

The treatment journey for Ph+ CML in chronic phase can be:

**ANYTHING BUT
A STRAIGHT LINE**



If your journey with Ph+ CML in chronic phase has had its ups and downs, ask your doctor about SCEMBLIX

Some people do not do as well as others on medication for Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Their body may not respond to treatment. Or side effects may become unmanageable.

If this sounds like your journey, ask your doctor if SCEMBLIX may be right for you.

Who is SCEMBLIX for?

SCEMBLIX is a prescription medicine used to treat adults with:

- ▶ Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs)
- ▶ Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.

Be your own advocate – talk with your doctor

If your experience with Ph+ CML in chronic phase has been anything but a straight line, let your doctor know your concerns. By being your own advocate, you can work with your doctor to determine whether SCEMBLIX may be right for you.

To learn more, visit www.scemblix.com

IMPORTANT SAFETY INFORMATION for SCEMBLIX

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you:

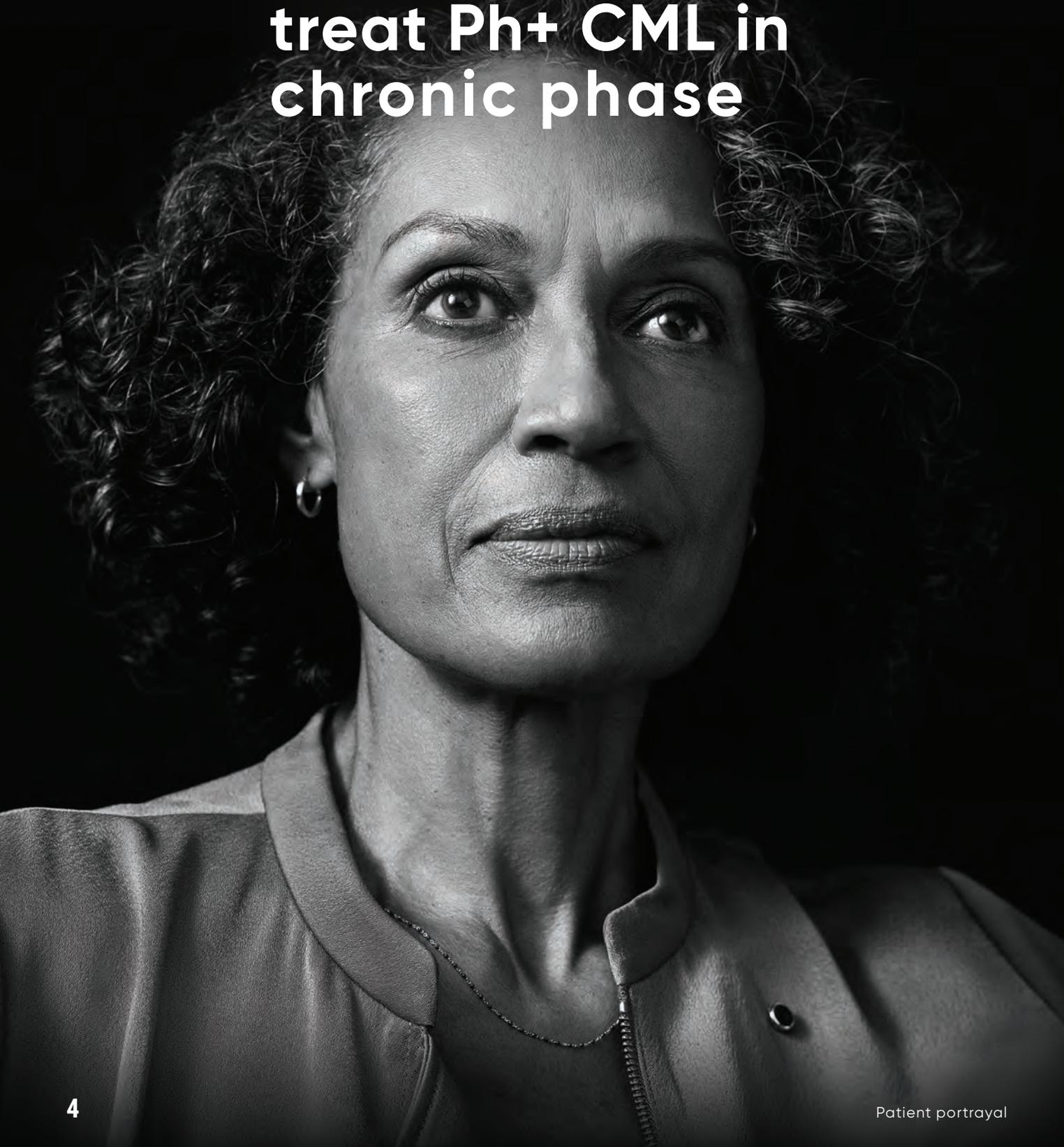
- ▶ have a history of inflammation of your pancreas (pancreatitis)
- ▶ have a history of heart problems or blood clots in your arteries and veins (types of blood vessels)
- ▶ are pregnant or plan to become pregnant. SCEMBLIX can harm your unborn baby
 - Your doctor will do a pregnancy test before you start treatment with SCEMBLIX
 - **Females** who are able to become pregnant should use effective birth control during treatment and for 1 week after your last dose of SCEMBLIX. Talk to your doctor about birth control methods that may be right for you
 - Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with SCEMBLIX
- ▶ are breastfeeding or plan to breastfeed. It is not known if SCEMBLIX passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of SCEMBLIX

