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FCS THE MAGAZINE

Leader in Transition

Dr. Lucio Gordan assumes new, 'data-driven' role

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For adults with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea (HU)

EVERY DAY COUNTS. JAKAFI CAN HELP.

PV is a hematologic malignancy that can become advanced in a subset of patients[1-6]

In a subset of patients, these characteristics may indicate advanced PV despite treatment with HU at the maximum tolerated dose and phlebotomy.[1,7-10]

Hct ≥45%	+	WBC count >11 × 10^9/L	or	Disease-related SYMPTOMS

In the phase 3 RESPONSE* trial, Jakafi demonstrated superior results† vs BAT‡

Composite Primary Endpoint

23% (25/110) of patients receiving Jakafi achieved Hct control and ≥35% spleen volume reduction at week 32 vs <1% (1/112) of patients receiving BAT ($P < 0.0001$)[11§]

BAT, best available therapy; Hct, hematocrit; MPN-SAF, Myeloproliferative Neoplasm Symptom Assessment Form; TSS, Total Symptom Score; WBC, white blood cell.

*The RESPONSE (Randomized study of Efficacy and Safety in POlycythemia vera with JAK iNhibitor ruxolitinib verSus bEst available care) trial was a randomized, open-label, active-controlled phase 3 trial comparing Jakafi with BAT in 222 patients with PV. Patients enrolled in the study had been diagnosed with PV for at least 24 weeks, had an inadequate response to or were intolerant of HU, required phlebotomy for Hct control, and exhibited splenomegaly. All patients were required to demonstrate Hct control between 40% and 45% prior to randomization. After week 32, patients were able to cross over to Jakafi treatment.[11,12]

†The composite primary endpoint was defined as Hct control without phlebotomy eligibility and a ≥35% spleen volume reduction as measured by CT or MRI. To achieve the Hct control endpoint, patients could not become eligible for phlebotomy between weeks 8 and 32. Phlebotomy eligibility was defined as Hct >45% that is ≥3 percentage points higher than baseline or Hct >48% (lower value).[11,12]

‡BAT included HU (60%), interferon/pegylated interferon (12%), anagrelide (7%), pipobroman (2%), lenalidomide/thalidomide (5%), and observation (15%).[11]

§Jakafi 95% CI, 0.15-0.32; BAT 95% CI, 0.00-0.05.[11]

Indications and Usage

Jakafi is indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea.

Important Safety Information

- Treatment with Jakafi® (ruxolitinib) can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated
- Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi
- Severe neutropenia (ANC <0.5 × 10^9/L) was generally reversible by withholding Jakafi until recovery
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and manage promptly. Prior to initiating Jakafi, evaluate patients for TB risk factors and test those at higher risk for latent infection. Consult a physician with expertise in the treatment of TB before starting Jakafi in patients with evidence of active or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination
- Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment
- Increases in hepatitis B viral load with or without associated elevations in alanine aminotransferase and aspartate aminotransferase have been reported in patients with chronic hepatitis B virus (HBV) infections. Monitor and treat patients with chronic HBV infection according to clinical guidelines
- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return within one week. After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi without consulting their physician. When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or neutropenia, consider gradual tapering rather than abrupt discontinuation
- Non-melanoma skin cancers (NMSC) including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations
- Treatment with Jakafi has been associated with increases in total cholesterol, low-density lipoprotein cholesterol, and triglycerides. Assess lipid parameters 8-12 weeks after initiating Jakafi. Monitor and treat according to clinical guidelines for the management of hyperlipidemia
- Another JAK-inhibitor has increased the risk of major adverse cardiovascular events (MACE), including cardiovascular death, myocardial infarction, and stroke (compared to those treated with tumor TNF

INTERVENE WITH JAKAFI IN YOUR PATIENTS WITH ADVANCED PV

Individual Component of the Primary Endpoint

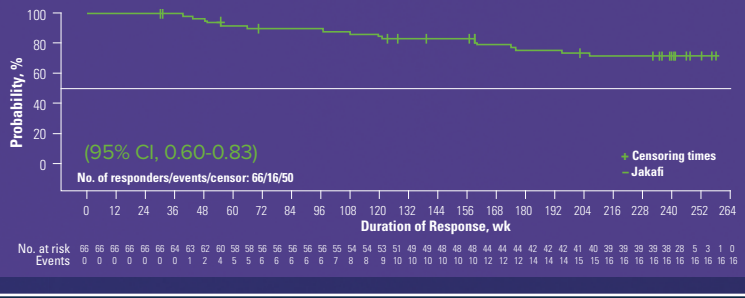
60% (66/110) of patients receiving Jakafi achieved Hct control at week 32 vs 19% (21/112) of patients receiving BAT[11]

To achieve the Hct control endpoint, patients could not become eligible for phlebotomy between weeks 8 and 32. Phlebotomy eligibility was defined as Hct >45% that is ≥3 percentage points higher than baseline or Hct >48% (lower value)[11,12]

73% **Probability of Maintaining Hct Control[a] at 5 Years in RESPONSE Trial[13,14]**

[a]Absence of phlebotomy eligibility

Kaplan-Meier Estimate: Durability of Hct Control at 5 Years



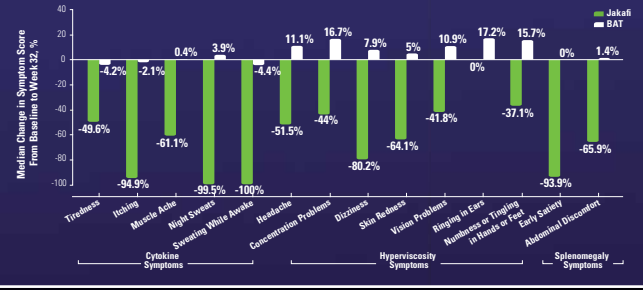
- Analysis was conducted in week 32 Hct control responders, beginning at week 32[13]
- Progression events for the evaluation of duration of absence of phlebotomy eligibility included first of 2 consecutive Hct assessments that confirms phlebotomy eligibility, death, or development of MF or acute leukemia[15]

Reprinted from *The Lancet Haematology*, 7(3), Kiladjian J-J, Zachee P, Hino M, Long-term efficacy and safety of ruxolitinib versus best available therapy in polycythaemia vera (RESPONSE): 5-year follow up of a phase 3 study, e226-e237, Copyright 2020, with permission from Elsevier.

Exploratory Endpoint

- RESPONSE was an open-label trial and, therefore, not designed to evaluate differences in symptoms[11]
- Patient-reported outcomes were assessed using the MPN-SAF symptom diary. The MPN-SAF diary was administered daily in an electronic diary format to score 14 disease-related symptoms on a scale of 0 (absent) to 10 (worst possible). At baseline, median TSS was 23.4 (range, 0-106) in the group receiving Jakafi and 33.3 (range, 0-118) in the group receiving BAT.[12,15]

Median Percent Change in Symptom Score From Baseline to Week 32[12a]



- At week 32, 49% (36/74) of patients receiving Jakafi and 5% (4/81) of patients receiving BAT had at least a 50% reduction in the 14-item MPN-SAF TSS[12]
- Patients receiving Jakafi had reductions in all symptom clusters reported, whereas patients receiving BAT had an increase in scores of many symptoms[12]

From *The New England Journal of Medicine*, Vannucchi AM, Kiladjian JJ, Griesshammer M, et al, Ruxolitinib versus Standard Therapy for the Treatment of Polycythemia Vera, 372(5), 426-435. Copyright © 2015 Massachusetts Medical Society. Reprinted with permission from Massachusetts Medical Society.

[a]Patients with data at both baseline (value >0) and week 32 were included in this analysis. Negative values indicate a reduction in the severity of symptoms.[12]

Intervene with Jakafi in your appropriate patients with advanced PV
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Jakafi® ruxolitinib (tablets)
5mg • 10mg • 15mg • 20mg • 25mg

blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur

- Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis (DVT), pulmonary embolism (PE), and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. In patients with myelofibrosis (MF) and polycythemia vera (PV) treated with Jakafi in clinical trials, the rates of thromboembolic events were similar in Jakafi and control treated patients. Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately
- Another JAK-inhibitor has increased the risk of lymphoma and other malignancies excluding NMSC (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Patients who are current or past smokers are at additional increased risk. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi, particularly in patients with a known secondary malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers
- In myelofibrosis and polycythemia vera, the most common nonhematologic adverse reactions (incidence ≥15%) were bruising, dizziness, headache, and diarrhea. In acute graft-versus-host disease, the most common nonhematologic adverse reactions (incidence >50%) were infections (pathogen not specified) and edema. In chronic graft-versus-host disease, the most common nonhematologic adverse reactions (incidence ≥20%) were infections (pathogen not specified) and viral infections
- Avoid concomitant use with fluconazole doses greater than 200 mg. Dose modifications may be required when administering Jakafi with fluconazole doses of 200 mg or less, or with strong CYP3A4 inhibitors, or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy
- Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breastfeed during treatment and for 2 weeks after the final dose

Please see Brief Summary of Full Prescribing Information for Jakafi on the following pages. To learn more about Jakafi, visit **HCP.Jakafi.com**

References: 1. Barosi G, et al. Br *J Haematol*. 2010;148(6):961-963. **2.** Parasuraman S, et al. *Exp Hematol Oncol*. 2016;5:3. **3.** Mascarenhas J. *Clin Lymphoma Myeloma Leuk*. 2016;16 Suppl:S124-S129. **4.** Rumi E, et al. *Blood*. 2017;129(6):680-692. **5.** Michiels JJ, et al. *World J Hematol*. 2013;2(3):71-88. **6.** Michiels JJ. *World J Crit Care Med*. 2015;4(3):230-239. **7.** Marchioli R, et al. *N Engl J Med*. 2013;368(1):22-33. **8.** Barbui T, et al. *Blood*. 2015;126(4):560-561. **9.** Emanuel RM, et al. *J Clin Oncol*. 2012;30(33):4098-4103. **10.** Verstovsek S, et al. *Cancer*. 2014;120(4):513-520. **11.** Jakafi Prescribing Information. Wilmington, DE: Incyte Corporation. **12.** Vannucchi AM, et al. *N Engl J Med*. 2015;372(5):426-435. **13.** Kiladjian J-J, et al. *Lancet Haematol*. 2020;7(3):e226-e237. **14.** Kiladjian J-J, et al. *Lancet Haematol*. 2020;7(Suppl):1-18. **15.** Data on file. Incyte Corporation. Wilmington, DE.

