SPRING 2021

FCS THE MAGAZINE

Genomic Testing

Finding the key to early diagnosis

THE **FIRST AND ONLY** ADC FDA APPROVED FOR ADULT PATIENTS WITH mTNBC WHO HAVE RECEIVED AT LEAST 2 PRIOR THERAPIES FOR METASTATIC DISEASE

33.3%

OVERALL RESPONSE RATE (n=36/108; CR+PR)

(95% CI: 24.6; 43.1)

7.7 MEDIAN MONTHS

DURATION OF RESPONSE (range: 1.9, 30.4)

(95% CI: 4.9; 10.8)

Based on investigator assessment.

TRODELVY was evaluated in an open-label, uncontrolled, single-arm phase 1/2 trial of 108 patients with mTNBC who had received at least 2 prior treatments for metastatic disease. TRODELVY was administered intravenously at a dose of 10 mg/kg on Days 1 and 8 of continuous 21-day treatment cycles, and patients were treated until disease progression or unacceptable toxicity. Major efficacy outcome measures were investigator-assessed overall response rate (ORR) using RECIST 1.1 and duration of response.

CI=confidence interval; CR=complete response; PR=partial response.

INDICATION

TRODELVY™ (sacituzumab govitecan-hziy) is indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least 2 prior therapies for metastatic disease.

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

WARNING: NEUTROPENIA AND DIARRHEA

TRODELVY can cause severe or life-threatening neutropenia. Withhold TRODELVY for absolute neutrophil count (ANC) below 1500/mm^3 on Day 1 of any cycle or ANC below 1000/mm^3 on Day 8 of any cycle. Withhold TRODELVY for neutropenic fever.

Monitor blood cell counts periodically during treatment. Consider Granulocyte Colony-Stimulating Factor (G-CSF) for secondary prophylaxis. Initiate anti-infective treatment in patients with febrile neutropenia without delay.

- Dose modifications may be required due to neutropenia. Febrile neutropenia occurred in 6% (24/408) of patients treated with TRODELVY, including 8% (9/108) of patients with mTNBC after at least 2 prior therapies. Less than 1% (1/408) of patients had febrile neutropenia leading to permanent discontinuation. The incidence of Grade 1-4 neutropenia was 64% in patients with mTNBC (n=108). In all patients treated with TRODELVY (n=408), the incidence of Grade 1-4 neutropenia was 54%; Grade 4 neutropenia occurred in 13%. Less than 1% (2/408) of patients permanently discontinued treatment due to neutropenia.

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.

- Diarrhea occurred in 63% (68/108) of patients with mTNBC and 62% (254/408) of all patients treated with TRODELVY. In each population, events of Grade 3-4 occurred in 9% (10/108) of mTNBC patients and 9% (36/408) of all patients treated with TRODELVY. Four out of 408 patients (<1%) discontinued treatment because of diarrhea. Neutropenic colitis was observed in 2% (2/108) of patients in the mTNBC cohort and 1% of all patients treated with TRODELVY

Contraindications: Severe hypersensitivity reaction to TRODELVY.

Hypersensitivity

- TRODELVY can cause severe and life-threatening hypersensitivity, including anaphylactic reactions. Hypersensitivity reactions occurred within 24 hours of dosing in 37% (151/408) and Grade 3-4 hypersensitivity occurred in 1% (6/408) of all patients treated with TRODELVY (n=408). The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 1% (3/408).
- Pre-infusion medication for patients receiving TRODELVY is recommended. Observe patients closely for infusion-related reactions during each TRODELVY 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.

Nausea and Vomiting

- TRODELVY is emetogenic. Nausea occurred in 69% (74/108) of patients with mTNBC and 69% (281/408) of all patients treated with TRODELVY. Grade 3 nausea occurred in 6% (7/108) and 5% (22/408) of these populations, respectively. Vomiting occurred in 49% (53/108) of patients with mTNBC and 45% (183/408) of all patients treated with TRODELVY. Grade 3 vomiting occurred in 6% (7/108) and 4% (16/408) of these patients, respectively.

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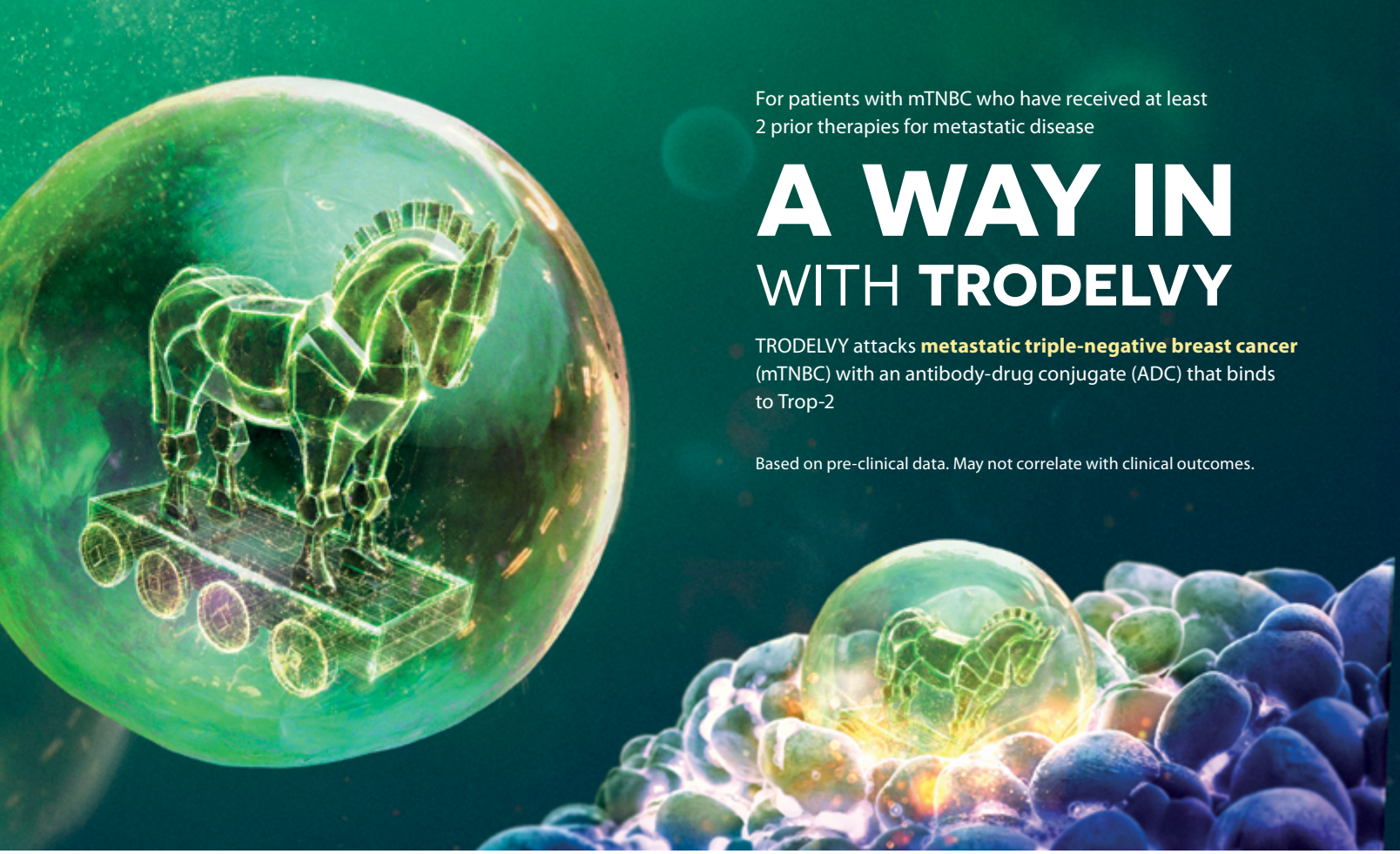

For patients with mTNBC who have received at least 2 prior therapies for metastatic disease

A WAY IN WITH TRODELVY

TRODELVY attacks **metastatic triple-negative breast cancer** (mTNBC) with an antibody-drug conjugate (ADC) that binds to Trop-2

Based on pre-clinical data. May not correlate with clinical outcomes.