Tell your doctor about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. SCEMBLIX and other medicines may affect each other and cause side effects.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

 **SCEMBLIX**[®]
(asciminib) 20 mg, 40 mg tablets

SCEMBLIX is FDA approved to treat Ph+ CML in chronic phase



FDA approved

SCEMBLIX was approved by the Food and Drug Administration (FDA) in 2021 to treat adults with:

- ▼ Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs)
- ▼ Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.



Proven effective

In clinical studies, SCEMBLIX has been shown to be an effective treatment option.

See pages 16 through 25 to learn more.



Savings options for those who have been prescribed SCEMBLIX

Learn about co-pay savings for eligible patients and how new patients starting on SCEMBLIX can receive up to a free 30-day supply. See page 41.

SCEMBLIX CONNEX

SCEMBLIX Connex patient support program

If your doctor prescribes SCEMBLIX, you can sign up for support from SCEMBLIX Connex. You'll receive information about Ph+ CML in chronic phase, financial resources, and materials to help you stay on track. See page 42 to learn more. To sign up, go to www.scemblix-support.com

IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

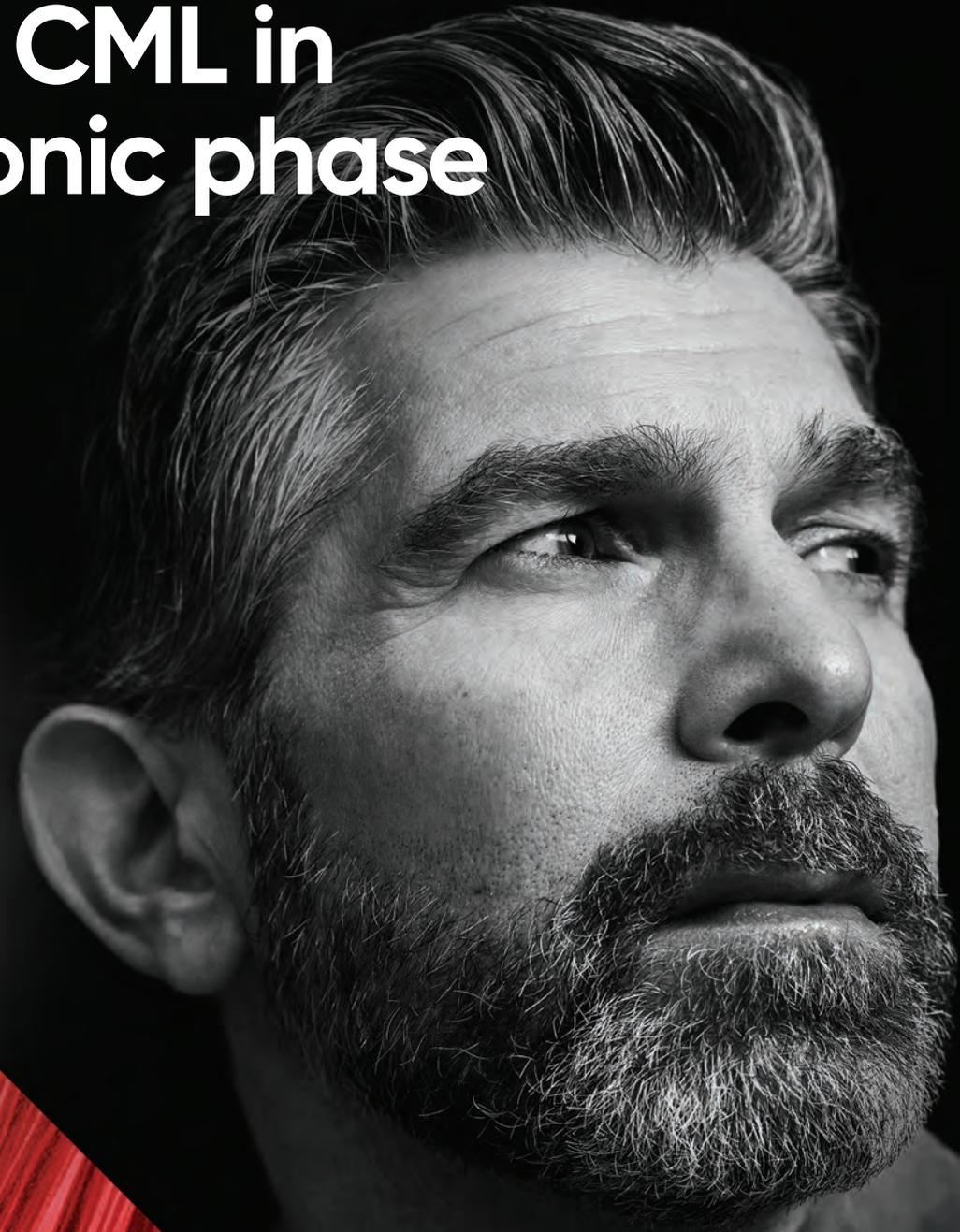
SCEMBLIX may cause serious side effects, including:

- ▼ **Low blood cell counts:** SCEMBLIX may cause low platelet counts (thrombocytopenia), low white blood cell counts (neutropenia), and low red blood cell counts (anemia). Your doctor will do blood tests to check your blood cell counts every 2 weeks for the first 3 months of treatment and then monthly or as needed during treatment with SCEMBLIX. Tell your doctor right away if you have unexpected bleeding or easy bruising, blood in your urine or stools, fever, or any signs of an infection

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

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Understanding Ph+ CML in chronic phase



Learn about the disease, mutations, and milestones

This section provides:

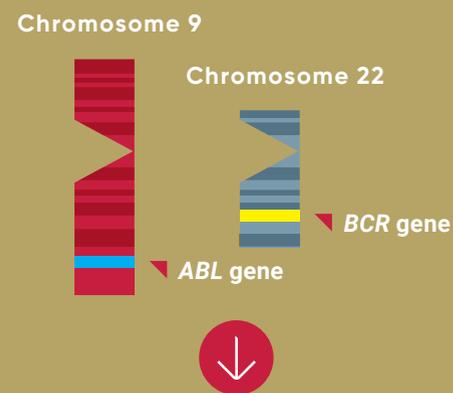
- ▶ A brief overview of Ph+ CML in chronic phase
- ▶ Information about drug resistance and mutations
- ▶ Background on treatment goals that you can discuss with your doctor