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Incyte

Jakafi®
ruxolitinib (tablets)
5mg • 10mg • 15mg • 20mg • 25mg

BRIEF SUMMARY: For Full Prescribing Information, see package insert.

INDICATIONS AND USAGE Myelofibrosis Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults. **Polycythemia Vera** Jakafi is indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. **Acute Graft-Versus-Host Disease** Jakafi is indicated for treatment of steroid-refractory acute graft-versus-host disease (aGVHD) in adult and pediatric patients 12 years and older. **Chronic Graft-Versus-Host Disease** Jakafi is indicated for treatment of chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.

CONTRAINDICATIONS None.

WARNINGS AND PRECAUTIONS Thrombocytopenia, Anemia and Neutropenia Treatment with Jakafi can cause thrombocytopenia, anemia and neutropenia. *[see Adverse Reactions (6.1) in Full Prescribing Information]*. Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary *[see Dosage and Administration (2) in Full Prescribing Information]*. Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi. Severe neutropenia (ANC less than 0.5×10^9/L) was generally reversible by withholding Jakafi until recovery. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated *[see Dosage and Administration (2) in Full Prescribing Information]*. **Risk of Infection** Serious bacterial, mycobacterial, fungal and viral infections have occurred *[see Adverse Reactions (6.1) in Full Prescribing Information]*. Delay starting therapy with Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines. *Tuberculosis* Tuberculosis infection has been reported in patients receiving Jakafi. Observe patients receiving Jakafi for signs and symptoms of active tuberculosis and manage promptly. Prior to initiating Jakafi, patients should be evaluated for tuberculosis risk factors, and those at higher risk should be tested for latent infection. Risk factors include, but are not limited to, prior residence in or travel to countries with a high prevalence of tuberculosis, close contact with a person with active tuberculosis, and a history of active or latent tuberculosis where an adequate course of treatment cannot be confirmed. For patients with evidence of active or latent tuberculosis, consult a physician with expertise in the treatment of tuberculosis before starting Jakafi. The decision to continue Jakafi during treatment of active tuberculosis should be based on the overall risk-benefit determination. *Progressive Multifocal Leukoencephalopathy* Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate. *Herpes Zoster* Advise patients about early signs and symptoms of herpes zoster and to seek treatment as early as possible if suspected. *Hepatitis B* Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking Jakafi. The effect of Jakafi on viral replication in patients with chronic HBV infection is unknown. Patients with chronic HBV infection should be treated and monitored according to clinical guidelines. **Symptom Exacerbation Following Interruption or Discontinuation of Treatment with Jakafi** Following discontinuation of Jakafi, symptoms from myeloproliferative neoplasms may return to pretreatment levels over a period of approximately one week. Some patients with MF have experienced one or more of the following adverse events after discontinuing Jakafi: fever, respiratory distress, hypotension, DIC, or multi-organ failure. If one or more of these occur after discontinuation of, or while tapering the dose of Jakafi, evaluate for and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi therapy without consulting their physician. When discontinuing or interrupting therapy with Jakafi for reasons other than thrombocytopenia or neutropenia *[see Dosage and Administration (2.7) in Full Prescribing Information]*, consider tapering the dose of Jakafi gradually rather than discontinuing abruptly. **Non-Melanoma Skin Cancer (NMSC)** Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred in patients treated with Jakafi. Perform periodic skin examinations. **Lipid Elevations** Treatment with Jakafi has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides *[see Adverse Reactions (6.1) in Full Prescribing Information]*. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined in patients treated with Jakafi. Assess lipid parameters approximately 8-12 weeks following initiation of Jakafi therapy. Monitor and treat according to clinical guidelines for the management of hyperlipidemia. **Major Adverse Cardiovascular Events (MACE)** Another JAK-inhibitor has increased the risk of MACE, including cardiovascular death, myocardial infarction, and stroke (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. **Thrombosis** Another JAK-inhibitor has increased the risk of thrombosis, including deep venous thrombosis (DVT), pulmonary embolism (PE), and arterial thrombosis (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. In patients with MF and PV treated with Jakafi in clinical trials, the rates of thromboembolic events were similar in Jakafi and control treated patients. Patients with symptoms of thrombosis should be promptly evaluated and treated appropriately. **Secondary Malignancies** Another JAK-inhibitor has increased the risk of lymphoma and other malignancies excluding NMSC (compared to those treated with TNF blockers) in patients with rheumatoid arthritis, a condition for which Jakafi is not indicated. Patients who are current or past smokers are at additional increased risk. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Jakafi, particularly in patients with a known secondary malignancy (other than a successfully treated NMSC), patients who develop a malignancy, and patients who are current or past smokers. **ADVERSE REACTIONS** The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling: • Thrombocytopenia, Anemia and Neutropenia *[see Warnings and Precautions (5.1) in Full Prescribing Information]* • Risk of Infection *[see Warnings and Precautions (5.2) in Full Prescribing Information]* • Symptom Exacerbation Following Interruption or Discontinuation of Treatment with Jakafi *[see Warnings and Precautions (5.3) in Full Prescribing Information]* • Non-Melanoma Skin Cancer *[see Warnings and Precautions (5.4) in Full Prescribing Information]* • Lipid Elevations *[see Warnings and Precautions (5.5) in Full Prescribing Information]* • Major Adverse Cardiovascular Events (MACE) *[see Warnings and Precautions (5.6) in Full Prescribing Information]* • Thrombosis *[see Warnings and Precautions (5.7) in Full Prescribing Information]* • Secondary Malignancies *[see Warnings and Precautions (5.8) in Full Prescribing Information]*. **Clinical Trials Experience** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Myelofibrosis The safety of Jakafi was assessed in 617 patients in six clinical studies with a median duration of follow-up of 10.9 months, including 301 patients with MF in two Phase 3 studies. In these two Phase 3 studies, patients had a median duration of exposure to Jakafi of 9.5 months (range 0.5 to 17 months), with 89% of patients treated for more than 6 months and 25% treated for more than 12 months. One hundred and eleven (111) patients started treatment at 15 mg twice daily and 190 patients started at 20 mg twice daily. In patients starting treatment with 15 mg twice daily (pretreatment platelet counts of 100 to 200 $\times 10^9$/L) and 20 mg twice daily (pretreatment platelet counts greater than 200 $\times 10^9$/L), 65% and 25% of patients, respectively, required a dose reduction below the starting dose within the first 8 weeks of therapy. In a double-blind, randomized, placebo-controlled study of Jakafi, among the 155 patients treated with Jakafi, the most frequent adverse reactions were thrombocytopenia and anemia *[see Table 2]*. Thrombocytopenia, anemia and neutropenia are dose-related effects. The three most frequent nonhematologic adverse reactions were bruising, dizziness and headache *[see Table 1]*. Discontinuation for adverse events, regardless of causality, was observed in 11% of patients treated with Jakafi and 11% of patients treated with placebo. Table 1 presents the most common nonhematologic adverse reactions occurring in patients who received Jakafi in the double-blind, placebo-controlled study during randomized treatment.