- Premedicate with a 2- or 3-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 at the time of scheduled treatment administration 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.

Use in Patients with Reduced UGT1A1 Activity

- Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia and may be at increased risk for other adverse events following initiation of TRODELVY treatment. Closely monitor patients with reduced UGT1A1 activity for severe neutropenia. The appropriate dose for patients who are homozygous for UGT1A1*28 is not known and should be considered based on individual patient tolerance to treatment.
- In 84% (343/408) of patients who received TRODELVY (up to 10 mg/kg on Days 1 and 8 of a 21-day cycle) and had retrospective UGT1A1 genotype results available, the incidence of Grade 4 neutropenia was 26% (10/39) in patients homozygous for the UGT1A1*28 allele, 13% (20/155) in patients heterozygous for the UGT1A1*28 allele, and 11% (16/149) in patients homozygous for the wild-type allele.

Embryo-Fetal Toxicity

- TRODELVY contains a genotoxic component and can cause teratogenicity and/or embryo-fetal lethality when administered to a pregnant woman. 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 following 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.

Lactation

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.

Adverse Reactions

Most common adverse reactions (incidence >25%) in patients with mTNBC are nausea (69%), neutropenia (64%), diarrhea (63%), fatigue (57%), anemia (52%), vomiting (49%), alopecia (38%), constipation (34%), rash (31%), decreased appetite (30%), abdominal pain (26%), and respiratory infection (26%).

Please see the Brief Summary of full Prescribing Information, including boxed Warning, on the pages that follow.

Efficacy. Directed.

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

VISIT TRODELVY.COM TO LEARN MORE.

Brief Summary of Prescribing Information

TRODELVY™ (sacituzumab govitecan-hziy) for injection, for intravenous use

See package insert for full Prescribing Information.

INDICATIONS AND USAGE

TRODELVY is indicated for the treatment of adult patients with metastatic triple-negative breast cancer (mTNBC) who have received at least two prior therapies for metastatic disease.

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.

WARNING: NEUTROPENIA AND DIARRHEA

- **Severe 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 *[see Warnings and Precautions]*.**
- **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 *[see Warnings and Precautions]*. If severe diarrhea occurs, withhold TRODELVY until resolved to ≤ Grade 1 and reduce subsequent doses.**

CONTRAINDICATIONS

TRODELVY is contraindicated in patients who have experienced a severe hypersensitivity reaction to TRODELVY *[see Warnings and Precautions]*.

WARNINGS AND PRECAUTIONS

Neutropenia

TRODELVY can cause severe or life-threatening neutropenia. 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. Dose modifications may be required due to neutropenia.

Febrile neutropenia occurred in 6% (24/408) patients treated with TRODELVY, including 8% (9/108) patients with mTNBC after at least two prior therapies. Less than 1% (1/408) of patients had febrile neutropenia leading to permanent discontinuation.

The incidence of Grade 1-4 neutropenia was 64% in patients with mTNBC (n=108). In all patients treated with TRODELVY (n=408), the incidence of Grade1-4 neutropenia was 54%; Grade 4 neutropenia occurred in 13%. Less than 1% (2/408) of patients permanently discontinued treatment due to neutropenia.

Diarrhea

TRODELVY can cause severe diarrhea. 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.

Diarrhea occurred in 63% (68/108) of patients with mTNBC and 62% (254/408) of all patients treated with TRODELVY. In each population, events of Grade 3-4 occurred in 9% (10/108) of mTNBC patients and 9% (36/408) of all patients treated with TRODELVY. Four out of 408 patients (<1%) discontinued treatment because of diarrhea. Neutropenic colitis was observed in 2% (2/108) of patients in the mTNBC cohort and 1% of all patients treated with TRODELVY.

Hypersensitivity

TRODELVY can cause severe and life-threatening hypersensitivity. Anaphylactic reactions have been observed in clinical trials with TRODELVY.

Hypersensitivity reactions within 24 hours of dosing occurred in 37% (151/408) of patients treated with TRODELVY. Grade 3-4 hypersensitivity occurred in 1% (6/408) of patients treated with TRODELVY. The incidence of hypersensitivity reactions leading to permanent discontinuation of TRODELVY was 1% (3/408).

Pre-infusion medication for patients receiving TRODELVY is recommended. Observe patients closely for infusion-related reactions during each TRODELVY 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.

Nausea and Vomiting

TRODELVY is emetogenic. Nausea occurred in 69% (74/108) of patients with mTNBC and 69% (281/408) of all patients treated with TRODELVY. Grade 3 nausea occurred in 6% (7/108) and 5% (22/408) of these populations, respectively.

Vomiting occurred in 49% (53/108) of patients with mTNBC and 45% (183/408) of all patients treated with TRODELVY. Grade 3 vomiting occurred in 6% (7/108) and 4% (16/408) of these patients, respectively.

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 at the time of scheduled treatment administration 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.

Use in Patients with Reduced UGT1A1 Activity

Individuals who are homozygous for the uridine diphosphate-glucuronosyl transferase 1A1 (UGT1A1)*28 allele are at increased risk for neutropenia and may be at increased risk for other adverse reactions following initiation of TRODELVY treatment.

In 84% (343/408) of patients who received TRODELVY (up to 10 mg/kg on Days 1 and 8 of a 21-day cycle) and had retrospective UGT1A1 genotype results available, the incidence of Grade 4 neutropenia was 26% (10/39) in patients homozygous for the UGT1A1*28 allele, 13% (20/155) in patients heterozygous for the UGT1A1*28 allele and 11% (16/149) in patients homozygous for the wild-type allele.

Closely monitor patients with reduced UGT1A1 activity for severe neutropenia. The appropriate dose for patients who are homozygous for UGT1A1*28 is not known and should be considered based on individual patient tolerance to treatment.

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 *[see Use in Specific Populations]*.

ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the label:

- Neutropenia *[see Warnings and Precautions]*
- Diarrhea *[see Warnings and Precautions]*
- Hypersensitivity *[see Warnings and Precautions]*
- Nausea and Vomiting *[see Warnings and Precautions]*

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 clinical practice.

The data described in the Warnings and Precautions section reflect exposure to TRODELVY as a single agent in a single-arm, open-label study (IMMU-132-01) in 408 patients with mTNBC and other malignancies who had received prior systemic therapeutic regimen for advanced disease. TRODELVY was administered as an intravenous infusion once weekly on Days 1 and 8 of 21-day treatment cycles at doses up to 10 mg/kg until disease progression or unacceptable toxicity.

The data in Table 2 reflect exposure to TRODELVY in a subset of 108 patients with mTNBC who had received at least two prior treatments for metastatic disease in study (IMMU-132-01). Patients received TRODELVY 10 mg/kg via intravenous infusion on Days 1 and 8 of 21-day treatment cycles until disease progression or unacceptable toxicity. The median treatment duration in these 108 patients was 5.1 months (range: 0-51 months).

Serious adverse reactions were reported in 31% of the patients. The most frequent serious adverse reactions (reported in >1%) of the patients receiving TRODELVY were febrile neutropenia (6%) vomiting (5%), nausea (3%), dyspnea (3%), diarrhea (4%), anemia (2%), pleural effusion, neutropenia, pneumonia, dehydration (each 2%).

TRODELVY was permanently discontinued for adverse reactions in 2% of patients. Adverse reactions leading to discontinuation were anaphylaxis, anorexia/fatigue, and headache (each <1%, 1 patient for each event). Forty-five percent (45%) of patients experienced an adverse reaction leading to treatment interruption. The most common adverse reaction leading to treatment interruption was neutropenia (33%). Adverse reactions leading to dose reduction occurred in 33% of patients treated with TRODELVY, with 24% having one dose reduction and 9% with two dose reductions. The most common adverse reaction leading to dose reductions was neutropenia/febrile neutropenia.

