is strong."

MacClary praised FCS' resilience and staying power in the face of the ongoing coronavirus pandemic. "I really do think FCS has weathered the pandemic very, very well," he said. "The company can be very proud that it didn't furlough or lay off employees. Not many businesses can say that. While we certainly have had our challenges, the company has performed well."

MacClary attributes that success to the organization's leadership and diverse workforce.

Rich MacClary
Chief Financial Officer

"They are very, very smart people," he said. "We have such a broad group of scientists and professionals working under one roof."

An avid outdoorsman and fisherman, MacClary enjoys spending time with his wife, Kristin, and their four children. He has also served his community as a volunteer for several Catholic organizations.

When Nancy Ardell got her first look at Florida Cancer Specialists & Research Institute (FCS), she knew it was a place she wanted to be.

"The dynamic team won me over," she said. "Everyone I interviewed with, Dr. Lucio Gordan, Executive Board members and the leadership team, were all so dedicated and committed to advancing cancer care."

A seasoned attorney with more than 25 years of experience in healthcare, senior living and banking, Ardell has long been drawn to the mission of healthcare companies. "If you're in healthcare (even in a supporting role such as legal), you're playing a small role in changing the trajectory of people's lives. It's hard not to be motivated by that," she said.

When she was a senior in high school, she watched her mother start over and go to law school — a path that eventually led to her mother becoming a judge and sitting on the bench for 18 years. "My mom's enthusiasm really sparked the idea of my going to law school," said Ardell, who earned an undergraduate degree in economics from DePauw University and her law degree from the Chicago-Kent College of Law.

She enjoys helping healthcare organizations navigate the complex legal landscape. "The exciting thing about the field of health law is that it is constantly changing. No week or day is the same," she says.

Prior to joining FCS in April, she served as Executive Vice President and Chief Legal Officer for Northwest Community Healthcare, a $1.8 billion community-based health system in the Chicago area. Prior to that, Ardell was the Executive Vice President and General Counsel for Enlivant, which operates 230 assisted living and memory care facilities across 26 states. She has also held in-house counsel roles at Northwestern Memorial Healthcare and the Shirley Ryan AbilityLab in Chicago.

Since starting at FCS, Ardell has enjoyed touring clinics and connecting with FCS physicians and team members across the company. "The FCS legal team is here to serve as a trusted partner to the business people and clinicians. Involve us early in discussions, we are here to help," she says.

Nancy Ardell
Chief Legal Officer & General Counsel

Ardell and husband, Doug, recently relocated from Chicago to Tampa. Their three children, Hailey, JT and Grant, are all in college.

"We're having fun getting to know a new city," she said. "This move is a chance for us to have a new adventure."

SAVE THE DATE:

October 22-24, 2021

CLINICAL 2021 SUMMIT

Ritz Carlton Grande Lakes Orlando

4012 Central Florida Parkway, Orlando, FL 32837

For more information contact
Lynn Clemens at LClemens@FLCancer.com

FLORIDA CANCER SPECIALISTS
& Research Institute

FLCancer.com

A WAY IN
WITH TRODELVY

TRODELVY attacks tumors with an antibody-drug conjugate (ADC) that binds to Trop-2.[1]

Based on preclinical data. May not correlate with clinical outcomes.

OFFER A DIFFERENT POSSIBILITY. SCAN TO VISIT TRODELVYHCP.COM.

INDICATIONS

TRODELVY® (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with:

- Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.
- Locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: NEUTROPENIA AND DIARRHEA

- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤Grade 1 and reduce subsequent doses.**

CONTRAINDICATIONS

- Severe hypersensitivity reaction to TRODELVY.

WARNINGS AND PRECAUTIONS

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur and may require dose modification. Neutropenia occurred in 61% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 47% of patients. Febrile neutropenia occurred in 7%. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.

Diarrhea: Diarrhea occurred in 65% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 12% of patients. One patient had intestinal perforation following diarrhea. Neutropenic colitis occurred in 0.5% of patients. Withhold TRODELVY for Grade 3-4 diarrhea and resume when resolved to ≤Grade 1. At onset, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Hypersensitivity and Infusion-Related Reactions: Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 37% of patients. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.3%. The incidence of anaphylactic reactions was 0.3%. Pre-infusion medication is recommended. Observe patients closely for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Medication to treat such reactions, as well as emergency equipment, should be available for immediate use. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

GILEAD

ANNOUNCING **2 NEW FDA APPROVALS** FOR TRODELVY[1]

FOR METASTATIC TRIPLE-NEGATIVE BREAST CANCER (mTNBC)

NEW EXPANDED INDICATION

INDICATION: TRODELVY is indicated for the treatment of adult patients with unresectable locally advanced or mTNBC who have received 2 or more prior systemic therapies, at least one of them for metastatic disease.

GIVING YOU THE ABILITY TO OFFER AN OPTION AS EARLY AS 2L IN THE METASTATIC SETTING

In ASCENT, a phase 3 trial, ~1 out of 8 patients (13%) in the TRODELVY group in the full population received only 1 prior line of systemic therapy in the metastatic setting (in addition to having disease recurrence or progression within 12 months of neoadjuvant/adjuvant systemic therapy).[1]

FOR METASTATIC UROTHELIAL CANCER (mUC)

NEW INDICATION NOW APPROVED

INDICATION: TRODELVY is indicated for the treatment of adult patients with locally advanced or mUC who received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.

This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

Nausea and Vomiting: Nausea occurred in 66% of all patients treated with TRODELVY and Grade 3 nausea occurred in 4% of these patients. Vomiting occurred in 39% of patients and Grade 3-4 vomiting occurred in 3% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as well as other drugs as indicated) for prevention of chemotherapy-induced nausea and vomiting (CINV). Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to Grade ≤1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity: Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with TRODELVY. The incidence of Grade 3-4 neutropenia was 67% in patients homozygous for the UGT1A1*28, 46% in patients heterozygous for the UGT1A1*28 allele and 46% in patients homozygous for the wild-type allele. The incidence of Grade 3-4 anemia was 25% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 11% in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on clinical assessment of the onset, duration and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 function.

Embryo-Fetal Toxicity: Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

ADVERSE REACTIONS

In the ASCENT study (IMMU-132-05), the most common adverse reactions (incidence ≥25%) were fatigue, neutropenia, diarrhea, nausea, alopecia, anemia, constipation, vomiting, abdominal pain, and decreased appetite. The most frequent serious adverse reactions (SAR) (>1%) were neutropenia (7%), diarrhea (4%), and pneumonia (3%). SAR were reported in 27% of patients, and 5% discontinued therapy due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the ASCENT study were reduced neutrophils, leukocytes, and lymphocytes.