Table 1: Myelofibrosis: Nonhematologic Adverse Reactions Occurring in Patients on Jakafi in the Double-blind, Placebo-controlled Study During Randomized Treatment

	Jakafi (N=155)			Placebo (N=151)		
Adverse Reactions	All Grades[a] (%)	Grade 3 (%)	Grade 4 (%)	All Grades (%)	Grade 3 (%)	Grade 4 (%)
Bruising[b]	23	< 1	0	15	0	0
Dizziness[c]	18	< 1	0	7	0	0
Headache	15	0	0	5	0	0
Urinary Tract Infections[d]	9	0	0	5	< 1	< 1
Weight Gain[e]	7	< 1	0	1	< 1	0
Flatulence	5	0	0	< 1	0	0
Herpes Zoster[f]	2	0	0	< 1	0	0

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0

[b] includes contusion, ecchymosis, hematoma, injection site hematoma, periorbital hematoma, vessel puncture site hematoma, increased tendency to bruise, petechiae, purpura

[c] includes dizziness, postural dizziness, vertigo, balance disorder, Meniere's Disease, labyrinthitis

[d] includes urinary tract infection, cystitis, urosepsis, urinary tract infection bacterial, kidney infection, pyuria, bacteria urine, bacteria urine identified, nitrite urine present

[e] includes weight increased, abnormal weight gain

[f] includes herpes zoster and post-herpetic neuralgia

Description of Selected Adverse Reactions: Anemia In the two Phase 3 clinical studies, median time to onset of first CTCAE Grade 2 or higher anemia was approximately 6 weeks. One patient (< 1%) discontinued treatment because of anemia. In patients receiving Jakafi, mean decreases in hemoglobin reached a nadir of approximately 1.5 to 2.0 g/dL below baseline after 8 to 12 weeks of therapy and then gradually recovered to reach a new steady state that was approximately 1.0 g/dL below baseline. This pattern was observed in patients regardless of whether they had received transfusions during therapy. In the randomized, placebo-controlled study, 60% of patients treated with Jakafi and 38% of patients receiving placebo received red blood cell transfusions during randomized treatment. Among transfused patients, the median number of units transfused per month was 1.2 in patients treated with Jakafi and 1.7 in placebo treated patients. **Thrombocytopenia** In the two Phase 3 clinical studies, in patients who developed Grade 3 or 4 thrombocytopenia, the median time to onset was approximately 8 weeks. Thrombocytopenia was generally reversible with dose reduction or dose interruption. The median time to recovery of platelet counts above 50×10^9/L was 14 days. Platelet transfusions were administered to 5% of patients receiving Jakafi and to 4% of patients receiving control regimens. Discontinuation

of treatment because of thrombocytopenia occurred in < 1% of patients receiving Jakafi and < 1% of patients receiving control regimens. Patients with a platelet count of 100 × 10^9/L to 200 × 10^9/L before starting Jakafi had a higher frequency of Grade 3 or 4 thrombocytopenia compared to patients with a platelet count greater than 200 × 10^9/L (17% versus 7%). **Neutropenia** In the two Phase 3 clinical studies, 1% of patients reduced or stopped Jakafi because of neutropenia. Table 2 provides the frequency and severity of clinical hematology abnormalities reported for patients receiving treatment with Jakafi or placebo in the placebo-controlled study.

Table 2: Myelofibrosis: Worst Hematology Laboratory Abnormalities in the Placebo-Controlled Study[a]

	Jakafi (N=155)			Placebo (N=151)		
Laboratory Parameter	**All Grades[b] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Thrombocytopenia	70	9	4	31	1	0
Anemia	96	34	11	87	16	3
Neutropenia	19	5	2	4	< 1	1

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0

Additional Data from the Placebo-Controlled Study
• 25% of patients treated with Jakafi and 7% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in alanine transaminase (ALT). The incidence of greater than or equal to Grade 2 elevations was 2% for Jakafi with 1% Grade 3 and no Grade 4 ALT elevations. • 17% of patients treated with Jakafi and 6% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in aspartate transaminase (AST). The incidence of Grade 2 AST elevations was < 1% for Jakafi with no Grade 3 or 4 AST elevations. • 17% of patients treated with Jakafi and < 1% of patients treated with placebo developed newly occurring or worsening Grade 1 elevations in cholesterol. The incidence of Grade 2 cholesterol elevations was < 1% for Jakafi with no Grade 3 or 4 cholesterol elevations. Polycythemia Vera In a randomized, open-label, active-controlled study, 110 patients with PV resistant to or intolerant of hydroxyurea received Jakafi and 111 patients received best available therapy *[see Clinical Studies (14.2) in Full Prescribing Information]*. The most frequent adverse reaction was anemia. Discontinuation for adverse events, regardless of causality, was observed in 4% of patients treated with Jakafi. Table 3 presents the most frequent nonhematologic adverse reactions occurring up to Week 32.

Table 3: Polycythemia Vera: Nonhematologic Adverse Reactions Occurring in ≥ 5% of Patients on Jakafi in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment

	Jakafi (N=110)		Best Available Therapy (N=111)	
Adverse Reactions	**All Grades[a] (%)**	**Grade 3-4 (%)**	**All Grades (%)**	**Grade 3-4 (%)**
Diarrhea	15	0	7	< 1
Dizziness[b]	15	0	13	0
Dyspnea[c]	13	3	4	0
Muscle Spasms	12	< 1	5	0
Constipation	8	0	3	0
Herpes Zoster[d]	6	< 1	0	0
Nausea	6	0	4	0
Weight Gain[e]	6	0	< 1	0
Urinary Tract Infections[f]	6	0	3	0
Hypertension	5	< 1	3	< 1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0
[b] includes dizziness and vertigo
[c] includes dyspnea and dyspnea exertional
[d] includes herpes zoster and post-herpetic neuralgia
[e] includes weight increased and abnormal weight gain
[f] includes urinary tract infection and cystitis

Clinically relevant laboratory abnormalities are shown in Table 4.

Table 4: Polycythemia Vera: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment[a]

	Jakafi (N=110)			Best Available Therapy (N=111)		
Laboratory Parameter	**All Grades[b] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Hematology						
Anemia	72	< 1	< 1	58	0	0
Thrombocytopenia	27	5	< 1	24	3	< 1
Neutropenia	3	0	< 1	10	< 1	0
Chemistry						
Hypercholesterolemia	35	0	0	8	0	0
Elevated ALT	25	< 1	0	16	0	0
Elevated AST	23	0	0	23	< 1	0
Hypertriglyceridemia	15	0	0	13	0	0

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0

Acute Graft-Versus-Host Disease In a single-arm, open-label study, 71 adults (ages 18-73 years) were treated with Jakafi for aGVHD failing treatment with steroids with or without other immunosuppressive drugs *[see Clinical Studies (14.3) in Full Prescribing Information]*. The median duration of treatment with Jakafi was 46 days (range, 4-382 days). There were no fatal adverse reactions to Jakafi. An adverse reaction resulting in treatment discontinuation occurred in 31% of patients. The most common adverse reaction leading to treatment discontinuation was infection (10%). Table 5 shows the adverse reactions other than laboratory abnormalities.

Table 5: Acute Graft-Versus-Host Disease: Nonhematologic Adverse Reactions Occurring in ≥ 15% of Patients in the Open-Label, Single-Cohort Study

	Jakafi (N=71)	
Adverse Reactions[a]	**All Grades[b] (%)**	**Grade 3-4 (%)**
Infections (pathogen not specified)	55	41
Edema	51	13
Hemorrhage	49	20
Fatigue	37	14
Bacterial infections	32	28
Dyspnea	32	7
Viral infections	31	14
Thrombosis	25	11
Diarrhea	24	7
Rash	23	3
Headache	21	4
Hypertension	20	13
Dizziness	16	0

[a] Selected laboratory abnormalities are listed in Table 6 below
[b] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 4.03

Selected laboratory abnormalities during treatment with Jakafi are shown in Table 6.

Table 6: Acute Graft-Versus-Host Disease: Selected Laboratory Abnormalities Worsening from Baseline in the Open-Label, Single Cohort Study

	Jakafi (N=71)	
	Worst grade during treatment	
Laboratory Parameter	**All Grades[a] (%)**	**Grade 3-4 (%)**
Hematology		
Anemia	75	45
Thrombocytopenia	75	61
Neutropenia	58	40
Chemistry		
Elevated ALT	48	8
Elevated AST	48	6
Hypertriglyceridemia	11	1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03

Chronic Graft-Versus-Host Disease In a Phase 3, randomized, open-label, multi-center study, 165 patients were treated with Jakafi and 158 patients were treated with best available therapy for cGVHD failing treatment with steroids with or without other immunosuppressive drugs *[see Clinical Studies (14.4) in full Prescribing Information]*; sixty-five patients crossed over from best available therapy to treatment with Jakafi, for a total of 230 patients treated with Jakafi. The median duration of exposure to Jakafi for the study was 49.7 weeks (range, 0.7 to 144.9 weeks) in the Jakafi arm. One hundred and nine (47%) patients were on Jakafi for at least 1 year. There were five fatal adverse reactions to Jakafi, including 1 from toxic epidermal necrolysis and 4 from neutropenia, anemia and/or thrombocytopenia. An adverse reaction resulting in treatment discontinuation occurred in 18% of patients treated with Jakafi. An adverse reaction resulting in dose modification occurred in 27%, and an adverse reaction resulting in treatment interruption occurred in 23%. The most common hematologic adverse reactions (incidence > 35%) are anemia and thrombocytopenia. The most common nonhematologic adverse reactions (incidence ≥ 20%) are infections (pathogen not specified) and viral infection. Table 7 presents the most frequent nonlaboratory adverse reactions occurring up to Cycle 7 Day 1 of randomized treatment.

Table 7: Chronic Graft-Versus-Host Disease: All-Grade (≥ 10%) and Grades 3-5 (≥ 3%) Nonlaboratory Adverse Reactions Occurring in Patients in the Open-Label, Active-controlled Study up to Cycle 7 Day 1 of Randomized Treatment

	Jakafi (N = 165)		Best Available Therapy (N = 158)	
Adverse Reactions[b]	**All Grades[a] (%)**	**Grade ≥ 3 (%)**	**All Grades (%)**	**Grade ≥ 3 (%)**
Infections and infestations				
Infections (pathogen not specified)	45	15	44	16
Viral infections	28	5	23	5
Musculoskeletal and connective tissue disorders				
Musculoskeletal pain	18	1	13	0
General disorders and administration site conditions				
Pyrexia	16	2	9	1
Fatigue	13	1	10	2
Edema	10	1	12	1
Vascular disorders				
Hypertension	16	5	13	7
Hemorrhage	12	2	15	2
Respiratory, thoracic and mediastinal disorders				
Cough	13	0	8	0
Dyspnea	11	1	8	1
Gastrointestinal disorders				
Nausea	12	0	13	2
Diarrhea	10	1	13	1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 4.03
[b] Grouped terms that are composites of applicable adverse reaction terms.

