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

WHAT TO EXPECT WITH JAKAFI®

A guide for **patients** and their **caregivers**

Jakafi® (ruxolitinib) is used to treat adults and children 12 years of age and older with acute graft-versus-host disease (GVHD) who have taken corticosteroids and they did not work well enough.

Additional tools, information, and resources are available at UnderstandingJakafi.com

Please see Important Safety Information beginning on page 12 and click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

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About Jakafi and acute graft-versus-host disease

after corticosteroids did not work well enough

Your treatment journey depends on your individual circumstances and the decisions you make with your Transplant Team. Together, you may discuss Jakafi—the *first FDA-approved prescription medicine* used to treat adults and children 12 years of age and older with acute graft-versus-host disease (GVHD) who have taken corticosteroids and they did not work well enough.

Important Safety Considerations

Jakafi® (ruxolitinib) can cause serious side effects including low blood counts and infection. Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Increases in blood cholesterol levels can also occur. In patients who took another JAK inhibitor to treat rheumatoid arthritis, there was an increased risk of potentially fatal cardiovascular events like heart attack or stroke in patients with risk factors for these events who smoke now or smoked in the past, as well as an increased risk of blood clots in legs or lungs and new (secondary) cancers like lymphoma, especially in patients who smoke now or smoked in the past. The most common side effects of Jakafi for acute GVHD include: low platelet counts, low red or white blood cell counts, infections, and swelling. Call your doctor for medical advice about side effects. **To learn more about these and other risks, please read the Important Safety Information beginning on page 12 and click here for Full Prescribing Information**.

What is acute graft-versus-host disease?

Acute graft-versus-host disease (GVHD) is a serious complication that may affect people who have had a stem cell transplant using cells from a donor. This type of procedure is called an ***allogeneic (AL-oh-geh-NAY-ik) stem cell transplant***. During an allogeneic stem cell transplant, a patient's cells are replaced with donor cells. **(Figure A)**

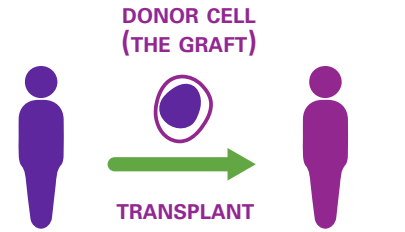


FIGURE A

FIGURE B

Acute GVHD occurs when donor cells (called the ***graft***) attack the organs and tissues of the patient who received them (or the ***host***). That's why the condition is known as graft-versus-host disease. **(Figure B)**

Although acute GVHD can occur any time after transplant, it is commonly diagnosed within the first few months. Your Transplant Team relies on a combination of factors—including your symptoms and what organs are affected—to diagnose acute GVHD.

What parts of the body are affected by acute GVHD?

Acute GVHD mainly affects the skin, liver, and gastrointestinal tract (stomach, intestines, and colon). Patients may experience symptoms or other health problems in any of these organs because of acute GVHD.

Symptoms and signs of acute GVHD

The following are all common symptoms and signs of acute GVHD. **If you or a loved one notice that you are experiencing any new or worsening symptoms, contact your Transplant Team right away**. Taking action early with acute GVHD can make a difference in your recovery and health.

Skin

Faint to severe sunburn-like rash (can appear anywhere, may cover entire body) | Blistering and peeling skin

Gastrointestinal tract (stomach, intestines, colon)