Adverse reactions occurring in ≥10% of patients with mTNBC in the IMMU-132-01 study are summarized in Table 2.

Table 2: Adverse Reactions in ≥ 10% of Patients with mTNBC in IMMU-132-01

Adverse Reaction	TRODELVY (n=108)	
	Grade 1-4 (%)	Grade 3-4 (%)
Any adverse reaction	100	71
Gastrointestinal disorders	95	21
Nausea	69	6
Diarrhea	63	9
Vomiting	49	6
Constipation	34	1
Abdominal pain[i]	26	1
Mucositis[ii]	14	1
General disorders and administration site conditions	77	9
Fatigue[iii]	57	8
Edema[iv]	19	0
Pyrexia	14	0
Blood and lymphatic system disorders	74	37
Neutropenia	64	43
Anemia	52	12
Thrombocytopenia	14	3
Metabolism and nutrition disorders	68	22
Decreased appetite	30	1
Hyperglycemia	24	4
Hypomagnesemia	21	1
Hypokalemia	19	2
Hypophosphatemia	16	9
Dehydration	13	5
Skin and subcutaneous tissue disorders	63	4
Alopecia	38	0
Rash[v]	31	3
Pruritus	17	0
Dry Skin	15	0
Nervous system disorders	56	4
Headache	23	1
Dizziness	22	0
Neuropathy[vi]	24	0
Dysgeusia	11	0
Infections and infestations	55	12
Urinary Tract Infection	21	3
Respiratory Infection[vii]	26	3
Musculoskeletal and connective tissue disorders	54	1
Back pain	23	0
Arthralgia	17	0
Pain in extremity	11	0

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Table 2: Adverse Reactions in ≥ 10% of Patients with mTNBC in IMMU-132-01 *(cont'd)*

Respiratory, thoracic and mediastinal disorders	54	5
Cough[viii]	22	0
Dyspnea[ix]	21	3
Psychiatric disorders	26	1
Insomnia	13	0

Graded per NCI CTCAE v. 4.0

[i]Including abdominal pain, distention, pain (upper), discomfort, tenderness

[ii]Including stomatitis, esophagitis, and mucosal inflammation

[iii]Including fatigue and asthenia

[iv]Including edema; and peripheral, localized, and periorbital edema

[v]Including rash; maculopapular, erythematous, generalized rash; dermatitis acneiform; skin disorder, irritation, and exfoliation

[vi]Including gait disturbance, hypoesthesia, muscular weakness, paresthesia, peripheral and sensory neuropathy

[vii]Including lower and upper respiratory tract infection, pneumonia, influenza, viral upper respiratory infection, bronchitis and respiratory syncytial virus infection

[viii]Includes cough and productive cough

[ix]Includes dyspnea and exertional dyspnea

Table 3: Laboratory Abnormalities observed in >10% of Patients while receiving TRODELVY

Laboratory Abnormality	TRODELVY (n=108)	
	All Grades (%)	Grade 3-4 (%)
Hematology		
Decreased hemoglobin	93	6
Decreased leukocytes	91	26
Decreased neutrophils	82	32
Increased activated partial thromboplastin time	60	12
Decreased platelets	30	3
Chemistry		
Increased alkaline phosphatase	57	2
Decreased magnesium	51	3
Decreased calcium	49	3
Increased glucose	48	3
Increased aspartate aminotransferase	45	3
Decreased albumin	39	1
Increased alanine aminotransferase	35	2
Decreased potassium	30	3
Decreased phosphate	29	5
Decreased sodium	25	4.7
Increased magnesium	24	4
Decreased glucose	19	2

Immunogenicity

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies in the studies described below with the incidence of antibodies in other studies or to other sacituzumab govitecan products may be misleading.

The analysis of immunogenicity of TRODELVY in serum samples from 106 patients with mTNBC was evaluated using an electrochemiluminescence (ECL)-based immunoassay to test for anti-sacituzumab govitecan-hziy antibodies. Detection of the anti-sacituzumab govitecan-hziy antibodies was done using a 3-tier approach: screen, confirm, and titer. Persistent anti-sacituzumab govitecan-hziy antibodies developed in 2% (2/106) of patients.

DRUG INTERACTIONS

Effect of Other Drugs on TRODELVY

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 *[see Warning and Precaution]*. Avoid administering UGT1A1 inhibitors with TRODELVY.

UGT1A1 Inducers

Exposure to SN-38 may be substantially reduced in patients concomitantly receiving UGT1A1 enzyme inducers *[see Warning and Precaution]*. Avoid administering UGT1A1 inducers with TRODELVY.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on its mechanism of action, 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. TRODELVY contains a genotoxic component, SN-38, and is toxic to rapidly dividing cells. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

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

Data

Animal data

There were no reproductive and developmental toxicology studies conducted with sacituzumab govitecan-hziy.

Lactation

Risk Summary

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

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential prior to the initiation of TRODELVY.

Contraception

Females

TRODELVY can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations]*. Advise females of reproductive potential to use effective contraception during treatment with TRODELVY and for 6 months after the last dose.

Males

Because of the potential for genotoxicity, 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

Females

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, 19/108 (18%) patients with mTNBC and 144/408 (35%) of all patients were ≥ 65 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 less than or equal to 1.5 ULN and AST/ALT < 3 ULN).

The exposure of TRODELVY in patients with mild hepatic impairment (bilirubin less than or equal to ULN and AST greater than ULN, or bilirubin greater than 1.0 to 1.5 ULN and AST of any level; n=12) was similar to patients with normal hepatic function (bilirubin or AST less than ULN; n=45).

The safety of TRODELVY in patients with moderate or severe hepatic impairment has not been established. TRODELVY has not been tested in patients with serum bilirubin > 1.5 ULN, or AST and ALT > 3 ULN, or AST and ALT > 5 ULN and associated with liver metastases.

No dedicated trial was performed to investigate the tolerability of TRODELVY in patients with moderate or severe hepatic impairment. No recommendations can be made for the starting dose in these patients.

OVERDOSAGE

In a clinical trial, planned doses of up to 18 mg/kg (approximately 1.8 times the maximum recommended dose of 10 mg/kg) of TRODELVY were administered. In these patients, a higher incidence of severe neutropenia was observed.

Pharmacogenomics

SN-38 is metabolized via UGT1A1. Genetic variants of the UGT1A1 gene such as the UGT1A1*28 allele lead to reduced UGT1A1 enzyme activity. Individuals who are homozygous for the UGT1A1*28 allele are at increased risk for neutropenia from TRODELVY *[see Warnings and Precautions]*. Approximately 20% of the Black or African American population, 10% of the White population, and 2% of the East Asian population are homozygous for the UGT1A1*28 allele. Decreased function alleles other than UGT1A1*28 may be present in certain populations.

PATIENT COUNSELING INFORMATION

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

Neutropenia

Advise patients of the risk of neutropenia. Instruct patients to immediately contact their healthcare provider if they experience fever, chills, or other signs of infection *[see Warnings and Precautions]*.

Diarrhea

Advise patients of the risk of diarrhea. Instruct patients to immediately contact their healthcare provider if they experience diarrhea for the first time during treatment; black or bloody stools; symptoms of dehydration such as lightheadedness, dizziness, or faintness; inability to take fluids by mouth due to nausea or vomiting; or inability to get diarrhea under control within 24 hours *[see Warnings and Precautions]*.

Hypersensitivity

Inform patients of the risk of serious infusion reactions and anaphylaxis. Instruct patients to immediately contact their healthcare provider if they experience facial, lip, tongue, or throat swelling, urticaria, difficulty breathing, lightheadedness, dizziness, chills, rigors, wheezing, pruritus, flushing, rash, hypotension or fever, that occur during or within 24 hours following the infusion *[see Warnings and Precautions]*.

Nausea/Vomiting

Advise patients of the risk of nausea and vomiting. Premedication according to established guidelines with a two or three drug regimen for prevention of chemotherapy-induced nausea and vomiting (CINV) is also recommended. Additional antiemetics, sedatives, and other supportive measures may also be employed as clinically indicated. All patients should receive take-home medications for preventing and treating delayed nausea and vomiting, with clear instructions. Instruct patients to immediately contact their healthcare provider if they experience uncontrolled nausea or vomiting *[see Warnings and Precautions]*.