Clinically relevant laboratory abnormalities are shown in Table 8.

Table 8: Chronic Graft-Versus-Host Disease: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study up to Cycle 7 Day 1 of Randomized Treatment[a]

	Jakafi (N=165)		Best Available Therapy (N=158)	
Laboratory Test	**All Grades[b] (%)**	**Grade ≥ 3 (%)**	**All Grades (%)**	**Grade ≥ 3 (%)**
Hematology				
Anemia	82	13	75	8
Thrombocytopenia	27	12	23	9
Neutropenia	58	20	54	17
Chemistry				
Hypercholesterolemia	88	10	85	8
Elevated AST	65	5	54	6
Elevated ALT	73	11	71	16
Gamma glutamyltransferase increased	81	42	75	38
Creatinine increased	47	1	40	2
Elevated lipase	38	12	30	9
Elevated amylase	35	8	25	4

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03

DRUG INTERACTIONS Fluconazole Concomitant use of Jakafi with fluconazole increases ruxolitinib exposure *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*, which may increase the risk of exposure-related adverse reactions. Avoid concomitant use of Jakafi with fluconazole doses of greater than 200 mg daily. Reduce the Jakafi dosage when used concomitantly with fluconazole doses of less than or equal to 200 mg *[see Dosage and Administration (2.5) in Full Prescribing Information]*. **Strong CYP3A4 Inhibitors** Concomitant use of Jakafi with strong CYP3A4 inhibitors increases ruxolitinib exposure *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*, which may increase the risk of exposure-related adverse reactions. Reduce the Jakafi dosage when used concomitantly with strong CYP3A4 inhibitors except in patients with aGVHD or cGVHD *[see Dosage and Administration (2.5) in Full Prescribing Information]*. **Strong CYP3A4 Inducers** Concomitant use of Jakafi with strong CYP3A4 inducers may decrease ruxolitinib exposure *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*, which may reduce efficacy of Jakafi. Monitor patients frequently and adjust the Jakafi dose based on safety and efficacy *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*.

USE IN SPECIFIC POPULATIONS Pregnancy: Risk Summary When pregnant rats and rabbits were administered ruxolitinib during the period of organogenesis adverse developmental outcomes occurred at doses associated with maternal toxicity *(see Data)*. There are no studies with the use of Jakafi in pregnant women to inform drug-associated risks. The background risk of major birth defects and miscarriage for the indicated populations is unknown. Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The background risk in the U.S. general population of major birth defects is 2% to 4% and miscarriage is 15% to 20% of clinically recognized pregnancies. **Data:** *Animal Data* Ruxolitinib was administered orally to pregnant rats or rabbits during the period of organogenesis, at doses of 15, 30 or 60 mg/kg/day in rats and 10, 30 or 60 mg/kg/day in rabbits. There were no treatment-related malformations. Adverse developmental outcomes, such as decreases of approximately 9% in fetal weights were noted in rats at the highest and maternally toxic dose of 60 mg/kg/day. This dose results in an exposure (AUC) that is approximately 2 times the clinical exposure at the maximum recommended dose of 25 mg twice daily. In rabbits, lower fetal weights of approximately 8% and increased late resorptions were noted at the highest and maternally toxic dose of 60 mg/kg/day. This dose is approximately 7% the clinical exposure at the maximum recommended dose. In a pre- and post-natal development study in rats, pregnant animals were dosed with ruxolitinib from implantation through lactation at doses up to 30 mg/kg/day. There were no drug-related adverse findings in pups for fertility indices or for maternal or embryofetal survival, growth and development parameters at the highest dose evaluated (34% the clinical exposure at the maximum recommended dose of 25 mg twice daily). **Lactation: Risk Summary** No data are available regarding the presence of ruxolitinib in human milk, the effects on the breast fed child, or the effects on milk production. Ruxolitinib and/or its metabolites were present in the milk of lactating rats *(see Data)*. Because many drugs are present in human milk and because of the potential for thrombocytopenia and anemia shown for Jakafi in human studies, discontinue breastfeeding during treatment with Jakafi and for two weeks after the final dose. **Data:** *Animal Data* Lactating rats were administered a single dose of [^{14}C]-labeled ruxolitinib (30 mg/kg) on postnatal Day 10, after which plasma and milk samples were collected for up to 24 hours. The AUC for total radioactivity in milk was approximately 13-fold the maternal plasma AUC. Additional analysis showed the presence of ruxolitinib and several of its metabolites in milk, all at levels higher than those in maternal plasma. **Pediatric Use** The safety and effectiveness of Jakafi for treatment of myelofibrosis or polycythemia vera in pediatric patients have not been established. The safety and effectiveness of Jakafi for treatment of steroid-refractory aGVHD has been established for treatment of children 12 years and older. Use of Jakafi in pediatric patients with steroid-refractory aGVHD is supported by evidence from adequate and well-controlled trials of Jakafi in adults *[see Clinical Studies (14.3) in Full Prescribing Information]* and additional pharmacokinetic and safety data in pediatric patients. The safety and effectiveness of Jakafi for treatment of steroid-refractory aGVHD has not been established in pediatric patients younger than 12 years old. The safety and effectiveness of Jakafi for treatment of cGVHD after failure of one or two lines of systemic therapy has been established for treatment of children 12 years and older. Use of Jakafi in pediatric patients with cGVHD after failure of one or two lines of systemic therapy is supported by evidence from adequate and well-controlled trials of Jakafi in adults and adolescents *[see Clinical Studies (14.3, 14.4) in Full Prescribing Information]* and additional pharmacokinetic and safety data in pediatric patients. The safety and effectiveness of Jakafi for treatment of cGVHD has not been established in pediatric patients younger than 12 years old. Jakafi was evaluated in a single-arm, dose-escalation study (NCT01164163) in 27 pediatric patients with relapsed or refractory solid tumors (Cohort A) and 20 with leukemias or myeloproliferative neoplasms (Cohort B). The patients had a median age of 14 years (range, 2 to 21 years) and included 18 children (age 2 to < 12 years), and 14 adolescents (age 12 to < 17 years). The dose levels tested were 15, 21, 29, 39, or 50 mg/m^2 twice daily in 28-day cycles with up to 6 patients per dose group. Overall, 38 (81%) patients were treated with no more than a single cycle of Jakafi, while 3, 1, 2, and 3 patients received 2, 3, 4, and 5 or more cycles, respectively. A protocol-defined maximal tolerated dose was not observed, but since few patients were treated for multiple cycles, tolerability with continued use was not assessed adequately to establish a recommended Phase 2 dose higher than the recommended dose for adults. The safety profile in children was similar to that seen in adults. *Juvenile Animal Toxicity Data* Administration of ruxolitinib to juvenile rats resulted in effects on growth and bone measures. When administered starting at postnatal day 7 (the equivalent of a human newborn) at doses of 1.5 to 75 mg/kg/day, evidence of fractures occurred at doses ≥ 30 mg/kg/day, and effects on body weight and other bone measures [e.g., bone mineral content, peripheral quantitative computed tomography, and x-ray analysis] occurred at doses ≥ 5 mg/kg/day. When administered starting at postnatal day 21 (the equivalent of a human 2-3 years of age) at doses of 5 to 60 mg/kg/day, effects on body weight and bone occurred at doses ≥ 15 mg/kg/day, which were considered adverse at 60 mg/kg/day. Males were more severely affected than females in all age groups, and effects were generally more severe when administration was initiated earlier in the postnatal period. These findings were observed at exposures that are at least 27% the clinical exposure at the maximum recommended dose of 25 mg twice daily. **Geriatric Use** Of the total number of patients with MF in clinical studies with Jakafi, 52% were 65 years and older, while 15% were 75 years and older. No overall differences in safety or effectiveness of Jakafi were observed between these patients and younger patients. Clinical studies of Jakafi in patients with aGVHD did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects. Of the total number of patients with cGVHD treated with Jakafi in clinical trials, 11% were 65 years and older. No overall differences in safety or effectiveness of Jakafi were observed between these patients and younger patients. **Renal Impairment** Total exposure of ruxolitinib and its active metabolites increased with moderate (CLcr 30 to 59 mL/min) and severe (CLcr 15 to 29 mL/min) renal impairment, and ESRD (CLcr less than 15 mL/min) on dialysis *[see Clinical Pharmacology (12.3) in Full Prescribing Information]*. Modify Jakafi dosage as recommended *[see Dosage and Administration (2.6) in full Prescribing Information]*. **Hepatic Impairment** Exposure of ruxolitinib increased with mild (Child-Pugh A), moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Reduce Jakafi dosage as recommended in patients with MF or PV with hepatic impairment *[see Dosage and Administration (2.6) in full Prescribing Information]*. Reduce Jakafi dosage as recommended for patients with Stage 4 liver aGVHD. Monitor blood counts more frequently for toxicity and modify the Jakafi dosage for adverse reactions if they occur for patients with Score 3 liver cGVHD *[see Dosage and Administration (2.6) and Clinical Pharmacology (12.3) in full Prescribing Information]*. **OVERDOSAGE** There is no known antidote for overdoses with Jakafi. Single doses up to 200 mg have been given with acceptable acute tolerability. Highe than recommended repeat doses are associated with increased myelosuppression including leukopenia, anemia and thrombocytopenia. Appropriate supportive treatment should be given. Hemodialysis is not expected to enhance the elimination of Jakafi.