Diarrhea | Abdominal pain | Nausea
Vomiting | Bloating | Blood in the stool

Liver

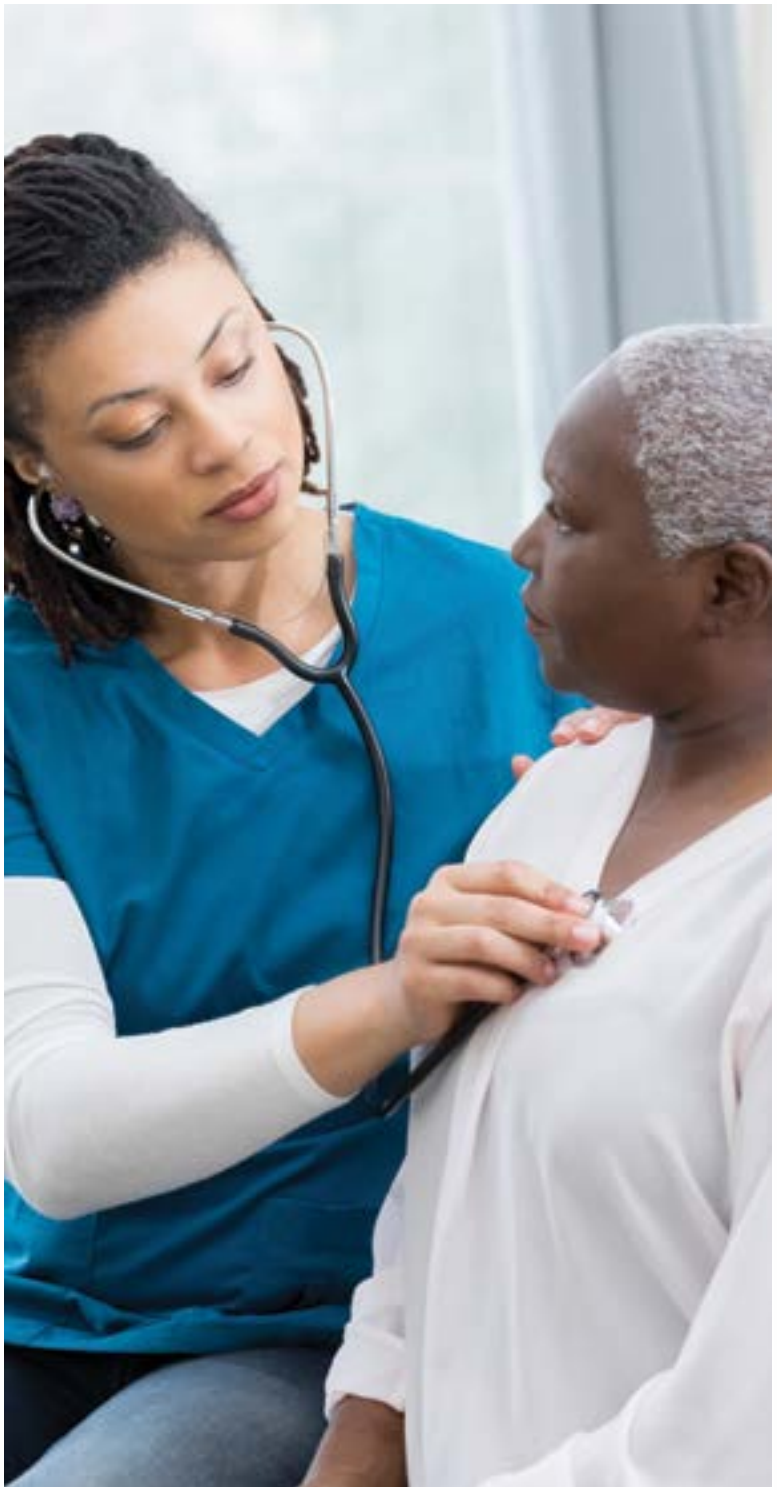
Effects identified by blood tests | Few outward signs, but may include: yellowing of skin or eyes (jaundice); pain in the upper part of your belly; dark, tea-colored urine

When steroids don't work well enough

Steroids (also known as corticosteroids) are the standard treatment for patients with newly diagnosed acute graft-versus-host disease (GVHD). Steroids may help to block or minimize the donor cells' attack on the patient's organs and reduce inflammation.

Although steroid treatment is successful for some patients, others do not respond initially or do not fully respond. This is known as ***steroid-refractory*** acute GVHD. These patients may need other therapies to treat their condition.

Please see Important Safety Information beginning on page 12 and click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.



What is Jakafi® (ruxolitinib)?

Jakafi (JAK-ah-fye), also known as ruxolitinib, is a prescription medicine available as a pill. It is used to treat adults and children 12 years of age and older with acute graft-versus-host disease (GVHD) who have taken corticosteroids and they did not work well enough.