Embryo-Fetal Toxicity

Advise female patients to contact their healthcare provider if they are pregnant or become pregnant. Inform female patients of the risk to a fetus and potential loss of the pregnancy *[see Use in Specific Populations]*.

Contraception

Advise female patients of reproductive potential to use effective contraception during treatment and for 6 months after the last dose of TRODELVY *[see Use in Specific Populations]*.

Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of TRODELVY *[see Use in Specific Populations]*.

Lactation

Advise women not to breastfeed during treatment and for 1 month after the last dose of TRODELVY *[see Use in Specific Populations]*.

Infertility

Advise females of reproductive potential that TRODELVY may impair fertility *[see Use in Specific Populations]*.

Manufactured by:
Immunomedics, Inc.
300 The American Road
Morris Plains, NJ 07950, USA U.S. License No. 1737

TRODELVY™
sacituzumab govitecan-hziy
180 mg for injection

IN THIS ISSUE

FEATURES

SPOTLIGHTS

DEPARTMENTS

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

Email to FCSCommunications@FLCancer.com

FCS THE MAGAZINE

NATHAN H. WALCKER, CHIEF EXECUTIVE OFFICER:

With a most challenging year now behind us, Florida Cancer Specialists & Research Institute is moving full force into 2021.

This issue of FCS Magazine showcases the impact that our leading community-based oncology practice is making each and every day in the lives and in the communities of those we serve and in the advancement of innovative new cancer treatments.

Our cover story is a touching example of how FCS providers walk step by step with each of their patients through their cancer journeys. Our use of genomic testing is providing greater insight into the nature of disease and enabling the development of more targeted and individualized treatment modalities for overall better outcomes.

And when helping patients through their journey, palliative and supportive care is essential. We are pleased with the positive response to our new palliative care service since it was launched last fall and look forward to expanding it to more locations in the coming months.

Our technology investments continue to reap rewards as well. The FCS Virtual Image Exchange (VIE) is a new cloud-based imaging and information portal that allows for the instant sharing of radiology images, reports and treatment plans among all members of the care team, regardless of location. This real-time access informs and speeds up care decisions.

I am extremely proud of our entire FCS team, whose members share an unwavering commitment to excellence, innovation and a patient-first approach.

LUCIO GORDAN, MD, PRESIDENT & MANAGING PHYSICIAN:

The authorization for the first COVID-19 vaccinations delivered a beacon of hope and will have far-reaching benefits across the globe. Combined with our continued use of masks, regular handwashing, physical distancing and avoiding large gatherings, vaccines are our best protection and a vital step towards controlling and stopping the spread of SARS-CoV-2.

With the swift development of these new vaccines came questions and concerns, understandably, about their safety and effectiveness, especially for cancer patients. FCS has moved quickly to provide education and information through all channels. I invite you to take advantage of the expert information provided in this publication.

As we reported in our last issue, COVID-19 prompted an alarming decline in cancer screenings and a subsequent increase in late-stage diagnoses and mortalities. We continue to use every opportunity to share cancer awareness facts and the importance of not delaying routine and recommended screenings. FCS Assistant Managing Physician Dr. Michael Diaz provides an update that includes detail about our collaborative efforts with the Community Oncology Alliance (COA) to launch an extensive public service advertising campaign to share this vital message.

I extend my thanks to all of my physician colleagues and the entire FCS team for their ongoing and diligent efforts to protect the health and safety of one another and those we serve.

A Patient Matter

Lung Cancer Treatment Advances with Genomic Testing, but Early Diagnosis is Still Crucial

BY KAREN MURPHY

In 2016, Stephanie Peace visited her dermatologist to have some skin lesions examined.

She never dreamed that simple visit would change her life forever, or teach her the meaning of true strength and the importance of being an advocate — not just for others, but for herself as well.

That skin lesion was just the tip of the iceberg. Under the surface, her body was being attacked by cancer, and she was eventually diagnosed with Stage IV lung cancer.

A beloved schoolteacher and mother of three, Stephanie was shattered but determined to find a way around this disease that threatened to wreck her life and take her away from everything and everyone she loved.

She never smoked. No one in her family had lung cancer. How could this happen to her? Sure, she had some shortness of breath, but she had attributed it to being a little overweight.

A battery of tests revealed spots on her bones and liver, fluid in her lungs and six brain tumors.

She was referred to FCS Fort Myers Cancer Center and medical oncologist Dr. Syed F. Zafar.

"Initially, it was a little bit confounding as to what might be going on. We kept pursuing answers, and we started unraveling the mystery further and further until we got them," said Dr. Zafar. "Once we found the source of Stephanie's problem, we dissected it genetically, and that helped us unravel this mystery and led us to a more effective care plan."

Zafar explained that FCS did somatic mutation testing on Stephanie's cancer, a type of genomic testing of the individual cancer subtypes or alterations that might have developed and caused the cancer.

They found she has very rare rearrangement in her genetics, which led to her being diagnosed with Anaplastic Lymphoma Kinase (ALK) positive lung cancer, a form of non-small cell lung cancer caused by a mutation of the ALK gene. This genetic mutation causes less than 4% of lung cancer diagnoses.

After nearly five years since that initial screening for skin cancer, Stephanie's journey still goes on with treatment successes.

Over those same five years, vast improvements have been made in the area of genomic testing. The field has transformed

enormously. Since the early 2000s, researchers have discovered more and more genomic alterations, called driver mutations, in lung cancer.

Dr. Zafar describes these as alterations in the genetic footprint of the cancer that causes the turning on of the switch in the circuitry of the cancer that leads to cancer cell growth and propagation. According to Dr. Zafar, the cancer becomes "addicted" to that gene for its growth, and that leads to its survival.

These genomic alterations are called oncogenes. With time, researchers have identified a number of oncogenes and developed targeted treatment that is very individualized. The goal is to turn off that circuitry so that that cancer cell will essentially die off.

The earlier a patient can be tested, the higher the likelihood of success.

All lung cancer patients should be tested, according to Dr. Zafar, regardless of their history and also in early stage. Usually it is the oncologist who would request the specific genomic testing to lead the patient toward the appropriate treatment strategy.

"I think it's very important for oncological providers and lung cancer patients to understand the genetic makeup of their cancer so it can guide them towards appropriate and more effective treatment strategy," he said. "Every treatment is individualized and personalized; different lung cancer patients may end up receiving completely different treatments. It's not a one-size-fits-all technique, and the more we learn about the genetic landscape of an individual's lung cancer, the better treatment can be designed."

Stephanie wants people to know that just because you have never smoked, it does not mean you can't get lung cancer.

"Anyone with lungs can get lung cancer," Stephanie said. "You can get it in your lungs just like you can get it in your breast, just like you can get it in your brain or in your colon. It's going to attack where your body is the weakest.

She added: "Once it is determined you have lung cancer, it is so important to get genetic testing done and a genetic sequencing, because there are so many different kinds of lung cancer markers."

Stephanie also said it is vitally important to have a good team around you, but you have to be your own biggest advocate.

"Dr. Zafar really worked hard at finding answers. He never had a problem with me getting a second opinion. But I still advocate for myself, "Stephanie says. "You have to fight with all you have."

"I think it's very important for oncological providers and lung cancer patients to understand the genetic makeup of their cancer so it can guide them towards appropriate and more effective treatment strategy."

ADVOCACY & WHITE RIBBONS

Founded by Colorado residents Heidi and Pierre Onda, the goal of the White Ribbon Project is to raise awareness that anyone with lungs can get lung cancer and to educate communities about the resources available to patients and physicians. To aid their efforts, Pierre created a 2-foot-tall wooden ribbon, painted white for lung cancer awareness.

FCS patient Stephanie Peace is part of a group of advocates, cancer patients and survivors and community members who are creating replicas of these wooden ribbons to distribute throughout Florida.