Jakafi is a registered trademark of Incyte.
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DEPARTMENTS

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

Email to FCSCommunications@FLCancer.com

On the cover: Dr. Lucio Gordan with one of his horses at his Gainesville farm.
Photography by Blake Jones

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Scan the QR code below with your smartphone or visit annexushealth.com/fcs to view a **personal message from our Co-Founder and CEO Joe Baffone** to all of you at Florida Cancer Specialists. We are passionate about helping you **help your patients gain access to the care they need**—faster and with less financial toxicity.

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FCS THE MAGAZINE

PHYSICIAN LEADERSHIP

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MICHAEL DIAZ, MD

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NATHAN H. WALCKER, CHIEF EXECUTIVE OFFICER

Across our practice, we have embraced this new year of opportunities and challenges at full speed.

Data increasingly drives the actions we take and the decisions we make. In this issue, we shine the spotlight on our recently launched Data Governance Program. It's a significant initiative that is enhancing our ability to consistently provide exceptional patient care.

You'll also want to read about our value-based care activities, which continue to rank FCS among the top-performing oncology practices in the country for quality and cost-saving measures.

At all times our work is centered around those who entrust their care to us. There is no greater reward than to hear from our patients that choosing FCS was their best decision ever.

Amy Rodriquez, a breast cancer survivor, tells of her experience with Dr. David Wright and the Tampa Cancer Center team. She describes how every person she encountered welcomed and embraced her like family. The care and support she received enabled her to return to military service, cancer free.

I could not be more proud of the hard work and dedication of our talented and caring physicians and team members. Together we will continue to push FCS to new heights of success and deliver on our promise to our patients by providing world-class cancer care, close to home.

MICHAEL DIAZ, MD, PRESIDENT & MANAGING PHYSICIAN

As an oncologist, it is a privilege and an amazing opportunity to help make the world a better place for cancer patients. In my new role as FCS President & Managing Physician, I look forward to helping FCS achieve many more milestones as an innovative leader in community-based oncology care.

While I am energized by the successes that are ahead of us, certain things will remain constant — above all, our commitment as one team to one mission.

We will continue to lead the way in cutting-edge cancer innovations and discoveries and introduce supportive services that ease stress for patients and families and improve their overall quality of life.

Another constant is our steadfast commitment to improving the access and affordability of cancer care. No voices are better equipped to make an impact than our dedicated CPAN advocates. They are the patients, survivors, caregivers and clinicians who have experienced cancer firsthand. We are so fortunate for their partnership, and in this issue, you will learn how they are helping eliminate barriers to life-saving community-based cancer care.

Every day, it is our privilege and our passion to serve our patients. Thank you for all you do to help us deliver on our mission.

Following his passion, Chief Medical Officer of Therapeutics and Analytics Dr. Lucio Gordan shifts his focus to data and technology and spending more time with his family, wife Valeria and daughter Julia, on their farm.

Physician Leaders Take on New Roles in the New Year

BY EMMA WITMER, PHOTOS BY BLAKE JONES

A bit of rearranging at the executive level has positioned FCS to achieve new heights of success.

Michael Diaz, MD, FCS Executive Board member, Director of Patient Advocacy and medical oncologist at two FCS locations in St. Petersburg, began the new year as FCS President & Managing Physician. He succeeds Lucio Gordan, MD, who, after serving as FCS's physician leader for three years, has stepped into a new role that will allow him to continue supporting strategic initiatives in clinical advancements, value-based care and much more.

"Our journey in creating our national reputation has involved many years of hard work, dedication and commitment, and we are so grateful to Dr. Gordan for his outstanding leadership," said FCS Chief Executive Officer Nathan H. Walcker. "Dr. Diaz is perfectly positioned to take on this role at this time," he added, citing his long-term commitment to patients and his career focus on ensuring access and affordability to cancer care.

Diaz has been influential in both state and national policy, often organizing grassroots campaigns to block legislation that could pose harm to cancer patients. As a member of the Florida Medicaid Pharmaceutical and Therapeutics Committee, Diaz has worked to revamp the practices of pharmacy benefit managers and helped develop alternative oncology payment models with the American Society of Clinical Oncology, Community Oncology Alliance and the Centers for Medicare and Medicaid Services Innovation.

Diaz says, "Patients need and deserve to get excellent quality, and there is no reason that should be sacrificed for monetary reasons. You can balance both, and that's what I have been striving to do."

As FCS President & Managing Physician, Diaz is committed to working on behalf of patients and healthcare

Michael Diaz, MD
President & Managing Physician

Lucio Gordan, MD
Chief Medical Officer of Therapeutics and Analytics

providers and continuing his focus on quality, research, advocacy and innovation. His priorities involve networking with other medical disciplines to centralize patient care, addressing health disparities with pharmaceutical companies and investing in more personalized treatment through the continued advancement of next-generation sequencing.

"It's an amazing honor and privilege to take on the role of president," Diaz said. "My colleagues have expressed their confidence in what I've done in the past, and they are trusting me to continue to do that in the future. I take that very seriously. I am going to continue to do everything I can to earn that confidence and respect."

For Gordan, his new role as Chief Medical Officer of Therapeutics and Analytics is a thrilling opportunity to dive more deeply into a topic that has been a lifelong passion and can prove revolutionary in the quality of care offered to FCS patients.

Data and informatics have always fascinated Gordan. As a child growing up in Brazil, Gordan taught himself to do coding and developed computer software beginning at age 11. He was insatiably curious about how data could be used to help others and to improve understanding of the challenges in the world around him.

As a practicing medical oncologist with FCS's Gainesville Cancer Center, Gordan understands the importance of data to improve patient care.

Data allows clinicians to provide personalized treatment based on key factors in the patient's demographic information, medical history and genomics. A data-driven approach expedites the process of finding the right medications and leads to improvement in drug adherence, dose density and dose intensity. Well-organized data is also a key factor in getting qualified patients into potentially life-saving clinical trials. FCS is sitting on a treasure trove of data. It's a massive undertaking to sort through all of it, but with the help of the Data Governance Committee and other FCS teams, Gordan is ready for the challenge.

"As it was during my time as President & Managing Physician, my goal as Chief Medical Officer of Therapeutics and Analytics is to move the needle a bit faster to impact our full patient population," he said.

A DIFFERENT KIND OF SADDLE AND REINS PROVIDE PASTIME AND PASSION

Gordan reserves weekend mornings for exercising his horses. He owns a 30-acre farm near Gainesville, where he keeps a few mini-donkeys and a dozen horses. His favorite horse, a Hanoverian-Tennessee Walker named Redford, is always up for a ride.

"They are my psychiatrists on staff," Gordan said of his horses, with whom he spends regular non-office hours. "When I was president, the executives knew not to call me between 8 a.m. and noon on Saturday and Sunday. If they did, they knew not to expect an answer."

Refreshed by pastoral pursuits, Gordan returns to data, whose utility he understands and appreciates.

PATIENT SPOTLIGHT

Conquering Breast Cancer

Warrior spirit helped Amy Rodriguez stay positive

BY HANNAH BURKE

Those who know Amy Rodriguez will tell you she's more than a fighter.

She's a warrior.

Her 17 years of service as a U.S. Army National Guard Staff Sergeant have earned Rodriguez more than a dozen honors, including the Joint Service Commendation Medal, the Army Achievement Medal and the Army Commendation Medal.

Still, Rodriguez's recent triumph over breast cancer is her sweetest victory yet. After a long and arduous year-and-a-half of treatment, Rodriguez is grateful for the chance to keep serving her community and country and to continue raising her son and watching him grow up.

"I have FCS to thank for that," Rodriguez said.

The Tampa native received her breast cancer diagnosis in 2020, after a concerning self-exam.

"I had an aunt who had breast cancer years prior, so I was very adamant about regularly checking myself," she said. "When I found a lump, I didn't think much of it, but I mentioned it to my mother-in-law. She insisted I get it checked out."

Two weeks later, Dr. Abigail Beard at USF Health confirmed Rodriguez's worst fear and referred her to Dr. David D. Wright at FCS. Seeing Wright for treatment, Rodriguez said, was "the best decision ever, hands down. I felt very comfortable with him and with his patient care staff. The way they welcomed me made me feel like I was a part of their family."

Wright, who sees patients at FCS's Brandon Cancer Center, New Tampa and the Tampa Cancer Center, attended medical school at the University of South Florida's Moffitt Cancer Center. It was during his first year of school that Wright's mother received her own cancer diagnosis.

"My mother's oncologist treated her like she was family," Wright told FCS in a video testimony. "He spent time with her like she was the only person that mattered to him, and I'm sure he had about 20 other patients waiting. Her outcome was very good; he became a friend of the family and she's still with us. I realized the important thing, for me, was the personal touch. Now, I have patients that have become part of my life."

Rodriguez remembers how, at her very first visit with Wright, he called her by her first name, as if they were already friends. Wright took the time to get to know her, she said, and ensured that she was comfortable from the very beginning.