In the TROPHY study (IMMU-132-06), the most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, neutropenia, nausea, any infection, alopecia, anemia, decreased appetite, constipation, vomiting, abdominal pain, and rash. The most frequent serious adverse reactions (SAR) (≥5%) were infection (18%), neutropenia (12%, including febrile neutropenia in 10%), acute kidney injury (6%), urinary tract infection (6%), and sepsis or bacteremia (5%). SAR were reported in 44% of patients, and 10% discontinued due to adverse reactions. The most common Grade 3-4 lab abnormalities (incidence ≥25%) in the TROPHY study were reduced neutrophils, leukocytes, and lymphocytes.

DRUG INTERACTIONS

UGT1A1 Inhibitors: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers: Exposure to SN-38 may be substantially reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

Reference: 1. TRODELVY [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2021.

Please see Brief Summary of full Prescribing Information, including BOXED WARNING, on the next page.

TRODELVY® (sacituzumab govitecan-hziy) for injection, for intravenous use
Brief Summary of full Prescribing Information. See full Prescribing Information. Rx Only.

WARNING: NEUTROPENIA AND DIARRHEA

- **Severe or life-threatening neutropenia may occur. Withhold TRODELVY for absolute neutrophil count below 1500/mm^3 or neutropenic fever. Monitor blood cell counts periodically during treatment. Consider G-CSF for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.**
- **Severe diarrhea may occur. Monitor patients with diarrhea and give fluid and electrolytes as needed. Administer atropine, if not contraindicated, for early diarrhea of any severity. At the onset of late diarrhea, evaluate for infectious causes and, if negative, promptly initiate loperamide. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤ Grade 1 and reduce subsequent doses.**

[See Warnings and Precautions and Dosage and Administration]

INDICATIONS AND USAGE

*Also see **Clinical Studies***

TRODELVY (sacituzumab govitecan-hziy) is a Trop-2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of adult patients with:

- Unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.
- Locally advanced or metastatic urothelial cancer (mUC) who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

DOSAGE AND ADMINISTRATION

*Also see **Warnings and Precautions***

Do NOT substitute TRODELVY for or use with other drugs containing irinotecan or its active metabolite SN-38.

The recommended dose of TRODELVY is 10 mg/kg administered as an intravenous infusion once weekly on Days 1 and 8 of 21-day treatment cycles. Continue treatment until disease progression or unacceptable toxicity. Do not administer TRODELVY at doses greater than 10 mg/kg. Administer TRODELVY as an intravenous infusion only. Do not administer as an intravenous push or bolus.

- First infusion: Administer infusion over 3 hours. Observe patients during the infusion and for at least 30 minutes following the initial dose, for signs or symptoms of infusion-related reactions.
- Subsequent infusions: Administer infusion over 1 to 2 hours if prior infusions were tolerated. Observe patients during the infusion and for at least 30 minutes after infusion.
- Premedication: Prior to each dose of TRODELVY, premedication for prevention of infusion reactions and prevention of chemotherapy-induced nausea and vomiting (CINV) is recommended. Premedicate with antipyretics, H1 and H2 blockers prior to infusion, and corticosteroids may be used for patients who had prior infusion reactions. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist, as well as other drugs as indicated).

Dose Modifications for Infusion-related Reactions: Slow or interrupt the infusion rate of TRODELVY if the patient develops an infusion-related reaction. Permanently discontinue TRODELVY for life-threatening infusion-related reactions.

Dose Modifications for Adverse Reactions: Withhold or discontinue TRODELVY to manage adverse reactions as described below. Do not re-escalate the TRODELVY dose after a dose reduction for adverse reactions has been made.

Severe Neutropenia, defined as Grade 4 neutropenia ≥7 days, OR Grade 3 febrile neutropenia (absolute neutrophil count or ANC <1000/mm^3 and fever ≥38.5°C), OR at time of scheduled treatment, Grade 3-4 neutropenia which delays dosing by 2 or 3 weeks for recovery to ≤ Grade 1:

- At first occurrence, 25% dose reduction and administer granulocyte-colony stimulating factor (G-CSF). At second occurrence, 50% dose reduction. At third occurrence, discontinue TRODELVY.
- At time of scheduled treatment, if Grade 3-4 neutropenia occurs which delays dosing beyond 3 weeks for recovery to ≤Grade 1, discontinue TRODELVY at first occurrence.

Severe Non-Neutropenic Toxicity, defined as Grade 4 non-hematologic toxicity of any duration, OR any Grade 3-4 nausea, vomiting or diarrhea due to treatment that is not controlled with antiemetics and anti-diarrheal agents, OR other Grade 3-4 non-hematologic toxicity persisting >48 hours despite optimal medical management, OR at time of scheduled treatment, Grade 3-4 non-neutropenic hematologic or non-hematologic toxicity, which delays dose by 2 or 3 weeks for recovery to ≤Grade 1:

- At first occurrence, 25% dose reduction. At second occurrence, 50% dose reduction. At third occurrence, discontinue TRODELVY.
- In the event of Grade 3-4 non-neutropenic hematologic or non-hematologic toxicity, which does not recover to ≤Grade 1 within 3 weeks, discontinue TRODELVY at first occurrence.

CONTRAINDICATIONS

*Also see **Warnings and Precautions***

TRODELVY is contraindicated in patients who have experienced a severe hypersensitivity reaction to TRODELVY.

WARNINGS AND PRECAUTIONS

*Also see **BOXED WARNING, Dosage and Administration, Contraindications, Clinical Pharmacology, Nonclinical Toxicology,** and **Use in Specific Populations***

Neutropenia: Severe, life-threatening, or fatal neutropenia can occur in patients treated with TRODELVY. Neutropenia occurred in 61% of patients treated with TRODELVY. Grade 3-4 neutropenia occurred in 47% of patients. Febrile neutropenia occurred in 7% of patients. Withhold TRODELVY for ANC below 1500/mm^3 on Day 1 of any cycle or neutrophil count below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever. Dose modifications may be required due to neutropenia.

Diarrhea: TRODELVY can cause severe diarrhea. Diarrhea occurred in 65% of all patients treated with TRODELVY. Grade 3-4 diarrhea occurred in 12% of all patients treated with TRODELVY. One patient had intestinal perforation following diarrhea. Neutropenic colitis occurred in 0.5% of patients. Withhold TRODELVY for Grade 3-4 diarrhea at the time of scheduled treatment administration and resume when resolved to ≤ Grade 1. At the onset of diarrhea, evaluate for infectious causes and if negative, promptly initiate loperamide, 4 mg initially followed by 2 mg with every episode of diarrhea for a maximum of 16 mg daily. Discontinue loperamide 12 hours after diarrhea resolves. Additional supportive measures (e.g., fluid and electrolyte substitution) may also be employed as clinically indicated. Patients who exhibit an excessive cholinergic response to treatment with TRODELVY (e.g., abdominal cramping, diarrhea, salivation, etc.) can receive appropriate premedication (e.g., atropine) for subsequent treatments.