FCS remains open and dedicated to safely caring for patients during the pandemic.

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.

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FLCancer.com

Fighting the Spread

FCS encourages patients, employees to get COVID-19 vaccine

BY KARI C. BARLOW

As the United States and the rest of the world continue to weather the coronavirus pandemic, much of the focus is now on vaccinations.

Distribution of the COVID-19 vaccines is being directed by individual states. In Florida, officials initially rolled out a vaccination program that prioritized three groups — healthcare workers, long-term care residents and people 65 and older.

In the midst of this massive public health effort, FCS is doing its part to encourage its patients and employees to participate while also addressing questions and concerns.

Dr. Lucio Gordan, FCS President & Managing Physician, received the Moderna vaccine in Gainesville and filmed a brief video to share his experience. He said he is confident that COVID-19 vaccines are safe.

"The COVID-19 disease is much more lethal than any concerns related to the toxicities of the vaccine itself," he added. "The chance of having a severe allergic reaction is very, very small. It's 11 cases per million, or one in 100,000."

Deemed safe for cancer patients.

Medical experts at the CDC and the National Comprehensive Cancer Network (NCCN) recommend that cancer patients be prioritized for vaccination.

According to Kristen Boykin, PharmD, BCOP, BCPS, Director of Pharmacy Operations for FCS, based on experience with other similar types of vaccines, no major or unique side effects have been reported in immunocompromised patients.

"Generally speaking, it's not so much a question if vaccination will be safe for this patient population, but how effective it will be," she said. "Since the success of a vaccine relies on the immune system's ability to mount a defense against the offending pathogen, these vaccines were only studied in immunocompetent patients."

FCS urges patients to discuss COVID-19 vaccination with their physicians to make the most informed decision. "Each case is unique," Boykin said.

Advancements allowed for huge strides in less time.

Although the development of the Pfizer-BioNTech and Moderna vaccines happened quickly, Boykin does not believe the development or approval process was rushed. "Scientists have been studying the coronavirus family of viruses for over 50 years," she noted, "so we had a baseline level of knowledge regarding the structure, life cycle and, most importantly, potential vaccine targets."

In addition, the universal urgency of the pandemic opened the doors for worldwide collaboration never seen before, as evidenced by the fact they were able to sequence SARS-CoV-2 shortly after the first cases of infection were reported. "The FDA has rigorous guidelines for clinical trials, and none of these

Lucio Gordan, MD
President &
Managing Physician

Kristen Boykin, PharmD, BCOP, BCPS
Director of
Pharmacy Operations

steps were skipped," Boykin said, adding that the companies developing the vaccines were able to run trials in concurrent phases to save time.

The Pfizer-BioNTech and Moderna vaccines are both 90-to-95 percent effective; the Johnson & Johnson single dose vaccine is 66 percent effective. "The preliminary results we are seeing are amazing," Boykin said. "In clinical trials, both vaccines had very high efficacy rates, which is seen equally across all racial and ethnic groups. As worldwide vaccination efforts proceeds, we're seeing these results upheld in the general population."

A critical step forward.

Boykin said the immunity that the vaccines produce is critical to controlling and eventually stopping the spread of the coronavirus.

"We know in order for the pandemic to stop, for herd immunity to happen, at least 70 to 80 percent of the entire population must be vaccinated," she said. "We have to do our share."

Dr. Gordan agreed, adding that widespread acceptance of the vaccines will have far-reaching public health, social and economic benefits across the nation.

"If only a few people get the vaccine, COVID-19 will be here for years, and the disruption in the way of life and wearing masks and the hit to the economy and unemployment will persist much longer than it should," Dr. Gordan said. "It's the right thing to do."

FCS has collaborated with county health departments statewide to secure supplies of the COVID-19 vaccines for patients and employees.

Florida has launched a centralized system that allows state residents to pre-register for COVID-19 vaccination appointments. Go to MyVaccine.fl.gov.

COVID DELAYS INTRODUCE NEW DANGER

While many people were understandably reluctant to visit their clinicians during the early stages of the pandemic, these actions have led to unfortunate consequences for many.

Skipping a mammogram, prostate exam or colonoscopy didn't reduce the instance of disease, but it often meant that a patient's disease was more advanced when finally discovered.

Dr. Michael Diaz, FCS Assistant Managing Physician, said this troubling trend could have implications for years to come. "If cancers are not diagnosed at an early stage," he said, "we could face years of rising death rates."

That said, being late for a scan is also no reason to delay it further. After all, scans only show what is or isn't present, and the sooner patients and their healthcare team know what they're dealing with, the sooner they can embark on an effective treatment plan.

"It is critical," Dr. Diaz said, "that adults with a family history of cancer and others who may be experiencing symptoms do not delay their screenings for the fear of being exposed to or contracting coronavirus.

"Medical practices now have numerous strategies in place to protect the safety and health of patients, doctors, nurses and other staff members."

All of which means that the risk of further waiting for an overdue screening far outweighs any risks related to COVID-19.

Michael Diaz, MD
Assistant Managing
Physician

PALLIATIVE CARE

Support Structure

Palliative care program offers comfort and care during the toughest of times

BY TIM LINAFELT

Watching an episode of *A Place to Call Home*, a six-season series set against the backdrop of life down under in the 1950s, Vicki Caraway, RN, BSN, MBA, NE-BC, FCS Vice President of Nursing & Research, couldn't help but connect with one of the show's storylines.

In it, a lead character is living with cancer and, reflective of the times, doesn't find much in the way of support or information.

"That," Caraway said, "is how it used to be."

But not today at FCS, thanks to its new palliative and supportive care program.

Launched last September, the program is focused on providing comfort, easing stress and improving quality of life for patients with serious illness.

"I'm super excited about it," said Caraway, an oncology nurse of more than 30 years who joined FCS in 2019. "When helping patients through their journey, which sometimes does include death and dying, palliative and supportive care is absolutely necessary."

Yes, the term "palliative care" is often associated with hospice and end-of-life support.

But Caraway is quick to remind that the field offers so much more than that.

Palliative and supportive care patients at FCS can expect a focus on goals for care, pain and symptom management, support for psychological, social or spiritual issues, and advanced care planning.

Perhaps more than anything, though, the program provides patients and their families with professional advocates devoted to helping them navigate a difficult period.

What started as a half-day clinic at FCS Port Charlotte has already expanded to a full day and an additional half-day at FCS Gladiolus in Fort Myers.

"The program gives patients an added layer of support and tools to make the decisions that are best for them," Caraway said.

Expansion plans are in development for palliative care services to be offered in Orlando, Tampa, St. Petersburg, Brandon, West Palm Beach, Naples, Ocala, The Villages and Gainesville, among others.

She adds, "These kinds of things really are what makes the difference in our organization between really good care and exceptional care that supports patients throughout the whole journey."