Jakafi is the *first prescription medicine approved by the FDA* for the treatment of these patients.

How does Jakafi work?

Proteins known as ***Janus kinases***, or JAKs, are involved in multiple steps leading to inflammation and related issues in acute GVHD. Jakafi helps to reduce the activity of JAKs.

Jakafi may also help to decrease the level of proteins called cytokines. Cytokines contribute to inflammation and the attack on the host's organs by the cells transplanted from the donor.

What is a clinical trial?

In order to better understand how medicines work and what side effects they may cause, researchers perform clinical trials in which patients with a disease often receive a medicine and researchers observe the results.

Was there a clinical trial with Jakafi in acute GVHD?

Yes, Jakafi was studied in a clinical trial in patients with acute GVHD who had taken steroids and they did not work well enough.

Please see Important Safety Information beginning on page 12 and click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

Who was included in the clinical trial of Jakafi® (ruxolitinib) for aGVHD?

71 patients with **acute graft-versus-host disease (GVHD)** who were not responding well to steroids with or without other medicines that suppress the immune system were enrolled in the clinical trial for Jakafi. All patients were treated with Jakafi.

49 patients who had not responded to steroid treatment *alone* ***(steroid-refractory acute GVHD)*** were evaluated to see how well treatment worked.

What else should I know about these 49 patients?

- Patients had moderate to severe acute GVHD with about 73% (36 patients) having **severe disease**
- Acute GVHD affected **at least 2 organs** in about 55% (27 patients)
- In addition to steroids, 96% (47 patients) were receiving other medications that suppress the immune system
- Average age of patients was 57 years

Important Safety Considerations

Jakafi® (ruxolitinib) can cause serious side effects including low blood counts and infection. Some people who take Jakafi have developed certain types of non-melanoma skin cancers. Increases in blood cholesterol levels can also occur. In patients who took another JAK inhibitor to treat rheumatoid arthritis, there was an increased risk of potentially fatal cardiovascular events like heart attack or stroke in patients with risk factors for these events who smoke now or smoked in the past, as well as an increased risk of blood clots in legs or lungs and new (secondary) cancers like lymphoma, especially in patients who smoke now or smoked in the past. The most common side effects of Jakafi for acute GVHD include: low platelet counts, low red or white blood cell counts, infections, and swelling. Call your doctor for medical advice about side effects.

How was response to Jakafi defined?

Response was measured at 1 month (the 28th day of treatment) and meant either:

- Complete resolution of signs and symptoms of acute GVHD or
- At least some improvement in skin, gastrointestinal tract, or liver signs and symptoms, without worsening or new symptoms in another organ

Possible benefits of Jakafi

28 of 49 patients
who had not responded to steroid treatment alone
had a response at 1 month

About 68% of those who responded (19 of 28 patients) did so **within 7 days**

In a separate evaluation: About 47% of patients (14 of 30) who were still receiving both steroids and Jakafi at 1 month had their steroid dose **reduced by 50% or more**

Your results with Jakafi may vary. **Talk to your Transplant Team** about any questions you have.

Important Safety Considerations (cont)

To learn more about these and other risks, please read the Important Safety Information beginning on page 12 and click here for Full Prescribing Information.

IMPORTANT SAFETY INFORMATION

What important safety information do I need to know?

Jakafi can cause serious side effects, including:

Low blood counts: Jakafi® (ruxolitinib) may cause low platelet, red blood cell, and white blood cell counts. If you develop bleeding, stop taking Jakafi and call your healthcare provider. Your healthcare provider will do a blood test to check your blood counts before you start Jakafi and regularly during your treatment. Your healthcare provider may change your dose of Jakafi or stop your treatment based on the results of your blood tests. Tell your healthcare provider right away if you develop or have worsening symptoms such as unusual bleeding, bruising, tiredness, shortness of breath, or a fever.

Infection: You may be at risk for developing a serious infection during treatment with Jakafi. Tell your healthcare provider if you develop any of the following symptoms of infection: chills, nausea, vomiting, aches, weakness, fever, painful skin rash or blisters.