"When I walked in for treatment every day after, I was always greeted with a smile," Rodriguez said. "From the front door staff to the individuals who put in my IV, everyone was amazing."

Traveling the world, U.S. Army National Guard Staff Sergeant Amy Rodriguez has built a lifetime of unforgettable experiences.

"I 100% believe that Florida Cancer Specialists helped me beat cancer…Thank you, care team. Thank you for loving me through both your actions and words, and thank you for making this experience something I will never forget."

One day, Rodriguez took it upon herself, while undergoing chemotherapy, to shave her head. She continued filling in her eyebrows and doing her makeup, but she still grappled with the insecurities that follow such a drastic change. What if she was now unrecognizable? Turns out, at Rodriguez's next appointment, an FCS staff member would supply her with a much-needed boost of confidence.

"I can't recall her name, but I remember coming in and seeing her look at me with just the widest smile," Rodriguez said. "Her eyes were just gleaming, and she told me, 'You are so beautiful.' She remembered me."

After months of treatment, a double mastectomy and reconstructive surgery, Rodriguez said she's "feeling great — as though I'm back to myself." She finished her last round of treatment in May 2021, is forging ahead with her military career, and reports that, despite everything, she continues to pass her physical fitness tests.

Rodriguez is, to many, a hero.

Last November, she was officially recognized as such by the Tampa Bay Buccaneers at Raymond James Stadium. Prior to the Bucs' home game against the Chicago Bears, Rodriguez, the "Hero of the Game," received the traditional honor of "rallying the Krewe" by ringing the bell of the team's pirate ship. She beamed, danced and beckoned the crowd to match her enthusiasm.

For Rodriguez, that fervor isn't reserved just for game days, but for every day she can continue living, serving others and loving her family.

"I 100% believe that Florida Cancer Specialists helped me beat cancer," Rodriguez said. "Thank you, care team. Thank you for loving me through both your actions and words, and thank you for making this experience something I will never forget."

Data Governance

Company-wide initiative will provide standards for collection and storage

BY HANNAH BURKE

Last year, Florida Cancer Specialists enthusiastically launched its Data Governance Program, an initiative designed to institute policies, processes and standards for how data is collected, organized, stored and used throughout the organization.

The FCS Data Governance Committee was established to oversee the program's implementation and monitor its progress. FCS Chief Executive Officer Nathan H. Walcker serves as executive sponsor of the committee and Vice President of Informatics Trevor Heritage, PhD has taken on the role of committee chair.

It was important to FCS that the committee include representatives from the organization's teams and departments. Data plays a role in every sector of FCS operations, so this initiative impacts everyone.

For instance, FCS data may also correlate with how clinical interventions and observations are documented, or the way in which patient information is attained at intake and later stored, analyzed and secured. Data can relate to billing and claims, or even include the acronyms used by FCS to refer to its clinic locations.

"Like other organizations of our size, complexity and structure, there are many possible ways in which the cross-system exchange of data and information could be inconsistent," Heritage said. "So, it is vital that we have a plan in place to strengthen the management of our data and ensure that it is reliable, secure and being properly used. By doing this, we can more efficiently and deliberately use our organization's data to continue providing world-class cancer care for our patients."

For more than three decades, FCS has been dedicated to its mission of providing communities across Florida with premier cancer care and treatment. As the organization continues to grow and evolve, FCS believes it is imperative that its data infrastructure, practices and protocols follow suit.

Walcker said employees will be kept apprised of developments in its new "data driven culture" via updates from the Data Governance Committee members, who will serve as the program's central decision makers. They plan to furnish reports on process improvement milestones and contemporary examples of the program's impact across FCS.

In addition to the Data Governance Committee, subject matter users and experts who frequently use and interact with data comprise the FCS Data Stewards Council. They will work to break down data silos by identifying the best ways for individual departments to gather, manage and implement data, as well as how to effectively receive and apply data created by other FCS branches.

While the framework for data governance has been set, it will take time, patience and cooperation from all team members to realize the program's full vision. The Data Governance Committee has already identified both short- and long-term goals, and, Walcker said, "Its progress will be frequently monitored and communicated."

"By doing this, we can more efficiently and deliberately use our organization's data to continue providing world-class cancer care for our patients."

ADVOCACY SPOTLIGHT

Strategic Partnership

FCS and COA advance interests of patients

BY EMMA WITMER

Building a better system for cancer care is a job too big for one organization, no matter how dedicated its staff may be.

Given that reality, FCS partners with organizations such as the Community Oncology Alliance (COA).

Rose Gerber is Director of Patient Advocacy and Education for COA's Patient Advocacy Network (CPAN) that works closely with FCS and other practices around the country to spearhead policymaking, innovation and reform of the cancer care system.

"I just love the FCS chapter," Gerber said. "They keep me inspired. A lot of what I do is educating and mentoring others. I try my best to keep leaders interested, and when I have leaders like Beth Wittmer, Dr. Mike Diaz and Dr. Lucio Gordan, who are high-ranking within the practice and truly support advocacy, I know we can accomplish great things."

FCS launched its CPAN chapter in 2014, under the joint leadership of then Director of Care Management Don Champlain, RN, MHA, and current Director of Care Management Beth Wittmer, RN, OCN. The two served as co-chairs of the chapter for three years until, sadly, Champlain lost his battle with cancer.

Over the last eight years, Wittmer and Gerber have worked side by side to educate clinicians, patients, survivors and their families on the complex system of cancer care and empower them to act.

As the CPAN chapter leader for FCS, Wittmer is in constant contact with liaisons throughout the FCS network to garner support. She organizes quarterly physician-led speaking events with patients and families to provide education and identify what

"Our goal with CPAN is to make people more aware of what they can do by standing up and advocating for cancer care and the difference that it truly makes in the community setting."

Top: Dr. Lucio Gordan and Alachua County representatives participate in Sit in My Chair, an opportunity for local representatives to gain an understanding of the community oncology experience from the patient's perspective.
Bottom: Members of the CPAN committee join together at the last in-person COA Conference in 2019.

legislation is coming up that could be helpful or detrimental to their care. Even with the challenges posed by COVID-19 restrictions, Wittmer has persevered with virtual events.

"Our goal with CPAN is to make people more aware of what they can do by standing up and advocating for cancer care and the difference that it truly makes in the community setting," Wittmer said. "We are always looking for ways to bring more awareness to the importance of this chapter and the need for more patients, families and FCS team members to get involved.

FCS doctors and nurses have added powerful voices to numerous state and national CPAN events by identifying patients willing to share their cancer stories through the "I AM Community Oncology" campaign. In addition, FCS has invited Sen. Rick Scott and Sen. Marco Rubio to experience FCS facilities through the "Sit in My Chair" event. Prior to the pandemic, live visits were hosted in FCS clinics throughout the state.

Time and again, CPAN advocates from FCS have espoused the importance of affordable and easily accessible care and the value of clinical trials, and they regularly speak on CPAN patient advisory boards at statewide events and on Capitol Hill.

One issue that the chapter has worked to address is the impact of pharmacy benefit managers on access to medication.

FCS and CPAN have also worked in tandem to block legislation like the Trump administration's Most Favored Nation proposal, which would have barred at least 20 percent of cancer patients on Medicare from access to treatment.

"We want to de-complicate these issues so that patients and their families have a good understanding of what their rights are and so that their voices can be heard at the legislative level," Wittmer said.

"The work we do with CPAN is so important," added FCS President & Managing Physician Michael Diaz, MD. "The better we initiate and educate our patients, the better they can advocate for themselves. It helps them understand how and where they can turn for support, and it helps them understand that they are not alone in this process. If we can work together, we can help them navigate through what can be one of the most difficult times in anyone's life."

Email the FCS CPAN group for more information or to learn how you can get involved at CPAN@FLCancer.com.

VALUE-BASED CARE PROGRAM

FCS Retains Top Ranking Among OCM Participants

BY HANNAH BURKE

In 2016, the Center for Medicare & Medicaid Innovation (CMMI) developed the Oncology Care Model (OCM), a national payment program that provides high-caliber, efficiently managed cancer care at a lower price to Medicare beneficiaries.

FCS has been enrolled in the program since its inception, and according to CMMI's most recent OCM reconciliation data, has once again been ranked at the top among the 126 participating oncology practices across the country.

With its community-based and personalized practices, state-of-the-art clinical trial offerings and dedication to offering patients individualized, world-class cancer care, FCS's ranking comes as no surprise to FCS Chief Executive Officer Nathan H. Walcker.

"Our value-based practice initiatives at FCS are programmatic, intentional and thoughtfully designed to be organized squarely around the patient, yielding consistent results that outpace industry benchmarks and make good on our commitment to prioritize patient outcomes and quality," Walcker said.

"I could not be prouder of our entire team and their steadfast commitment to delivering value-based oncology care in communities across Florida."

FCS provides care for more than 22,000 OCM beneficiaries annually and has recorded more than

FCS has recorded over **$140M** in Medicare savings since 2016

FCS had **21%** fewer cases of emergency visits, preventing admission

FCS had **8%** fewer hospital admissions than other practices

$140 million in Medicare savings since 2016. In the last six-month performance period of 2021, FCS saved Medicare $31.7 million.