Hypersensitivity and Infusion-Related Reactions: Serious hypersensitivity reactions including life-threatening anaphylactic reactions have occurred with TRODELVY treatment. Severe signs and symptoms included cardiac arrest, hypotension, wheezing, angioedema, swelling, pneumonitis, and skin reactions. Hypersensitivity reactions within 24 hours of dosing occurred in 37% of patients treated with TRODELVY. Grade 3-4 hypersensitivity occurred in 2% of patients. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 0.3%. The incidence of anaphylactic reactions was 0.3%. Premedication for infusion reactions in patients receiving TRODELVY is recommended. Have medications and emergency equipment to treat infusion-related reactions, including anaphylaxis, available for immediate use when administering TRODELVY. Closely monitor patients for hypersensitivity and infusion-related reactions during each infusion and for at least 30 minutes after completion of each infusion. Permanently discontinue TRODELVY for Grade 4 infusion-related reactions.

Nausea and Vomiting: TRODELVY is emetogenic. Nausea occurred in 66% of all patients treated with TRODELVY. Grade 3 nausea occurred in 4% of patients. Vomiting occurred in 39% of patients. Grade 3-4 vomiting occurred in 3% of these patients. Premedicate with a two or three drug combination regimen (e.g., dexamethasone with either a 5-HT3 receptor antagonist or an NK_1 receptor antagonist as well as other drugs as indicated) for prevention of CINV. Withhold TRODELVY doses for Grade 3 nausea or Grade 3-4 vomiting and resume with additional supportive measures when resolved to ≤Grade1. Additional antiemetics and other supportive measures may also be employed as clinically indicated. All patients should be given take-home medications with clear instructions for prevention and treatment of nausea and vomiting.

Increased Risk of Adverse Reactions in Patients with Reduced UGT1A1 Activity: Patients homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia, febrile neutropenia, and anemia and may be at increased risk for other adverse reactions with TRODELVY. The incidence of neutropenia and anemia was analyzed in 701 patients who received TRODELVY and had UGT1A1 genotype results. The incidence of Grade 3-4 neutropenia was 67% in patients homozygous for the UGT1A1*28 (n=87), 46% in patients heterozygous for the UGT1A1*28 allele (n=301), and 46% in patients homozygous for the wild-type allele (n=313). The incidence of Grade 3-4 anemia was 25% in patients homozygous for the UGT1A1*28 allele, 10% in patients heterozygous for the UGT1A1*28 allele, and 11% in patients homozygous for the wild-type allele. Closely monitor patients with known reduced UGT1A1 activity for adverse reactions. Withhold or permanently discontinue TRODELVY based on onset, duration, and severity of the observed adverse reactions in patients with evidence of acute early-onset or unusually severe adverse reactions, which may indicate reduced UGT1A1 enzyme activity.

Embryo-Fetal Toxicity: Based on its mechanism of action, TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. TRODELVY contains a genotoxic component, SN-38, and targets rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

ADVERSE REACTIONS

*Also see **BOXED WARNING, Warnings and Precautions,** and **Clinical Studies***

The pooled safety population described in the Warnings and Precautions section reflect exposure to TRODELVY as a single agent in 795 patients from three studies, IMMU-132-01, IMMU-132-05 and IMMU-132-06 which included 366 patients with mTNBC who had received prior systemic chemotherapy for advanced disease and 180 patients with mUC. Among the 795 patients treated with TRODELVY, the median duration of treatment was 4.1 months (range: 0 to 59 months). The most common (≥ 25%) adverse reactions were nausea (66%), diarrhea (65%), fatigue (62%), neutropenia (61%), alopecia (45%), anemia (42%), vomiting (39%), constipation (37%), decreased appetite (34%), rash (32%) and abdominal pain (28%).

Metastatic Triple-Negative Breast Cancer

The safety of TRODELVY was evaluated in a randomized, active-controlled, open-label trial (ASCENT, IMMU-132-05) in patients with mTNBC who had previously received a taxane and at least two prior therapies. Patients were randomized (1:1) to receive either TRODELVY (n=258) or single agent chemotherapy (n=224) and were treated until disease progression or unacceptable toxicity. For patients treated with TRODELVY, the median duration of treatment was 4.4 months (range: 0 to 23 months). Serious adverse reactions occurred in 27% of patients, and those in > 1% included neutropenia (7%), diarrhea (4%), and pneumonia (3%). Fatal adverse reactions occurred in 1.2% of patients, including respiratory failure (0.8%) and pneumonia (0.4%). TRODELVY was permanently discontinued for adverse reactions in 5% of patients. These adverse reactions (≥1%) were pneumonia (1%) and fatigue (1%). The most frequent (≥5%) adverse reactions leading to a treatment interruption in 63% of patients were neutropenia (47%), diarrhea (5%), respiratory infection (5%), and leukopenia (5%). The most frequent (>4%) adverse reactions leading to a dose reduction in 22% of patients were neutropenia (11%) and diarrhea (5%). G-CSF was used in 44% of patients who received TRODELVY. The most common adverse reactions (≥25%) were fatigue, neutropenia, diarrhea, nausea, alopecia, anemia, constipation, vomiting, abdominal pain, and decreased appetite. The most common Grade 3-4 lab abnormalities (≥25%) were decreased neutrophils (49%), decreased leukocytes (41%), and decreased lymphocytes (31%).