Vicki Caraway, RN, BSN, MBA, NE-BC
Vice President of Nursing & Research

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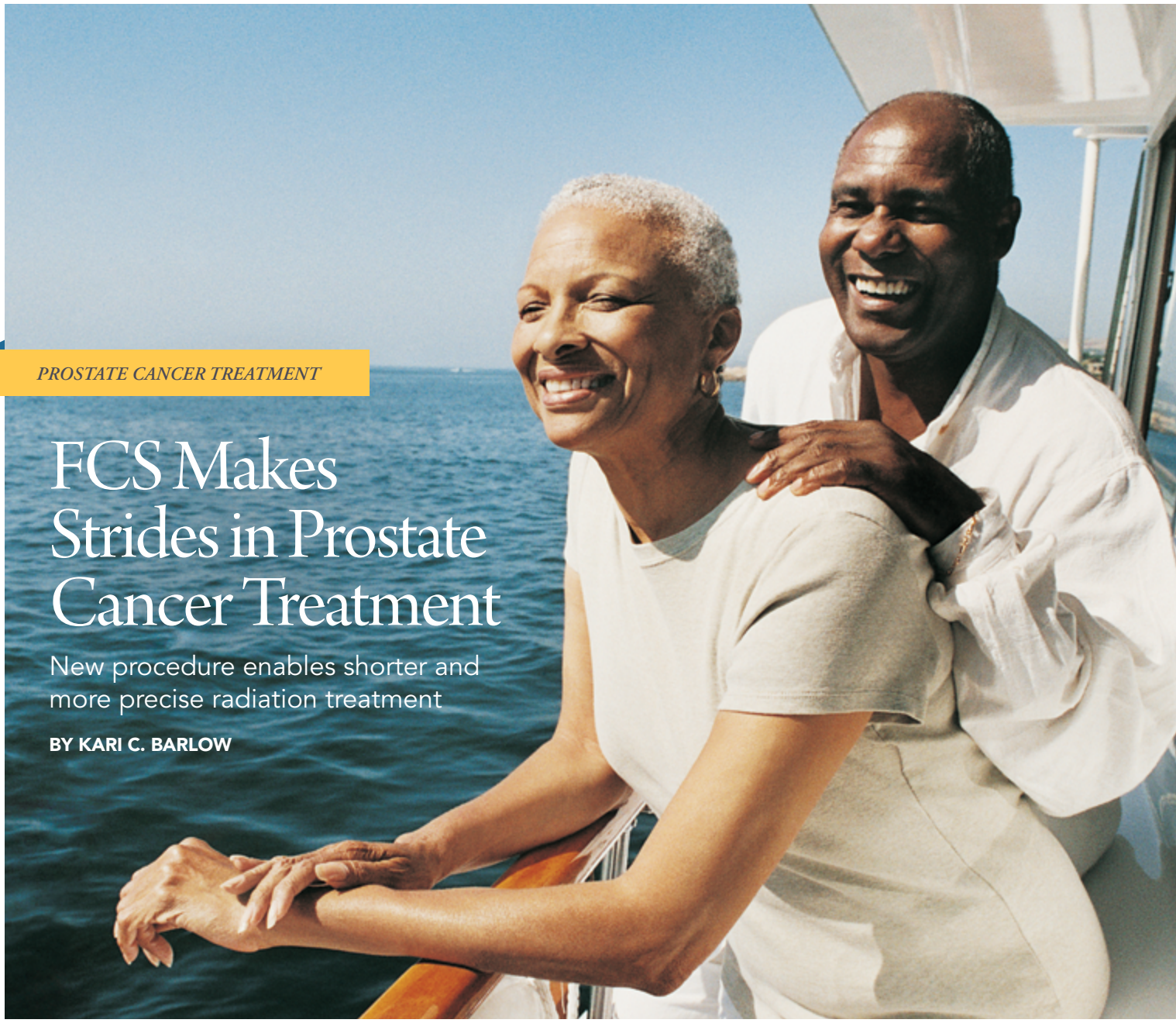


PROSTATE CANCER TREATMENT

FCS Makes Strides in Prostate Cancer Treatment

New procedure enables shorter and more precise radiation treatment

BY KARI C. BARLOW

An innovative procedure that improves outcomes in prostate cancer patients undergoing radiation therapy is now offered exclusively in many areas by Florida Cancer Specialists (FCS) and Florida Healthcare Specialists.

"Prostate cancer can be treated in different ways," said FCS Radiation Oncologist Dr. Luis Carrascosa, "but when we utilize radiation, we are now able to do shorter treatments by placement of a hydrogel."

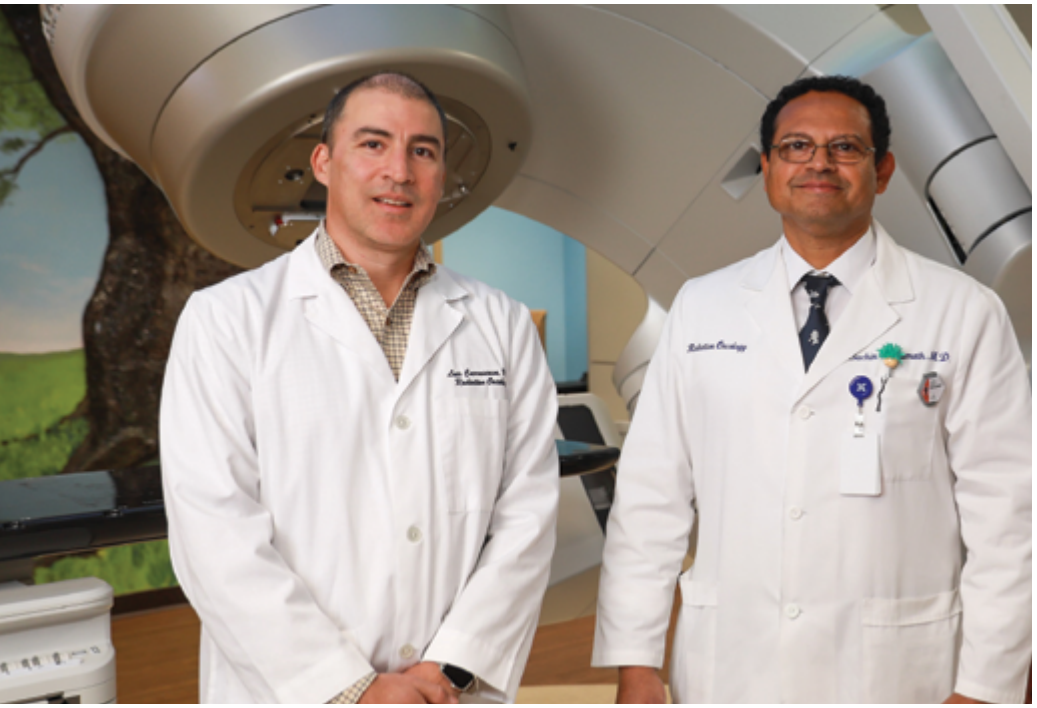
SpaceOAR™ Hydrogel is a groundbreaking product that is the first and only FDA-cleared spacer designed to minimize the amount of radiation delivered to the rectum.

While the goal of radiation therapy is to kill cancer cells, the treatment can unintentionally cause damage to surrounding healthy tissue. Because the prostate sits in such close proximity to the rectum, radiation therapy has been known to damage the rectum, which can result in issues with bowel function.

"Radiation therapy is extremely effective in targeting and treating prostate cancer," Dr. Carrascosa said. "As with any procedure, there are potential side effects.

In a simple, same-day procedure conducted prior to the start of radiation treatment, the soft, absorbable hydrogel is implanted one half inch away from the prostate to provide adequate separation.

"This is a material that we place in between the rectum and the prostate, which creates an artificial space for a brief period of time, usually about three months, which allows me to treat the prostate with very precise, high doses of radiation, but minimize the amount of radiation that reaches the rectum," Dr. Carrascosa explained. The gel is naturally absorbed into the body after roughly six months.



Luis Carrascosa, MD (left) and Sachin Kamath, MD (right)

In many ways, the advanced technique has revolutionized the way FCS radiation oncologists are able to manage prostate cancer.

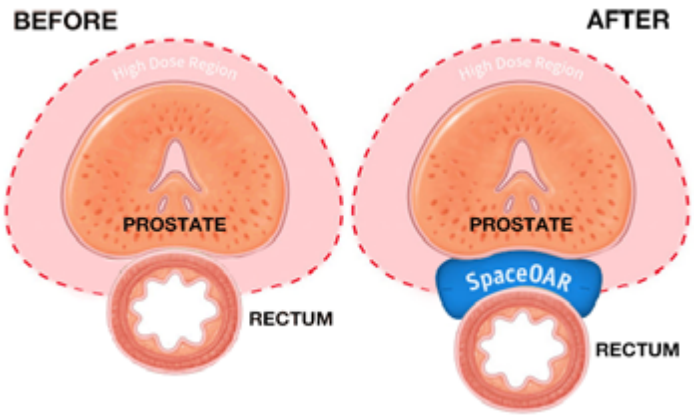
"Patients no longer need to be treated for eight to nine weeks," Dr. Carrascosa said. "Now the guidelines tell us we can treat them with four to five weeks of treatment, and one way that we can achieve that is utilizing this hydrogel spacer."