Cancer: Some people have had certain types of non-melanoma skin cancers during treatment with Jakafi. Your healthcare provider will regularly check your skin during your treatment with Jakafi. Tell your healthcare provider if you develop any new or changing skin lesions during treatment with Jakafi.

Increases in cholesterol: You may have changes in your blood cholesterol levels during treatment with Jakafi. Your healthcare provider will do blood tests to check your cholesterol levels about every 8 to 12 weeks after you start taking Jakafi, and as needed.

Increased risk of major cardiovascular events such as heart attack, stroke or death in people who have cardiovascular risk factors and who are current or past smokers while using another JAK inhibitor to treat rheumatoid arthritis: Get emergency help right away if you have any symptoms of a heart attack or stroke while taking Jakafi, including: discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back, severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw, pain or discomfort in your arms, back, neck, jaw, or stomach, shortness of breath with or without chest discomfort, breaking out in a cold sweat, nausea or vomiting, feeling lightheaded, weakness in one part or on one side of your body, slurred speech

Increased risk of blood clots: Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) have happened in people taking another JAK inhibitor for rheumatoid arthritis and may be life-threatening. Tell your healthcare provider right away if you have any signs and symptoms of blood clots during treatment with Jakafi, including: swelling, pain, or tenderness in one or both legs, sudden, unexplained chest or upper back pain, shortness of breath or difficulty breathing

Possible increased risk of new (secondary) cancers: People who take another JAK inhibitor for rheumatoid arthritis have an increased risk of new (secondary) cancers, including lymphoma and other cancers. People who smoke or who smoked in the past have an added risk of new cancers.

The most common side effects of Jakafi include: for certain types of myelofibrosis (MF) and polycythemia vera (PV) – low platelet or red blood cell counts, bruising, dizziness, headache, and diarrhea; for acute GVHD – low platelet counts, low red or white blood cell counts, infections, and swelling; and for chronic GVHD – low red blood cell or platelet counts and infections including viral infections.

These are not all the possible side effects of Jakafi. Ask your pharmacist or healthcare provider for more information. Call your doctor for medical advice about side effects.

Before taking Jakafi, tell your healthcare provider about: all the medications, vitamins, and herbal supplements you are taking and all your medical conditions, including if you have an infection, have or had low white or red blood cell counts, have or had tuberculosis (TB) or have been in close contact with someone who has TB, had shingles (herpes zoster), have or had hepatitis B, have or had liver or kidney problems, are on dialysis, have high cholesterol or triglycerides, had cancer, are a current or past smoker, had a blood clot, heart attack, other heart problems or stroke, or have any other medical condition. Take Jakafi exactly as your healthcare provider tells you. Do not change your dose or stop taking Jakafi without first talking to your healthcare provider.

Women should not take Jakafi while pregnant or planning to become pregnant. Do not breastfeed during treatment with Jakafi and for 2 weeks after the final dose.

Please click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit **www.fda.gov/medwatch**, or call **1-800-FDA-1088**.

You may also report side effects to Incyte Medical Information at 1-855-463-3463.

What should you tell your Transplant Team before taking Jakafi® (ruxolitinib)?

Before taking Jakafi, tell your Transplant Team about all the medicines you take, including vitamins and herbal supplements, and especially medicines for fungal or bacterial infections or HIV/AIDS. Taking Jakafi with certain other medicines may affect how Jakafi works.

Tell your Transplant Team about all your medical conditions, including if you have an infection or if you have or ever had tuberculosis (or been in close contact with someone who has it), hepatitis B, liver or kidney problems, skin cancer, or high cholesterol or triglycerides, or if you are on dialysis (Jakafi should be taken after your dialysis).

You should also tell your Transplant Team if you are pregnant or planning to become pregnant, or if breastfeeding.