Locally Advanced or Metastatic Urothelial Cancer

The safety of TRODELVY was evaluated in a single-arm, open-label study (TROPHY, IMMU-132-06) in patients (n=113) with mUC who had received previous platinum-based and anti-PD-1/PD-L1 therapy. Serious adverse reactions occurred in 44% of patients, and those in >1% included infection (18%), neutropenia (12%, including febrile neutropenia in 10%), acute kidney injury (6%), urinary tract infection (6%), sepsis or bacteremia (5%), diarrhea (4%), anemia, venous thromboembolism, and small intestinal obstruction (3% each), pneumonia, abdominal pain, pyrexia, and thrombocytopenia (2% each). Fatal adverse reactions occurred in 3.6% of patients, including sepsis, respiratory failure, epistaxis, and completed suicide. TRODELVY was permanently discontinued for adverse reactions in 10% of patients. The most frequent of these adverse reactions was neutropenia (4%, including febrile neutropenia in 2%). The most common adverse reactions leading to dose interruption in 52% of patients were neutropenia (27%, including febrile neutropenia in 2%), infection (12%), and acute kidney injury (8%). The most common (>4%) adverse reactions leading to a dose reduction in 42% of patients were neutropenia (13%, including febrile neutropenia in 3%), diarrhea (11%), fatigue (8%), and infection (4%). G-CSF was used in 47% of patients who received TRODELVY. The most common adverse reactions (incidence ≥25%) were diarrhea, fatigue, neutropenia, nausea, any infection, alopecia, anemia, decreased appetite, constipation, vomiting, rash, and abdominal pain. The most common Grade 3-4 lab abnormalities (≥25%) were decreased neutrophils (43%), decreased leukocytes (38%), and decreased lymphocytes (35%). Other clinically significant adverse reactions (≤15%) include: peripheral neuropathy (12%), sepsis or bacteremia (9%), and pneumonia (4%).

DRUG INTERACTIONS

*Also see **Warnings and Precautions** and **Clinical Pharmacology***

UGT1A1 Inhibitors: Concomitant administration of TRODELVY with inhibitors of UGT1A1 may increase the incidence of adverse reactions due to potential increase in systemic exposure to SN-38. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers: Exposure to SN-38 may be substantially reduced in patients concomitantly receiving UGT1A1 enzyme inducers. Avoid administering UGT1A1 inducers with TRODELVY.

USE IN SPECIFIC POPULATIONS:

*Also see **Warnings and Precautions, Clinical Pharmacology,** and **Nonclinical Toxicology***

Pregnancy: TRODELVY can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Lactation: There is no information regarding the presence of sacituzumab govitecan-hziy or SN-38 in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 1 month after the last dose of TRODELVY.

Females and Males of Reproductive Potential: Verify the pregnancy status of females of reproductive potential prior to initiation. TRODELVY can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose.

Males: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRODELVY and for 3 months after the last dose.

Infertility: Based on findings in animals, TRODELVY may impair fertility in females of reproductive potential.

Pediatric Use: Safety and effectiveness of TRODELVY have not been established in pediatric patients.

Geriatric Use: Of the patients who received TRODELVY, 264/795 (33%) of all patients were ≥ 65 years old, and 11% were ≥75 years old. No overall differences in safety and effectiveness were observed between these patients and younger patients.

Hepatic Impairment: No adjustment to the starting dose is required when administering TRODELVY to patients with mild hepatic impairment (bilirubin ≤ 1.5 ULN and AST/ALT < 3 ULN). The safety of TRODELVY in patients with moderate or severe hepatic impairment has not been established, and no recommendations can be made for the starting dose in these patients.

See PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

GILEAD

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

Your treatment. Our Journey.

A cancer diagnosis can feel unexpected, leaving you questioning what to do next. But, within 72 hours*, Florida Cancer Specialists gives you and your family the comfort of a personalized treatment plan. Our experienced doctors and nurses provide immunotherapy, the latest technologies from clinical trials and targeted treatment based on your cancer's genomic profile. And with world-class care that's close to home, we're always here to make treatment simple and clear.

By your side – every step of the way.

ACCESS TO
85+
NATIONAL
CLINICAL TRIALS

Caring for patients for over 37 years at our locations throughout Florida.

FLORIDA CANCER SPECIALISTS
& Research Institute

All required paperwork must be provided at time of referral.

FLCancer.com

GENETICS PROGRAM EXPANSION

Genetic Testing, Counseling Set to Expand at FCS

BY KARI C. BARLOW

Florida Cancer Specialists & Research Institute (FCS) will launch an array of new genetic testing capabilities this summer, ushering in some of the most personalized patient care in the organization's history.

Starting in July, the FCS Laboratory will expand to provide in-house molecular testing, or next-generation sequencing (NGS), for its oncology patients. The effort, initiated by FCS physicians, including Ryan Olson, MD, Medical Director of the FCS Pathology Laboratory, was brought to fruition under the guidance of Claudia French, FCS Vice President of Laboratory Services & Operational Excellence.

For French and her team, the end goal is better and faster diagnosis and treatment planning, which leads to more positive outcomes. Cancer is not really a single disease but a conglomeration of thousands or tens of thousands of individual diseases that share the commonality of disordered cell growth. NGS testing detects mutations in hundreds of different genes simultaneously, thus giving a more unique understanding of each patient's individual diagnosis. This information can then be used to personalize therapy, increasing cure rates and extending lives.

"We want to make sure we can provide genetic testing when it is needed," French said. "Many times, treatment decisions are made on NGS sequencing test results and turnaround time in the commercial labs can be over a month."

Jennifer Gass, PhD, who completed her fellowship training in Laboratory Genetics and Genomics, recently joined FCS as Associate Director of the Genetics Laboratory. She and Gina Elhammady, MD, a molecular pathologist on the FCS Lab team, are playing a key role in bringing these expanded capabilities to fruition.

"When I got here, there was nothing in the lab," Dr. Gass recalled. "I had to start from scratch, which has been challenging during a pandemic. A lot of the instruments we needed were the same instruments used in COVID-19 testing, so it's been a challenge … but we finally have everything and are finishing up validations." The new laboratory is equipped with multiple Illumina NextSeq sequencing systems, Hamilton robotic liquid handlers and various supporting instruments to provide state-of-the-art clinical NGS testing.

Initially, Gass and Dr. Elhammady, along with three FCS technologists, will offer NGS testing on solid tumors, hematologic malignancies and lymph nodes, and they are aiming for a turnaround time of 10 to 15 days.

"One of the great things about having it in-house is that we are in direct communication with the clinicians," Dr. Elhammady said. "We are the ones who sign off on the original diagnosis, and so we make the decision whether an NGS test is needed or not."

The lab will be able to correlate the patient's diagnosis with any mutation that was found through NGS testing, she added.

"Previously, physicians have told patients, 'You have lung cancer.' By adding NGS, it is, 'You have lung cancer, with this specific mutation, in this specific gene,' " Gass said. "When we know the specific genetic alteration that person has, there may be a therapy that actually targets that mutation."

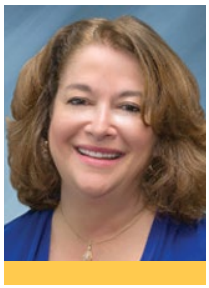
The new in-house NGS testing also aligns with FCS' recent efforts to expand its genetic counseling capabilities.

FCS Genetics Counselor Cathy Marinak, AOCNP welcomes the in-house NGS testing and sees it as a vital tool in helping her patients understand the big-picture implications of a single cancer diagnosis.