"We can better target tumors, reduce side effects, shorten treatment schedules and improve outcomes for our patients," said Dr. Sachin Kamath, FCS Medical Director of Radiation Oncology.

The procedure is a valuable and much-needed tool, as prostate cancer is the most common cancer in men in the United States, with more than 248,500 new cases projected to be diagnosed this year.

Dr. Carrascosa said prostate cancer patients can feel confident in this new treatment option and what it has to offer. "It is an outpatient procedure. It's very brief, and we have been utilizing it successfully without any issues to our patients."

The hydrogel procedure is currently available to patients at the FCS Ocala Cancer Center, Villages and Brownwood locations, and from FCS urologist Dr. Hugo Davila at Florida Healthcare Specialists.

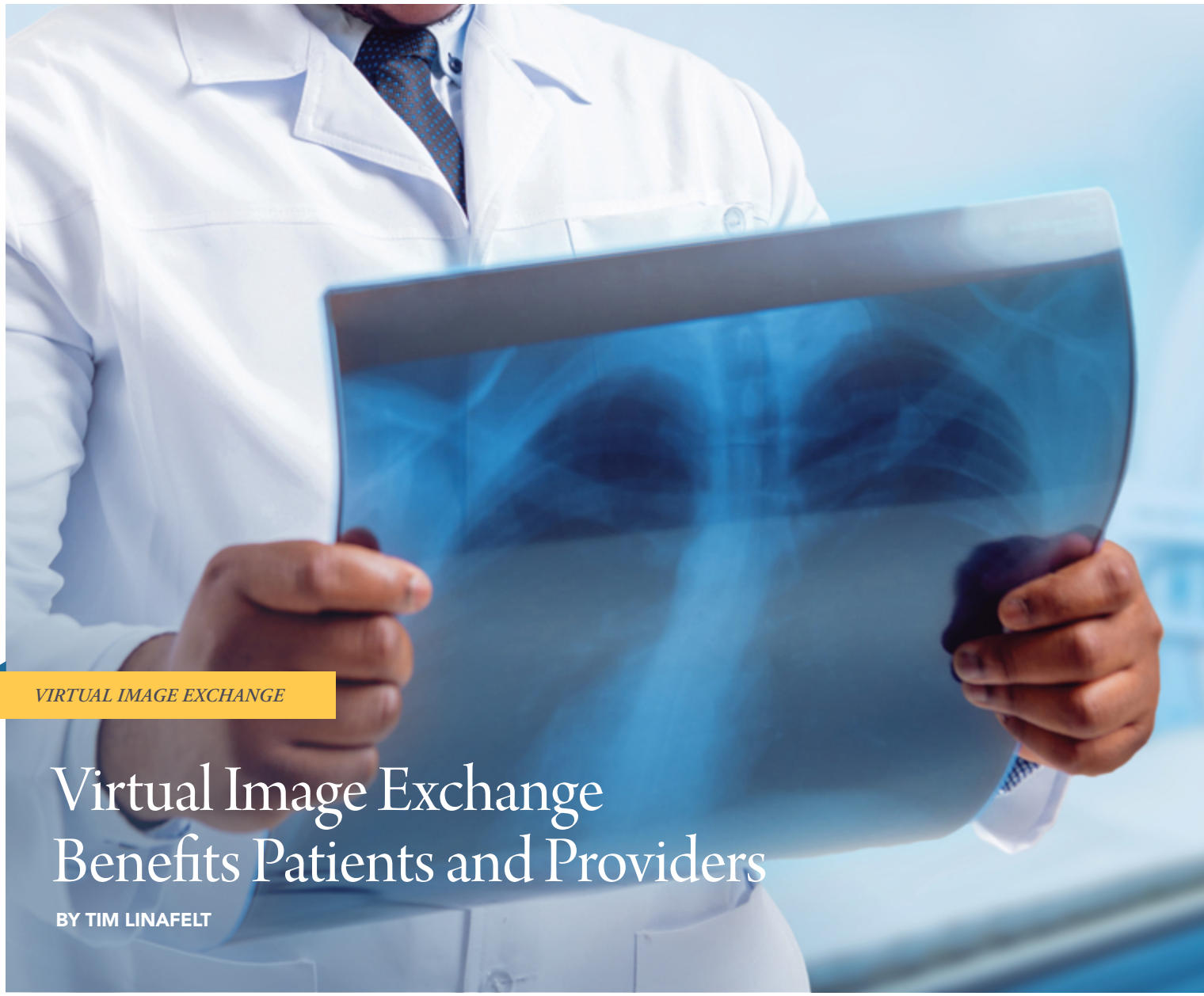


The SpaceOAR™ Hydrogel procedure is also available from FCS urologist Hugo Davila, MD of Florida Healthcare Specialists, a clinical division of Florida Cancer Specialists, in Sebastian and Vero Beach.

"We have been providing this procedure in our community with excellent outcomes. It is well known, based on clinical trials, that its use reduces the volume of the rectum receiving radiation by 73 percent. As a result, patients had less rectal pain and a 71 percent reduction in long-term rectal complications.

"One year following radiation treatment, clinical trial patients who received SpaceOAR™ were 46 percent less likely to experience long-term bowel quality of life issues than patients who did not receive the system. It is certainly helping men maintain their normal activities and lifestyle."

Hugo Davila, MD
Urologist, Florida Healthcare Specialists



VIRTUAL IMAGE EXCHANGE

Virtual Image Exchange Benefits Patients and Providers

BY TIM LINAFELT

Helping patients find ease and efficiency on their treatment journey is more crucial than ever.

Florida Cancer Specialists (FCS) recently took a big step toward that goal with the unveiling of the FCS Virtual Image Exchange (VIE), a new cloud-based imaging and information portal.

Through a partnership with Thinking Systems Corporation, the industry leader in picture archiving communications systems, FCS has developed and implemented a cutting-edge system that allows for the instant sharing of radiology images, reports and treatment plans among each member of a patient's care team — no matter where they are located.

The data hub is secure, cost-efficient and, most importantly, fast.

What used to take hours, days or weeks — manually saving images to a compact disc then shipping them through the mail or a parcel service — can now be done in seconds.

A scan performed in Tampa can be viewed by a clinician in Jacksonville moments after it is performed.

This provides a tremendous benefit to patients and providers, in ways both obvious and not-so-obvious.

"A cancer patient's care team often involves multiple physicians, clinicians and imaging professionals who may be working with different electronic records systems," said FCS President & Managing Physician Dr. Lucio Gordan. "When all providers are able to view and exchange patient information in real time, it aids timely clinical decision making and enhances the patient experience."

The new system, accessible through a secure URL, also aids physicians and imaging professionals when they're comparing current scans with previous results.

Whereas a patient's scan from months or years ago might have been performed at another location and stored on a different physical or digital platform, all patient

Lucio Gordan, MD
President & Managing Physician

Jeff Esham, MBA, RT(R)(T)
Vice President of Radiation & Radiology

Sandra Connor, MHA, RT(N)
Director of Radiology Services

records will be current and maintained in a single portal.

"Using the FCS VIE system," says Jeff Esham, MBA, RT(R)(T), FCS Vice President of Radiation and Radiology, "clinicians at any location now have easy access to complete and up-to-date patient records."

"The FCS Radiology department is keeping pace with technology advances through the development of this state-of-the-art portal," said Sandra Connor, MHA, RT(N), FCS Director of Radiology Services. "We are delighted that it is becoming standard practice, with so many benefits for our patients and physicians."

VIRTUAL IMAGE EXCHANGE

Secure way to share images

Eliminates burning CDs

Saves money

Better patient experience

NEW LOCATION OPENS IN DELRAY BEACH

A ribbon-cutting ceremony in December marked the opening of a new state-of-the-art facility in Delray Beach, the fifth FCS facility in Palm Beach County. The new 5,000-square-foot clinic provides advanced treatments and includes some on-site lab testing, as well as in-house oral oncolytic pharmacy and care management services for patients participating in value-based care initiatives.