Helpful hint:

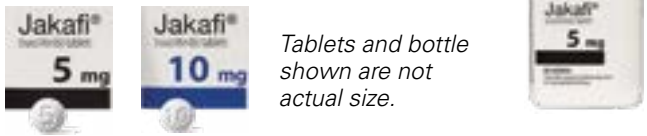
It's important for you or your caregiver to keep track of the various medicines that you take and discuss them with your various Healthcare Professionals. Consider using the fold-out Medicine Diary inside this brochure to record all prescription and over-the-counter medicines, vitamins, and natural/herbal supplements that you are taking.

How will I get Jakafi?

If you are in the hospital, your care team will provide Jakafi for you. If you're at home, Jakafi will come to you from a specialty or mail order pharmacy. You will not be able to pick up Jakafi at a local pharmacy. It is important to let your local pharmacist know that you are taking Jakafi and also important to tell the specialty pharmacy about any other medicines, vitamins, and supplements you are taking. That way, your pharmacists can help you avoid any possible interactions between drugs.

What dose should I take?

Take only the dose of Jakafi your Healthcare Professional prescribes, following your Healthcare Professional's instructions.



Tablets and bottle shown are not actual size.

The recommended starting dose for most patients with acute graft-versus-host disease is 5 mg taken by mouth twice a day.

Your Healthcare Professional will determine the appropriate dose of Jakafi for you by taking several factors into account, including:

- Results of your blood work, including liver function test
- Other medical conditions you may have
- Other medications you may be taking

Depending on these criteria, your Healthcare Professional may change your dose or have you stop taking Jakafi at some point. Do not change your dose or stop taking Jakafi without first talking to your Healthcare Professional. However, if you start bleeding, stop taking Jakafi and call your Healthcare Professional immediately.

It is important to take the dose you were prescribed and as often as prescribed. If you miss a dose of Jakafi, take your next dose as scheduled. **Do not take an additional dose**.

If you take more than the prescribed dose, call your Healthcare Professional or go to the nearest hospital emergency department right away. Take the bottle of Jakafi with you.

How do I take Jakafi® (ruxolitinib)?

Take Jakafi exactly as your Healthcare Professional tells you. It is important to take Jakafi as prescribed.

In certain cases, your Healthcare Professional **may start you at a lower dose, temporarily reduce your dose of Jakafi, or interrupt or stop your dose**. Always follow your Healthcare Professional's directions.

It is important to take your medicine at about the same time each day. It may help you remember to take your Jakafi if you take it at the same time as you perform another daily activity, like brushing your teeth.

You can take Jakafi **with or without food**.

How will my Healthcare Professional monitor me while I'm taking Jakafi?

Before you start treatment, and periodically during treatment, your Healthcare Professional may perform a blood test called a ***complete blood count***.

Your Healthcare Professional may also perform a blood test of your liver function.

The results of these tests can help your Healthcare Professional:

- **Monitor your blood counts and liver function** during treatment
- **Adjust your dose of Jakafi**, if necessary (most dosage adjustments will happen in the first couple of months but could happen any time during treatment)

Your Healthcare Professional may monitor your blood cholesterol levels, as you may have changes in these levels during your treatment with Jakafi.

Your Healthcare Professional may also perform regular physical examinations, update your medical history, or ask if you are taking any new medicines.

Do not stop taking Jakafi without speaking with your Healthcare Professional. However, if you start bleeding, stop taking Jakafi and call your Healthcare Professional immediately.

Talking with your Transplant Team

It is important for you and your caregiver to talk to your Transplant Team about how you are feeling and how your condition is affecting you, even if you're not sure that how you are feeling is caused by your condition. Talking to your Transplant Team helps you both:

- Understand how your condition is affecting you
- Follow how your condition is changing over time
- Discuss options for managing your condition

Helpful hint:

The fold-out Medicine Diary, inside this brochure, lets you record your daily doses of medicine and also provides space for listing your various Healthcare Professionals and their contact information—so everything is in one handy place for you and your caregiver.

How long will I need to take Jakafi® (ruxolitinib)?

How long you continue to take Jakafi depends on your unique situation and how you and your Healthcare Professional decide to move your treatment forward.