"It's really rare that a genetic mutation results in risk for only one cancer," she said. "It just doesn't happen. Think about the BRCA1 mutation — it increases risk for ovarian cancer, melanoma, pancreatic cancer, breast cancer and prostate cancer. It goes on and on."

In-house NGS testing will allow physicians to test for somatic or acquired mutations and inherited germline mutations, to develop more comprehensive cancer risk assessments.

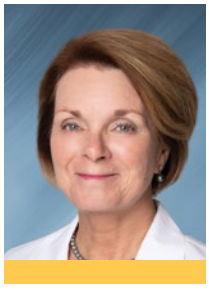
"That would be done concurrently," added Marinak, a nurse practitioner with specialized training in genetic counseling. "What we would ultimately love to have is if a patient came in with a specific diagnosis, the physician knows they can access the pancreatic



Claudia French
Vice President of Laboratory Services & Operational Excellence

Jennifer Gass, PhD
Associate Director, Genetics Laboratory

Gina Elhammady, MD
Molecular Pathologist



Cathy Marinak, AOCNP
Genetics Counselor

panel, for instance, or the breast panel, or melanoma panel.

"We would just make it simple — one stop shopping."

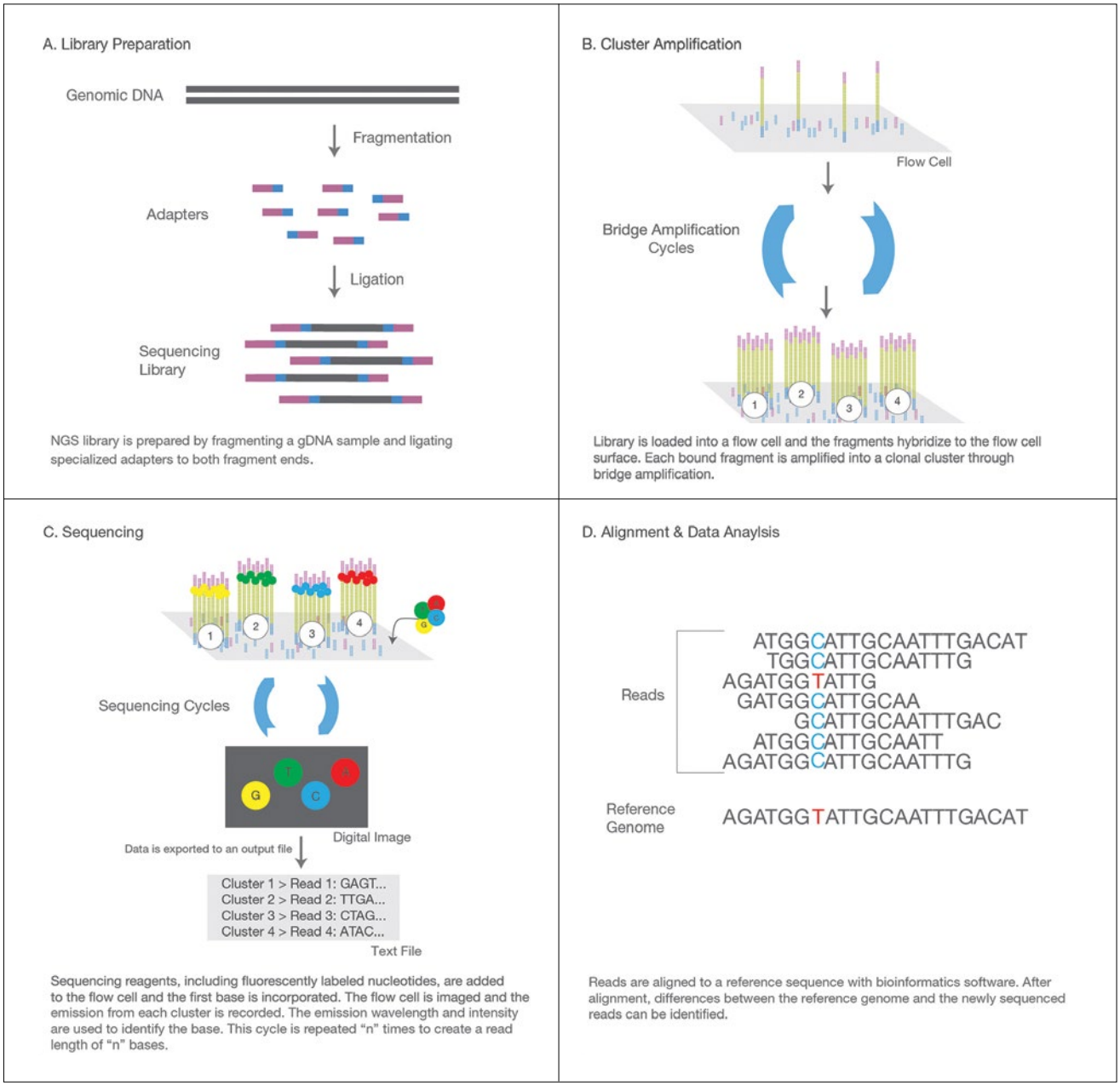
With those test results, Marinak can better counsel her patients as they go through treatment, make important lifestyle changes, undergo preventative surgery or explore reproductive options.

"From my perspective, I think it is just such a privilege to work for an organization that understands the value of the genetic counseling piece," Marinak said. "The FCS physicians embrace it, and they understand the role that it plays — not just for the patient but also for the families."

French agreed, adding that making these new testing capabilities the norm will ultimately mean better, more targeted care for FCS patients.

"The whole field of molecular medicine is just really exciting," she said. "Standardization improves quality. So as we can standardize how our doctors order this kind of testing and what testing they order and what profiles they get, we are going to be able to make better decisions for patients."

ARRAY GENOTYPING WORKFLOW



The next-generation sequencing workflow contains four basic steps: library preparation, amplification, sequencing and data analysis. Following preparation, the DNA and RNA sample is amplified and sequenced, allowing the geneticist or pathologist to analyze each patient's genetic information. *Graphic courtesy of Illumina.*

INFORMATICS

Mining Mission

Seeking truth in data

BY ZANDRA WOLFGRAM

In the fictional franchise *Star Trek: The Next Generation*, the crew of the USS Enterprise relies on Lt. Cmdr. Data to help navigate them to victory by using his innate gift of leveraging data intelligence.

Similarly, Trevor Heritage, PhD, FCS Vice President of Informatics, and the first mate of his growing crew, FCS Senior Director of Informatics Amy Ming, are leading a mission for Florida Cancer Specialists & Research Institute (FCS).

The task for this dynamic data duo is not small. Although their mandate is far from science fiction, it is one they relish.