Participation in OCM, said FCS Director of Value-Based Care TR Strickland, has allowed FCS to make "substantial strides and investments in our strategic focus on value-based programs." FCS has succeeded in partnering with Accountable Care Organizations (ACOs), Managed Service Organizations (MSOs) and commercial/Medicare Advantage payers "across our Florida markets to continue reducing care costs and prioritizing patient satisfaction."

FCS embodies all the values engaged by the spirit and the goals of the OCM demonstration initiative, which aims to not only cut costs, but more importantly, incentivize and promote enhanced systems and processes that promote "better care, smarter spending and healthier people," according to the CMMI website. This is, in essence, the overriding goal of the triple aim – improving care experience, population health and reducing costs – for all of healthcare delivery.

FCS consistently reports on upwards of 50 quality-of-care metrics per performance period to help measure OCM effectiveness. Of those 50, FCS received exceptional scores in the areas of pain assessment, emergency room visits/inpatient hospital stays, prevention/screenings, appropriate utilization of hospice, patient-reported experience and patient satisfaction.

CMMI's most recent report also shows that FCS hospital admissions were 8% lower than those of other OCM-enrolled practices and, in that same period, FCS had 21% fewer cases of emergency room visits, preventing admission.

FCS Chief Medical Officer for Therapeutics & Analytics Lucio Gordan, MD attributes the organization's success with OCM and other value-based programs to prioritizing a "well-built" infrastructure.

"At FCS, our guiding principle is to put the patient first in everything we do; we are laser-focused on providing world-class cancer care while reducing the overall cost of that care for our patients," Gordan said. "In the long run, quality care doesn't increase costs, as quality delivered at the right time in the most appropriate venue often decreases overall costs and prevents adverse events."

FCS will continue to leverage OCM value principles and infrastructure and expand the scope of its own value-based care programs to support the long-term objective of consistent, high-quality treatment. To do so, we continuously refine our patient education libraries, supply expanded resources for after-hours symptom management, and ancillary services like nutritional health and behavioral health to improve access and reduce care costs through the use of generic and biosimilar drugs when possible.

"Simply put, exceptional, value-based cancer care centered around our patients, and within their own communities and support systems, is the core of our organizational mission and a fixed focus we will never waver from," Walcker said.

2021 OpportUNITY Annual Operations Meeting Recap

For the first time in nearly two years, our operations team gathered in person at Raymond James Stadium in Tampa for their annual meeting. The November meeting's theme, "OpportUNITY," reinforced the unification of our teams across Florida in our efforts to provide patient-centered care.

Throughout the day, the group of over 250 office and nurse managers heard from FCS leaders, gaining insight and perspective of past accomplishments and a glimpse at the road ahead. Undoubtedly, the past several months have been challenging, especially for our operations teams, but the message echoed throughout the day was one of pride and gratitude. The perseverance and dedication of this team is undeniably what has enabled our patients to continue trusting in our care, our physicians to continue practicing medicine and our research to continue fueling the majority of the new oncology treatments in the country.

The day was filled with moments of appreciation, recognition, reflection and preparation. Chief Operating Officer Jason Coe kicked off the meeting, while Immediate Past President and Managing Physician Dr. Lucio Gordan thanked the group for their hard work and encouraged them to take care of themselves and their teams. Chief Executive Officer Nathan H. Walcker recapped FCS's accomplishments and shared strategies for the new year, which include engaging every FCS team member as new technologies and processes are put in place to improve our delivery of cancer care. Dr. Michael Diaz, President and Managing Physician, spoke of the future, complimenting the teams' efforts and sharing his confidence in achieving the goals set forth by the executive board and the leadership team. They also heard from Chief Administrative Officer Joyce Nelson, who shared how FCS continues to be an employer of choice, highlighting the numerous benefits available to all FCS employees.

With this in mind, the focus shifted inward to the individuals in the room and those they lead. Inspired by thought-provoking presentations from Senior Vice President of Organizational Effectiveness and Learning Marilyn Morales and Director of Clinical Education Delia Edson, they took a deep look at how every individual in FCS impacts patient experience and explored the necessary steps to prioritizing how we take care of our own team members. Statistically, when individuals are engaged and feel valued, it is projected through their work, and our practices are no exception. In our case especially, this cascades to the patients in the care we provide.

With Thanksgiving right around the corner, the final team-building activity of the day involved filling baskets with the necessities for a complete holiday dinner. Teams competed in minute-to-win-it challenges earning a trip to the "store" to gather food supplies. When all was said and done, the group had assembled more than 20 overflowing baskets for some of our own FCS patients.

At the end of the day, the goal was for the group to have a clear understanding of where the organization is headed and feel empowered in leading and uplifting their own teams to deliver better patient-centered care across the organization. Equally as important, all left with the understanding that their executive leadership team and physicians are aligned and dedicated to supporting them in their roles as we head into the new year. One team. One mission.

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1. OpportUNITY 2021 brought the FCS Operations Team together in person for the first time in nearly two years. **2.** Participants raced to the "store" to fill holiday dinner baskets for patients. **3.** Teams competed in minute-to-win-it challenges. **4.** Team members were energized after spending a day focusing on building better teams and delivering better patient care.

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5. Team members stocked up on all the necessities for patients to create the ultimate holiday meal. **6.** At times, carrying the supplies back to the tables was the most challenging task. **7.** It took real teamwork to solve the puzzles. **8.** Each challenge required full team participation to meet the time restriction. **9.** Teams arrange and decorate baskets filled to the brim with all the necessities for a holiday meal. **10.** Chief Operating Officer Jason Coe kicks off OpportUNITY 2021.

11. Hearing from executive leaders on future FCS strategies was insightful and entertaining. **12.** Senior Vice President of Organizational Effectiveness & Learning Marilyn Morales led a breakthrough discussion on evolving patient care delivery. **13.** Chief Executive Officer Nathan H. Walcker sets the stage for the strategies coming in 2022. **14.** Director of Clinical Education Delia Edson spoke to the team about the importance of continuing clinical education and leadership opportunities. **15.** Throughout the day, team members were connecting and laughing, and working together toward a better future. **16.** After spending nearly two years apart, it felt good to bring everyone together.

NEWEST DRUG DEVELOPMENT UNIT OPENS IN LAKE NONA

In collaboration with Sarah Cannon and the University of Central Florida College of Medicine (UCF), FCS has opened its newest drug development unit (DDU). Located in the Sarah Cannon UCF Lake Nona Cancer Center, the new 10,000-square-foot DDU is part of a new treatment facility which combines medical oncology services and Phase 1 clinical trial options for cancer patients in one convenient location. Led by Cesar Augusto Perez, MD, a recognized expert in Phase 1 oncology research, the DDU focuses exclusively on oncology clinical trials at the earliest phases of research and was designed to meet the specialized needs of patients seeking advanced cancer treatment options.

STATE-OF-THE-ART CANCER CENTER OPENS IN NORTH PORT

A ribbon-cutting celebrated the opening of the new North Port Cancer Center located at 1390 Grand Venture Drive. In nearly 20,000 square feet of space with 16 exam rooms, 45 chemotherapy infusion chairs and PET/CT scan technology, along with laboratory, oral oncolytic specialty pharmacy and care management services, patients receive the most advanced and personalized treatments and services.

NEW TRINITY CANCER CENTER EXPANDS SERVICES IN PASCO COUNTY

The FCS Trinity Cancer Center is now open at 9320 State Road 54. The 37,000-square-foot facility has replaced the two prior FCS locations in Trinity. It includes 27 exam rooms and 54 chairs for chemotherapy and other infusion therapies, as well as radiation oncology and next-generation PET/CT imaging technology, laboratory, oral oncolytic specialty pharmacy and care management services for patients participating in value-based care. Even the Tampa Bay Lightning's Thunderbug came out to see the new space.

NEW CANCER CENTER OPENS IN MANATEE COUNTY

A ribbon-cutting marked the opening of the new state-of-the-art FCS Bradenton Cancer Center located at 3630 Manatee Ave. W., which replaces the two prior FCS locations in Bradenton. With greatly expanded treatment space, the clinic includes 18 exam rooms, 50 infusion chairs and on-site imaging, laboratory and pharmacy services. Care management and access to clinical trial research opportunities are also available to patients.

LEADERSHIP APPOINTMENTS & PROMOTIONS

Chris Chadwick
Vice President Service Delivery & Infrastructure

Chris oversees the management, development, delivery and maintenance of the FCS IT infrastructure and service delivery functions, and drives the planning and deployment of strategic initiatives to enhance all end-to-end IT solutions. An accomplished leader in enterprise support and infrastructure management, Chris has extensive experience in global team building, client management and data-driven process engineering with a focus on maximizing efficiency, service delivery and client satisfaction.

Josh Eaves
Senior Vice President Corporate Development

A seasoned business development and sales professional with nearly 20 years of experience, Josh is responsible for FCS's new business development initiatives, including strategic partnerships, service line innovation and expansion. He brings a wealth of expertise developing strategies designed to improve access to the scope of oncology services and resources.

Inga Gonzalez
Senior Vice President Practice Operations

Inga oversees clinic locations covering FCS's presence in Central and Northeast Florida, leading the implementation of strategic imperatives to drive patient satisfaction, physician and team member engagement, and improve efficiencies and effectiveness within the clinical setting. She has a key role in the development and redesign of new sites of care to support the growth of the practice and also works to strengthen and expand relationships with healthcare systems, referring physicians, vendors and other market-based partners. Inga joined the FCS operations team in 2009 and was named FCS Vice President of Operations for Central Florida in 2017.