RIBBON-CUTTING FOR LAKE NONA CANCER CENTER

Representatives from FCS, HCA Healthcare, University of Central Florida (UCF) Lake Nona Medical Center and Sarah Cannon Research Institute gathered to celebrate the opening of the FCS Lake Nona Cancer Center. Located on the UCF Cancer Center Campus at 6400 Sanger Road, Suite A-2400, Orlando, the nearly 10,000-square-foot office provides a broad range of treatments and services for cancer patients in Orange County. Soon, Lake Nona patients will gain expanded opportunities to participate in both early and late phase clinical research with the opening of our third Drug Development Unit.

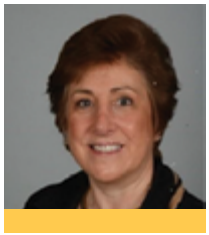
CONSTRUCTION OF NEW BRADENTON CANCER CENTER UNDERWAY

Manatee County is one of the fastest growing areas in Florida, and FCS is keeping pace. A ceremony was held in January to celebrate the start of construction for a new FCS clinic in Bradenton. The one-story building, located at 3630 Manatee Ave. W., will provide expanded treatment space for patients, with 18 exam rooms, 50 infusion chairs and on-site imaging capabilities. Scheduled to open in November 2021, the 20,250-square-foot building will replace the two existing FCS Bradenton locations.

LEADERSHIP APPOINTMENTS & PROMOTIONS

Rich MacClary, Chief Financial Officer

The newest member of the FCS Executive Team, Rich oversees the company's finance and accounting operations, financial planning analysis and investments, reporting and fiscal compliance policy and practices. During his professional career, he has held 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.



Mary Schnitzer, Senior Vice President of Managed Care & Revenue Cycle Management

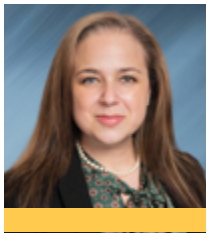
Mary is responsible for managed care strategy, value-based and fee-for-service contracting, as well as front- and back-office revenue cycle operations. She renegotiates and secures new contracts with regional and national payers and serves as a core connector between contracting and downstream revenue cycle operations. Mary brings more than 30 years of experience in healthcare to her new position at FCS and has a demonstrated track record of developing payer relationships.

Trevor Heritage, Ph.D., Vice President of Informatics

Trevor ensures that FCS and our patients derive the maximum benefit from data and technology. He oversees technology projects across all care settings to enhance digital precision medicine, clinical decision support, value-based care and quality improvement, as well as data improvement initiatives for research and clinical trials. During his over 30 years of experience, Trevor has held progressively more responsible leadership roles in healthcare, life sciences, software and informatics.

Michelle Robey, Vice President of Marketing

In this newly created senior leadership role, Michelle directs all marketing and communications strategies and activities to strengthen the FCS brand and support the company's long-term growth initiatives. She oversees branding, advertising and corporate sponsorships, media and employee relations, relationship marketing initiatives and creative services.



Susan Seltzer-Green, Vice President of Applications

Susan is responsible for ensuring FCS' enterprise-wide applications, vision, strategy and roadmap are in alignment with our organizational strategies and priorities. She leads the company's healthcare information technology specialists and directs the assessment, planning, implementation, integration and support of all software application platforms.

WE WELCOME THE FOLLOWING PHYSICIANS

Ashok Bapat, MD
Medical Oncologist/ Hematologist in Estero

Vitor Pastorini, MD
Medical Oncologist in Ocala and the Ocala Cancer Center

Neha Sharma, MD
Radiation Oncologist in New Port Richey

Jessica Stine, MD
Gynecologic Oncologist in New Port Richey and Wesley Chapel

Mahdi Taha, DO, FACOI, FACP
Hematologist/Medical Oncologist in Delray Beach

FCS Foundation News & Events

Service & Support. Healing & Hope. That's the celebratory theme we've selected to commemorate the 10th anniversary of the FCS Foundation and the meaningful ways in which the FCS Foundation has impacted the lives of so many adult cancer patients and their families.

Since the Foundation's inception in 2011, over $7.7 million in financial grants have been provided to assist cancer patients throughout Florida while they are undergoing treatment. Thanks to the generosity of FCS physicians, along with other donors and community partners, we are able to provide peace of mind in place of worries about making rent, mortgage, utility or insurance payments. No qualified applicant has ever been turned away.

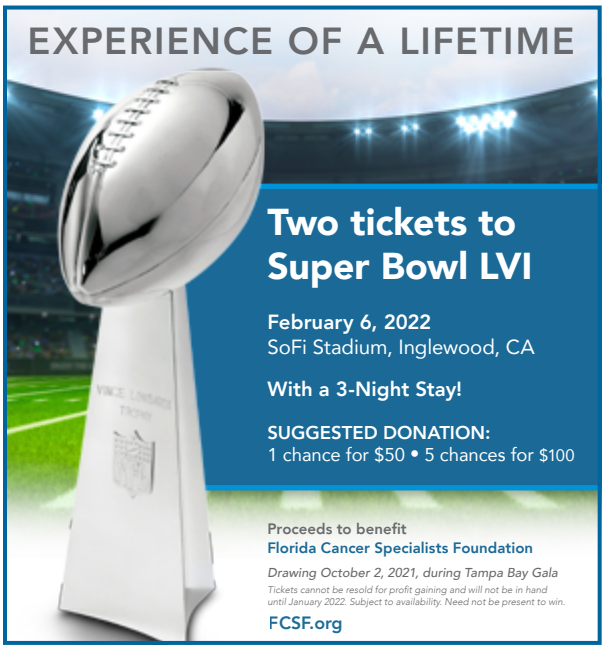
Our gratitude extends to the virtual volunteers who give of their time to process the ever-increasing numbers of grant requests or to lend their creative talents to our fundraising events.

While the pandemic severely impacted our fundraising opportunities in the past year, we're launching many new and exciting initiatives and activities to ensure our ability to continue delivering on our vital mission.

We look forward to your participation, and we extend our sincere thanks for your continued support and generosity.

10 YEARS of hope | FLORIDA CANCER SPECIALISTS Foundation

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.



For tickets & more information visit **FCSF.org/WWS2021** or **WineWomenandShoes.com/Naples**

From Our Patients

★★★★★

HEALTHGRADES REVIEW: 5 STARS

Dr. Dan was an amazing doctor to my father. He was caring and compassionate, and he made sure we knew he was there for us to help in any way. He was knowledgeable and made us feel he was fighting for us the whole time. My dad enjoyed his conversations and visits with him very much, and that's what meant the most to me.

Uday Dandamudi, MD

★★★★★

GOOGLE REVIEW: 5 STARS

Dr. Bustamante is an answer to my prayers! My husband and I had been traveling every two weeks to get my treatments elsewhere. We were told about Dr. Bustamante and were so impressed when we had our initial meeting. She has been providing my care and treatment plans for over a year now. She is knowledgeable, kind, caring and encouraging! I could not ask for a better oncologist and highly recommend her to others.

Liliana Bustamante, MD

Dear Michael,

Patricia and I hope you are keeping well. Thank you for your thoughtful email in June. It was greatly appreciated. Patricia continues to be well. The most recent scan showed stable disease. The next scan is in January, and fingers are firmly crossed. Palliative radiation to the bone lesions has had good results. Patricia and I continue to be eternally grateful to you and your team.

Best wishes,
Patient of Dr. Scott

Michael Scott, MD

★★★★★

HEALTHGRADES REVIEW: 5 STARS

Dr. Suleiman is a wonderful and caring oncologist. He has been a trusted doctor of ours for over three years, and he has been the best in every way.

Yaman Suleiman, MD

★★★★★

HEALTHGRADES REVIEW: 5 STARS

Dr. Esper is great. He will explain everything that is going on and will explain the treatment that is needed. He will make sure he answers any questions and concerns. He is also a very personable doctor. Highly recommend him!

Raymond Esper, MD

Have something to add?

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