Tapping into his 30-plus years of experience, Heritage oversees informatics projects across all care settings, enabling FCS to optimize its business processes while enhancing clinical decision support, as well as data enrichment initiatives for research and clinical trials. Ming, a registered nurse and a former Battalion Logistics Officer with the U.S. Army, brings a unique blend of informatics and clinical knowledge to her role, as well as the "clinical conscience" to do the right thing for patients.

Heritage, who joined FCS in December 2020, expounds on his team's mission to conquer five goals:

Trevor Heritage, PhD
Vice President
of Informatics

Amy Ming
Senior Director
of Informatics

"Each patient's cancer is different. Analyzing all the medical information gathered will allow us to identify specific targeted therapies for our patients, resulting in better outcomes with fewer side effects."

1. Help FCS find ways to leverage its data to make the best possible business and clinical decisions

"The reality throughout healthcare is that there are numerous types and formats for data that is captured and kept in multiple places. Before we can use data effectively, we must sort it and create a robust, reliable and consistent representation. Once we have trusted data, a huge opportunity sits before us to ultimately deliver a high-quality experience for both our physicians and our patients."

2. Using data to tell the entire story of a patient's health

"Although we capture a huge amount of information about our patients and their health, there are still more data opportunities that can help us better understand disease and guide care. We are especially excited about going live with FCS' next-generation sequencing operations this summer. Each patient's cancer is different. Analyzing all the medical information gathered will allow us to identify specific targeted therapies for our patients, resulting in better outcomes with fewer side effects. Additionally, we can use a patient's genetic profile to quickly and more selectively identify relevant trials that they can participate in close to home."

3. Looking at new ways FCS can create value from our data

"This digital age that we all live in today offers a wealth of opportunities for FCS to remain at the forefront of cancer care and research. We are able to provide our physicians with insights into individual patient disorders and treatment options and the tools to make decisions to optimize care. It also enables us to understand the demand for cancer care in specific regions and marry up our services to demand. Using our clinical data and patient response to specific therapies — what we call "real-world data" — will influence the standard of care and impact new drug discovery, development programs and clinical trials."

4. The protection of our data

"Our patients trust FCS not only to provide them with outstanding care but also to guard their personal health information. We operate according to regulatory guidelines of protected health information, and we also are pursuing HITRUST certification. This will give our patients the added confidence that FCS goes above and beyond in ensuring the security and meaningful use of the data they trust us with."

5. Up-keep of our data

"To make sure our data is healthy, we have launched a data governance initiative company-wide to protect, secure and accurately gather all the information FCS has access to. With the constant flow of patient visits, new data coming in constantly, new diagnostic testing technologies, and new therapies and guidelines, as well as new regulations, our data environment is extremely dynamic."

Clearly, the Informatics team's task is not small.

"It's challenging, given the complexities of healthcare, to accurately gather all relevant patient data, analyze it and deliver those insights across the organization," Heritage says. "I'm confident in our ability to accomplish this and thrilled that FCS has not only recognized the need, but also committed to the journey."

Michael Diaz, MD speaks at a recent Community Oncology Alliance (COA) session.

PATIENT ADVOCACY

The Crusaders

Champions in the fight for quality and affordability

BY ZANDRA WOLFGRAM

Drs. Michael Diaz and Paresh Patel are tireless champions for the greater good. Both are 10-year veterans with Florida Cancer Specialists & Research Institute (FCS). As patient advocacy ambassadors, they share an unwavering commitment to ensure that cancer patients have access to high-quality, state-of-the-art and affordable cancer care that is close to home. Their unwavering efforts to optimize the quality and value of the cancer care delivery system extend well beyond their clinic office hours.

Working in the state's capital gives Dr. Patel a convenient perch for his advocacy work through the Florida Society for Clinical Oncology (FLASCO). He is chairman of the Legislative Committee for FLASCO, which recently recognized him as the 2021 Advocate of the Year.

Dr. Diaz, based in St. Petersburg, is past president of the FLASCO board of directors and serves as Director of Advocacy and as Federal Legislative Chairman. His advocacy work with the American Society of Clinical Oncology ASCO®'s Payment Reform Work Group and the Community Oncology Alliance (COA), where he is immediate past president, allow him to work reform at the federal level.

Together, these two physicians are akin to "David" in the ancient parable, standing up to healthcare insurance and big pharma's "Goliath" in representing patients and community oncology providers in legislative health issues.

We spoke with them about their advocacy efforts and what it means to FCS and its patients. Here are highlights:

FCS: WHY DO YOU CHOOSE TO INVEST YOUR TIME IN THIS WAY?

MD: We have to live by our ideals and represent them. It's important. If we don't, no one else is going to.

PP: It's not everyone's thing. The patient drives you. Taking caring of patients is my priority.

FCS: WHY IS THERE A NEED FOR WHAT YOU DO?

MD: With the way society, governmental structures and the medical system are composed, someone needs to represent the patients because they're not informed enough to represent themselves adequately at the table compared to the government,

Dr. Paresh Patel (left) accepts the FLASCO 2021 Advocate of the Year Award.

insurers and hospital systems. It's not a fair fight.

FCS: WHAT SPECIFICALLY ARE YOU FOCUSING ON?

MD: We focus on issues that we can correct and/or prevent at the state and national level that make it difficult for cancer patients to get the quality cancer care they deserve. We also identify weaknesses in the system and try to help educate legislators to understand why the system is not working and why it needs to be addressed.

There are multiple other components. It might be working with insurers or local state payers to ensure that their cost-saving efforts may be compromising cancer patients, quality and access to care. We educate patients and caregivers about their cancer overall and their journey from cancer treatments to survivorship, social support and advocacy to give them an awareness of what is going on so that if we need to mobilize on a grassroots level, they're educated and motivated.

FCS: WHAT IS ON THE TABLE AT THE STATE LEVEL RIGHT NOW?

PP: There are a couple of things on the table. One is the Step Therapy Protocol bill (SB 1290) that has not been coming along as we like it. Over the past four or five years, we got one version passed, but we need to step up and build on it.

What it means is, if I prescribe a medication for patients on chemotherapy and I know this patient is going to have really bad issues with nausea, the insurance company may say I cannot use a certain medicine; they may say I have to use a cheaper or earlier version of it. Until the patient gets admitted to the hospital or goes to the ER, you cannot get the next line of nausea medications. That's cumbersome for a patient and it may be more expensive than getting the nausea medication upfront.

Another is the Health Insurance Cost Sharing bill (SB 1078/HB 1111), which addresses how pharmacy benefits managers are artificially inflating drug prices on one hand and making more profit on the other, and all the while delaying approval of needed drugs.