Ken Sturtz
Chief Information Officer

As Chief Information Officer, Ken Sturtz, MBA, MHA oversees all information technology operations and drives digital innovation company-wide. He joined FCS in March 2022, bringing more than 15 years of healthcare IT executive leadership experience across multiple care settings in military, academic, private and non-profit healthcare sectors. Prior to joining FCS, he served as Chief Information Officer for Brooks Rehabilitation in Jacksonville, Florida, where he led enterprise infrastructure, application, security, analytics and end-user support services encompassing multiple locations of inpatient and outpatient senior care and living facilities. During his 20-plus-year career with the U.S. Army, he held a variety of increasingly responsible positions and served within Chief Information and Chief Technology Officer roles, providing support to numerous hospitals and health care facilities in the U.S. and overseas.

Amy Pacey, MBA, SPHR
Senior Vice President People & Culture

A Senior Human Resource Executive with over 30 years of experience, Amy oversees strategic HR initiatives, supporting FCS in becoming a choice employer by enhancing talent management and attraction practices, improving efficiency and effectiveness of HR and implementing workforce planning, engagement and diversity initiatives. She also serves as FCS's Diversity Officer.

Marilyn Morales, EdS, MS, MBA, LBBP, CPT
Senior Vice President Organizational Effectiveness & Learning

Marilyn drives learning, performance improvement and engagement strategies to foster confidence, success and continuous learning for team members at all levels. Collaborating with key stakeholders across the organization, she oversees employee safety and well-being, enculturation of the patient experience and management of key external relationships with clinical programs and educational institutes. Marilyn joined FCS in 2018 as Vice President Organizational Effectiveness & Learning, also serving as FCS's Learning Officer.

Jeffrey Rubin
Senior Vice President Operations

Jeff joined FCS in 2003 and was named Vice President of Practice Operations in 2015, after serving as Senior Regional Director. He oversees clinical locations from Tallahassee to Naples, and leads implementation of strategic imperatives to drive patient satisfaction, physician and team member engagement and improve efficiencies and effectiveness within the clinical setting. Jeff also plays a key role in development and redesign of new care sites, supporting practice growth, and works to strengthen and expand relationships with healthcare systems, referring physicians, vendors and other market-based partners. He brings extensive practice management experience and a clinical perspective to his senior leadership role.

FCS Foundation News & Events

"Thank you so much. This is great news! Our home was destroyed by Hurricane Irma, and we have been accepted to receive a replacement home. You are proof that not all angels have wings. God bless you for all you have done for us."

— Gabriela and Sam Jauregui with their children, Kristin and Sam Jr.

Farm to Table 2022
In late January, guests joined the FCS Foundation for an evening in Ocala, Florida. The farm-to-table experience event included local fare, entertainment, auctions and more. All proceeds provided non-medical financial assistance to cancer patients.

FLORIDA CANCER SPECIALISTS Foundation

Our Mission:
Providing non-medical financial assistance to adults undergoing cancer treatment in Florida to allow them to focus on fighting cancer.

In 2021, the FCS Foundation awarded more than $1.4 million in grants.

Lyrics for Life
On March 5, Rich and Carissa Blaser partnered with the band Sister Hazel and special guest artists Ezra Ray Hart for a very special night in Gainesville to support Lyrics for Life's Camp Hazelnut, Stop Children's Cancer and Florida Cancer Specialists Foundation.

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Benefiting Florida Cancer Specialists Foundation

Wine Women & Shoes
May 21, 2022, JW Marriott, Orlando

FCSF.org | Phone: 941-677-7181 /FLCancerFoundation /florida-cancer-specialists-foundation

From Our Patients

Adewale A. Fawole, MD

I have been your patient for over five months. I want to thank you for the wonderful care you are giving me for my ferritin issues. You are a great physician, and it shows — not only by the excellent care you have given me but also your kind demeanor and your patience with me as we discuss my treatment.

Your staff is outstanding. I know I do not have all of the names, but please know that they ALL do an excellent job and truly show that they want to provide the best care for your patients. The check-in and check-out desks (Kim, Nabeela, Keri, Me'Shelle and Hannah), the lab (Ben, Carolyn, Tiffany and Chelsea), and the lab technicians that analyze the blood samples are all excellent.

The nurses (Tamara, Jessica and Connie) in the treatment area have a very stressful job treating the many cancer patients. They always have a positive and friendly attitude toward every patient. I actually enjoy my visits just because of the way I am treated with such great care.

Also, Florida Cancer Specialists has built a beautiful facility. It certainly helps patients, who are somewhat depressed having to go through rigorous treatments, to come to such a wonderful place with beautiful artwork and great caregivers.

I appreciate everything you are doing for me.

Scott D. Lunin, MD

HEALTHGRADES REVIEW: 5 STARS

Perfect. Dr. Lunin has the best staff I have ever dealt with. Prompt, professional and caring. They are perfect representatives of the best doctor I have had the pleasure of knowing in my 40 years as a patient. I have had dealings with great institutions like Columbia University Medical Center, The Cleveland Clinic and Sloan Kettering. Several of my surgeons are world-famous. In my book, if I had to choose one doctor to treat a loved one, Scott Lunin would be my choice.

Yaman Suleiman, MD

HEALTHGRADES REVIEW: 5 STARS

I highly recommend Dr. Suleiman and his staff. You cannot describe the caring feelings you get from Dr. Suleiman. He is a one-in-a-million physician that never gives up, treats the whole person and is extremely knowledgeable, kind and caring. He is the perfect physician.

Michel Velez, MD

HEALTHGRADES REVIEW: 5 STARS

Dr. Velez is the best doctor I've ever seen, and we see a lot of doctors. He's professional, extremely knowledgeable and thoughtful. The medical system is lucky to have him! His staff is amazing also. All-around great facility and care.

Thomas H. Tang, MD

GOOGLE REVIEW: 5 STARS

I love Dr. Tang. I was diagnosed with stage 4 breast cancer in July 2021. I'm 34, and before this diagnosis, I was always healthy — not even a cold could stop me. Months in, my scans are better and tumors throughout my body are disappearing. Dr. Tang is saving my life, and I couldn't have chosen a better doctor. Plus, he always sticks by me when I'm not always the best patient. I've had a hard time with doctors telling me what to do constantly, but I'm getting better as time moves along. I thank you, Dr. Tang and everyone at Florida Cancer Specialists, for your patience with me. You're all amazing to me, and I'm forever grateful.

GOOGLE REVIEW: 5 STARS

Dr. Gail Wright took excellent care of my husband for many years and due to her caring and expertise in oncology — he has been in remission for around 20 years. I'm so grateful to have her as his doctor.

Gail Lynn Shaw Wright, MD

GOOGLE REVIEW: 5 STARS

Dr. Bustamante has been, honestly, the absolute best. From my very first initial appointment where we met, she made me feel so comfortable. She made me feel like I would be in the best hands with the best care ever! Fifteen chemotherapies later, I can honestly say that I admire Dr. Bustamante so much. I love seeing her, speaking with her, sharing things with her. Having her as my doctor has been life-changing. She truly is passionate about what she does and doesn't treat you like just another patient. Truly blessed to have had the best doctors and nurses working at my side.

Liliana Bustamante, MD

GOOGLE REVIEW: 5 STARS

Dr. Patel is an amazing physician! I feel so fortunate that I was referred to her for my treatment. She takes time to listen and answer all questions. Her compassion and concern for her patient's physical and emotional well-being is unparalleled. Thank you Dr. Patel for saving my life!

Rina Patel, MD

GOOGLE REVIEW: 5 STARS

Dr. Heldreth and all of the staff at FCS saved my life! I was diagnosed with Stage 4 lung cancer in 2015, and I have now been treatment free for 2.5 years! Through their diligent testing and research, I never "fell through the cracks." I was always the first priority. To say "thank you" is such an understatement!

Douglas D. Heldreth, MD

GOOGLE REVIEW: 5 STARS

Dr. Sai's office is fantastic. The staff is attentive, hardworking, knowledgeable and highly qualified. Dr. Sai is very caring and knows her patients' needs. Flagler County is lucky to have the services of this office, and the patients who visit this office are very fortunate to benefit from the efforts of all staff. I have spoken to and know many people who are past patients of Dr. Sai and have been told in detail about what this office has accomplished for so many. Thank you Dr. Sai!

Padmaja Sai, MD

GOOGLE REVIEW: 5 STARS

I am so blessed to have connected with Florida Cancer Specialists, especially Dr. Jay Wang, who I trust completely, and the nurses and staff who are so welcoming, skillful, knowledgeable and compassionate. I had my first treatment for triple negative breast cancer recently and it was as pleasant as possible with such caring people. I know I have a journey ahead of me, but with the support of Dr. Jay Wang and staff, I will do well with all the support.

Jay Wang, MD

GOOGLE REVIEW: 5 STARS

Ayman Barakat is the best. I've been going to him for three years now and will continue to do so. He and his staff were always kind and most importantly, made me feel comfortable. Whatever concerns I had, he addressed them. He is honest, kind and, in my opinion, the best in what he does. I would not go anywhere else.

Ayman Barakat, MD

Have something to add?

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

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 38 years at our locations throughout Florida.

FLORIDA CANCER SPECIALISTS & Research Institute

*All required paperwork must be provided at time of referral.

FLCancer.com