After you've been taking Jakafi for 6 months, and if you've stopped taking your steroids, your Healthcare Professional may begin to gradually lower your Jakafi dose—assuming any signs or symptoms of acute graft-versus-host disease (GVHD) do not return or get worse during this lowering. If signs or symptoms of acute GVHD do return or get worse during this time, your Healthcare Professional can increase your dose of Jakafi again.

Do not stop taking Jakafi without speaking with your Healthcare Professional. However, if you start bleeding, stop taking Jakafi and call your Healthcare Professional immediately.

Helpful hint:

If you or your loved ones need additional support, our IncyteCARES representatives can help connect you with counseling, financial, and other helpful resources. See **pages 22–23** for information.

Please see Important Safety Information beginning on page 12 and click here for Full Prescribing Information, which includes a more complete discussion of the risks associated with Jakafi.

My Medicine Diary

Staying on track with your medicines after stem cell transplant can be challenging. This **Medicine Diary** is meant to help. It gives you a handy place to write down all your medicines and check them off as you take them each day—so you're less likely to forget.

Consider bringing your Medicine Diary to your healthcare appointments to share and discuss with your various Healthcare Professionals.

Following your healthcare team's recommendations is the **best way to keep moving forward** after transplant.

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OPEN HERE

My Healthcare Team

Name: _____
Specialty: _____
Phone: _____
Email: _____

Name: _____
Specialty: _____
Phone: _____
Email: _____

Name: _____
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Specialty: _____
Phone: _____
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One Day at a Time

List all your medicines once. Then check off your doses as you take them each day following your prescribing Healthcare Professionals' instructions.

Example:

Medication	Medicine 1	Medicine 2	
Dose	100 mg, 2x/day	75 mg, 4x/day	
Date 12/2/19	x x	x x x x	

Be sure to talk with your prescribing Healthcare Professional if you have trouble taking your medicine or have missed doses.

Download more schedules online at **JakafiMedicineDiary.com**

Medication															
Dose															
Date															

IncyteCARES for Jakafi: Helping You With Access and Support

An Assistance and Support Program for Patients Prescribed Jakafi® (ruxolitinib)

Coverage Verification
We can check with a patient's insurance plan about their coverage for Jakafi and any out-of-pocket costs required.

Insurance Assistance
We can help patients understand how their insurance plan works. We can also offer information about prior authorization requirements and appealing insurance denials or restrictions.

Delivery Coordination
We can arrange to have the patient's prescription for Jakafi filled by an approved specialty pharmacy and delivered directly to either the patient's home or Healthcare Professional's office.

Savings Program
For patients with commercial prescription drug coverage—eligible patients pay as little as $0 per month, subject to certain limits.*

Patient Assistance Program (PAP)
Free product is offered to eligible patients who are uninsured or underinsured for Jakafi.†

Temporary Coverage
For insurance coverage delays, eligible patients can receive a free short-term supply of Jakafi.†

*Amount of savings for the purchase of Jakafi will not exceed $11,977 per month and $25,000 per year. Uninsured, cash-paying patients are not eligible. Not valid for patients insured through Medicare Part D, Medicare Advantage, Medicaid, and TRICARE or any state medical or pharmaceutical assistance program. Valid prescription for Jakafi for an FDA-approved indication is required. Please see complete **Terms and Conditions** or call IncyteCARES. Update effective as of January 1, 2021.

†Terms, conditions, and additional eligibility criteria apply. Valid prescription for Jakafi for an FDA-approved indication is required. Patients insured through Medicare, Medicaid, and TRICARE, or a state medical assistance program, are not eligible. Free product is offered to eligible patients without any purchase contingency or other obligation.

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Patient Education and Support

Through our call center, IncyteCARES for Jakafi representatives can answer patient and caregiver questions about graft-versus-host disease and Jakafi.

Connection to Other Support Services

For patients who need additional support beyond what we can provide directly, IncyteCARES for Jakafi can offer information about other independent organizations that may be able to help.

Connect with IncyteCARES for Jakafi today!

Call **1-855-452-5234**
Monday through Friday,
8 AM–8 PM ET

Learn more at
IncyteCARES.com/Jakafi

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For more information about Jakafi,
visit **UnderstandingJakafi.com**