I also have a personal interest in HB 1021, which prohibits health insurers and HMOs from requiring patients to meet specific requirements before drugs are prescribed for stage 4 cancer.

FCS: HOW DO YOUR FCS COLLEAGUES HELP YOU SUCCEED?

PP: It takes time. Working against lobbyists is a difficult task, but it's not impossible. And when we need to move the mountains, the support from our colleagues does help.

MD: The healthcare system is broken. It is what it is. We have to improve it. And if we don't work together for the benefit of our cancer patients, then the overall quality and value of healthcare are going to suffer. We deserve to have much more than that as a society, and when our FCS colleagues take a few minutes now and then to listen, learn and get involved when asked, I think we will continue to do the best that we can for our patients.

CONSTRUCTION UNDERWAY FOR NEW CANCER CENTER IN SEMINOLE COUNTY

A one-story building at 750 Orienta Ave., Altamonte Springs, will replace the current FCS location on Altamonte Drive. The new clinic will include nine exam rooms, 36 infusion chairs, laboratory services and oral oncolytic pharmacy when it opens in April 2022. With greatly expanded space, it will offer enhanced comfort for patients, staff and visitors, and enable FCS to keep pace with ongoing growth in Seminole County.

GROUNDBREAKING CELEBRATED IN VOLUSIA COUNTY

Scheduled for completion by year's end, the new FCS Orange City Cancer Center at 2824 Enterprise Road will be nearly three times larger than the existing FCS location at 765 Image Way. The one-story, 16,000-square-foot clinic will include 12 exam rooms and 35 infusion chairs.

RIBBON-CUTTING FOR NEW LOCATION IN ESTERO

A ribbon was cut to celebrate the opening of the new state-of-the-art FCS cancer center at 8440 Murano Del Lago Drive in Estero. The nearly 16,000-square-foot clinic provides comprehensive cancer treatments alongside imaging services with fixed PET/CT technology, pathology and laboratory services and in-house specialty pharmacy, as well as care management services for patients participating in value-based care initiatives. It is the fifth FCS location in Lee County.

AmerisourceBergen
ION Solutions

Optimize your revenue cycle to maximize efficiencies and increase reimbursements

Outdated billing and coding processes lead to unpaid claims, which is money your practice needs to deliver quality patient care.

Our experienced team of business optimization consultants will work with your practice remotely to:

- Analyze denial trends by payer, drug, and Current Procedural Terminology (CPT)
- Review accounts receivable reports by payer, practice, and CPT
- Evaluate your practice's systems, and processes
- Improve efficiency, productivity and automation using your practice management system

For more information, visit iononline.com/consulting-os

GROUNDBREAKING FOR NEW CANCER CENTER IN LAKE CITY

The new FCS clinic in Lake City will include eight exam rooms and 25 infusion chairs, in addition to laboratory services, an oral oncolytic pharmacy, mobile PET/CT and care management services for patients participating in value-based care initiatives. Scheduled for completion in April 2022, the one-story building will replace the current FCS location at 1920 Don Wickham Way in Clermont.

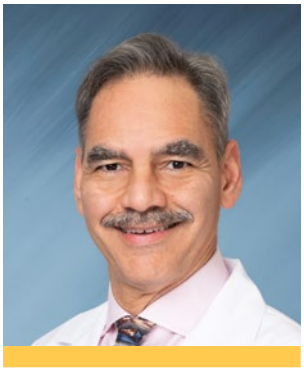
TALLAHASSEE CANCER CENTER RIBBON-CUTTING

The newly built FCS Tallahassee Cancer Center at 2351 Phillips Road replaced the two former FCS clinic locations in Leon County. With nearly double the space, the state-of-the-art clinic improves access and convenience for patients, with 16 exam rooms (previously 12) and 62 infusion treatment chairs (previously 42), along with PET/CT scan technology, centralized laboratory and pathology, an oral oncolytic specialty pharmacy, access to clinical trials and care management services for patients participating in value-based care initiatives. Services were expanded in 2020 to include gynecologic oncology.

RIBBON-CUTTING FOR BROWNWOOD CANCER CENTER

The fourth FCS clinic location in The Villages is located at 2955 Brownwood Blvd., Suite 107. With nearly 23,000 square feet, the facility has 18 patient exam rooms and 30 infusion treatment chairs. Treatment services include on-site radiation oncology, laboratory, pathology, a specialty pharmacy with convenient home delivery of oral medications and care management services for patients who participate in value-based care initiatives.

LEADERSHIP APPOINTMENTS



Gustavo Fonseca, MD, FACP
Medical Director of Clinical Research Program

Gustavo "Gus" Fonseca, MD, FACP has been named Medical Director of the FCS Clinical Research Program. Dr. Fonseca provides clinical leadership and oversight of Phase 1 through 4 clinical trials at more than 36 FCS locations in Florida. He succeeds James Reeves Jr., MD, who continues to participate in the FCS research division with a focus on leveraging OncoTrials®, Genospace, and other precision medicine platforms to enhance clinical trial activities and patient outcomes. Dr. Fonseca continues to provide care to patients at FCS clinic locations in Citrus County.

Ray Bailey, BPharm, RPh
Senior Vice President of Pharmacy Services

In this newly created senior leadership role, Ray continues to work closely with pharmaceutical and trade partnerships to support our company's long-term growth initiatives of pharmacy services, including Rx to Go and Pharmacy Operations. A highly respected leader throughout the industry who joined FCS in 2009, Ray has been instrumental in developing our pharmacy area and ensuring our patients receive the medications and support they need.

Charmion Patton, EdD, PHR
Senior Vice President of People & Culture

Bringing over 20 years of leadership-level experience, Charmion oversees the development of strategic people and culture initiatives to attract and engage the FCS workforce, encompassing recruitment, workforce planning, talent management, performance management and total rewards. She also serves as the company's Diversity & Inclusion Officer. In partnership with executive and senior leaders, she helps to set the stage for team member success and engagement.

NEW PHYSICIANS JOIN FCS

Irfan Ahmed, MD, MS
Radiation oncologist in Brownwood and The Villages Cancer Center

Tadeu Ambros, MD
Medical oncologist/hematologist in Colonial, Cape Coral and Cape Coral Cay West

Aamer Farooq, MD
Medical Oncologist in Orange and Seminole counties

FCS Foundation News & Events

For tickets and sponsorship information, visit FCSF.org/Events

10 YEARS of hope | FLORIDA CANCER SPECIALISTS Foundation

Service & Support. Healing & Hope.

As the FCS Foundation celebrates 10 years of Service & Support, Healing & Hope, we take great pride in knowing that we provide hope so patients can focus on healing. Here is a note of thanks from one recent grant recipient.

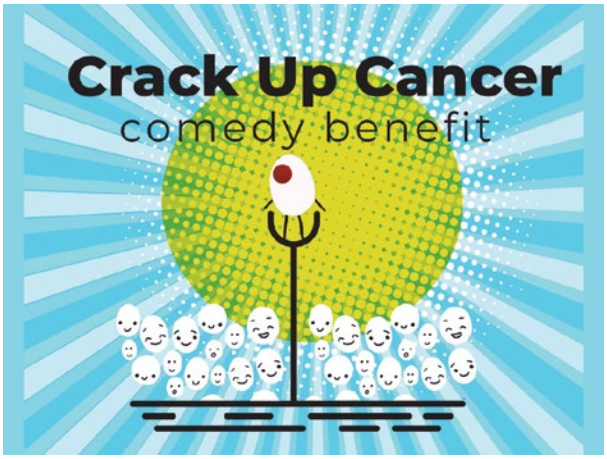
"I was in a tough spot when I was diagnosed with cancer. I didn't think I'd be able to keep up with any of the bills, so I applied for a grant through the FCS Foundation and was approved. It was a lifesaver because I was able to focus on getting through my treatment. The FCS Foundation took care of the bills that I couldn't pay at the time while I was out of work. I'm just so thankful that the FCS Foundation was there for me."

— Jim Williamson

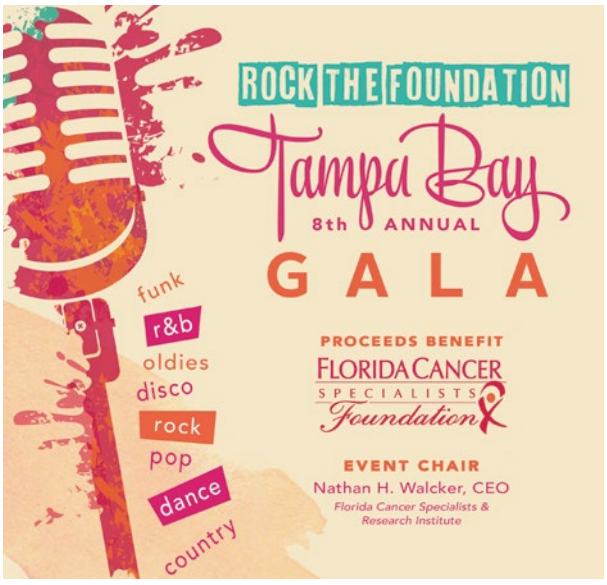
wine women&shoes®

Benefiting Florida Cancer Specialists Foundation

Wine Women and Shoes, Orlando
Nov. 6, JW Marriott, Orlando



Crack Up Cancer
Sept. 11, Straz Center, Tampa



Rock the Foundation Tampa Bay Gala
Oct. 2, Armature Works, Tampa

Shop at AmazonSmile and Amazon will make a donation to: FLORIDA CANCER SPECIALISTS Foundation

amazonsmile You shop. Amazon gives.

Share your support on Amazon. Go to Smile.Amazon.com, log-in and select Florida Cancer Specialists Foundation as your charity. For eligible purchases at AmazonSmile, the AmazonSmile Foundation will donate 0.5% of the purchase price to the customer's selected charitable organization.

From Our Patients

Shachar Peles, MD

HEALTHGRADES REVIEW: 5 STARS

Dr. Peles has been my oncologist for the past two years. He is a wonderful doctor in every way: super smart, compassionate, caring and thorough. He is up to date on research and treatments and provided a wealth of knowledge for my chemotherapy options, and he carefully monitored my progress during and after chemo. Dr. Peles and his staff helped me through the hardest time of my life and I am eternally grateful.

Padmaja Sai, MD

HEALTHGRADES REVIEW: 5 STARS

I have been a patient of Dr. Sai for several years. She is excellent. Her staff is equally caring and compassionate. A wonderful balance when you need it most. Simply the best.

Eric Harris, DO

I felt compelled to share that you really meant a lot to my mom. You gave her so much hope. Every time she left your office, her faith was restored & I could see the fight in her eyes again. She loved that you talked with her about God & made her feel like she was so special & worthy of being healed. You gave her hope & you gave us time. The memories we made with my mom in the past year will stay with me forever & I could never express to you how very much that means to me. They were some of the greatest moments we ever had together. The time we got with her in her last months was so special & our gift from God that he gave to us through you. People like you change the world over & over again because I know we are not the only family who you have touched.

Thank you for caring about my mom. My family & I are so grateful for you.

Adewale Fawole, MD

GOOGLE REVIEW: 5 STARS

Dr. Fawole is an exceptional oncologist. His upbeat attitude always makes you feel more at ease, and it is evident that he truly cares about his patients. He always takes the extra time to answer all questions and explains things in a way that makes them easy to understand. He always makes you feel as if you are his only patient and that he is personally vested in your health and wellness.

William Grow, MD

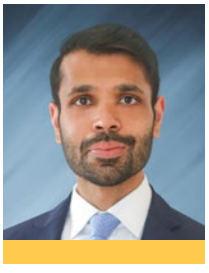
GOGGLE REVIEW: 5 STARS

Dr. Grow is one of my favorite humans on the planet. He is uplifting, compassionate and always takes care of the person in front of him as if they were his own family. Thank you, Dr. Grow, for being you!

Rakesh Rohatgi, MD

GOOGLE REVIEW: 5 STARS

Dr. Rohatgi has always been caring, concerned and extremely thorough. He is a wonderful doctor if you want a doctor who will be completely vigilant about you as a person and your well-being. He is the best.



Raji Shameem, MD

FACEBOOK REVIEW

Dr. Shameem in Oviedo is taking excellent care of my mom throughout her treatment. He treats her like a family member – kind and patient every time. The office staff is excellent – efficient and friendly. We highly recommend him if you need a medical oncologist.

Have something to add?

You can submit your feedback by emailing us at FCSCommunications@FLCancer.com

AmerisourceBergen
ION Solutions

Elevate business performance with InfoDive®

Gain actionable insights into key performance areas:

- Monitor drugs dispensed and billed to ensure claims accuracy with GapFinder®
- Leverage analytics to see exactly how much your practice is being paid and improve negotiations with payers
- Review and audit single dose vials and identify potential missed billings
- Determine net cost recovery of drugs with Buy and Bill
- Compare inventory key metrics such as daily dispense, days on hand, and inventory turns
- Monitor compliance to reduce audit risk
- Utilize robust analytics to support success in value-based payment models such as the Oncology Care Model

For more information, visit iononline.com/infodive-os