Information about Ph+ CML in chronic phase that you may find helpful

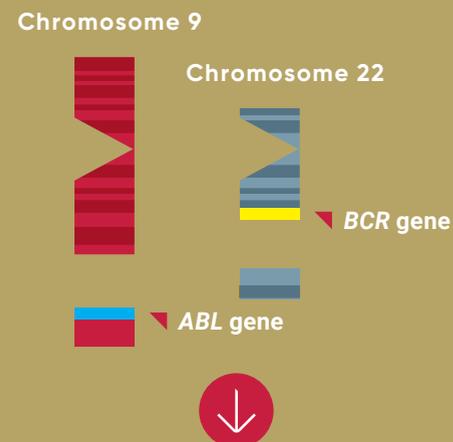


A swap between chromosomes 9 and 22 creates the Ph chromosome

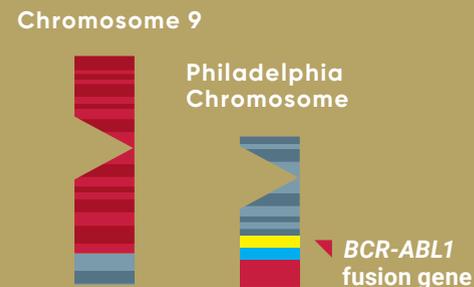
Normal Chromosomes



Chromosomes Break



Chromosomes Change



Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

Even if you've been living with Ph+ CML for a while, it's still helpful to understand the biology behind the disease and what's happening in your body.

What causes Ph+ CML?

Ph+ CML is caused by an abnormal fusion gene called *BCR-ABL1*. It is the result of pieces of 2 chromosomes in the body trading places (as shown in the illustration at the left).

Here's a brief overview:

- ▼ Each cell in the human body has 23 pairs of chromosomes
- ▼ In Ph+ CML, pieces from chromosomes 9 and 22 break off and swap places
- ▼ This can create a new abnormal chromosome known as the Philadelphia (Ph) chromosome
- ▼ The Ph chromosome creates the abnormal *BCR-ABL1* fusion gene
- ▼ This abnormal gene then produces an abnormal protein called BCR-ABL

See the following pages for more details about Ph+ CML.

Learn more at www.scemblix.com



What's going on inside your body?



Ph+ CML affects your bone marrow and your blood. Your bone marrow is a sponge-like tissue in the center of most of your bones.

Here's what happens in the bone marrow:

- ▼ The BCR-ABL protein sends too many signals to the bone marrow
- ▼ The bone marrow starts creating too many immature white blood cells (commonly referred to as blast cells)
- ▼ These cells, which your doctor may call leukemic cells, grow abnormally and do not become healthy white blood cells
- ▼ The leukemic cells start to grow and divide and build up in the bone marrow, crowding out red blood cells and platelets

Here's what happens in the bloodstream:

- ▼ As the bone marrow becomes overcrowded with leukemic cells, these cells move into the bloodstream
- ▼ Over time, the leukemic cells crowd out healthy red blood cells, white blood cells, and platelets
- ▼ This can lead to serious health problems, including, but not limited to, a greater risk of infections, as well as anemia, bruising easily, and bleeding that takes longer to stop

Doctors categorize the disease in phases instead of stages

While many types of cancer are categorized into stages, doctors assign 1 of 3 phases to Ph+ CML:

- ▼ **Chronic phase:** The first phase of Ph+ CML, when the number of white blood cells is higher than normal. Most adults are diagnosed in chronic phase
- ▼ **Accelerated phase:** The second phase of Ph+ CML, in which the number of immature white blood cells in the blood and bone marrow may increase rapidly
- ▼ **Blast phase:** The third and final phase of Ph+ CML. This phase has the highest number of immature blood cells in the blood and bone marrow

If you haven't responded to 2 or more medications for Ph+ CML in chronic phase, **see pages 18–21.**



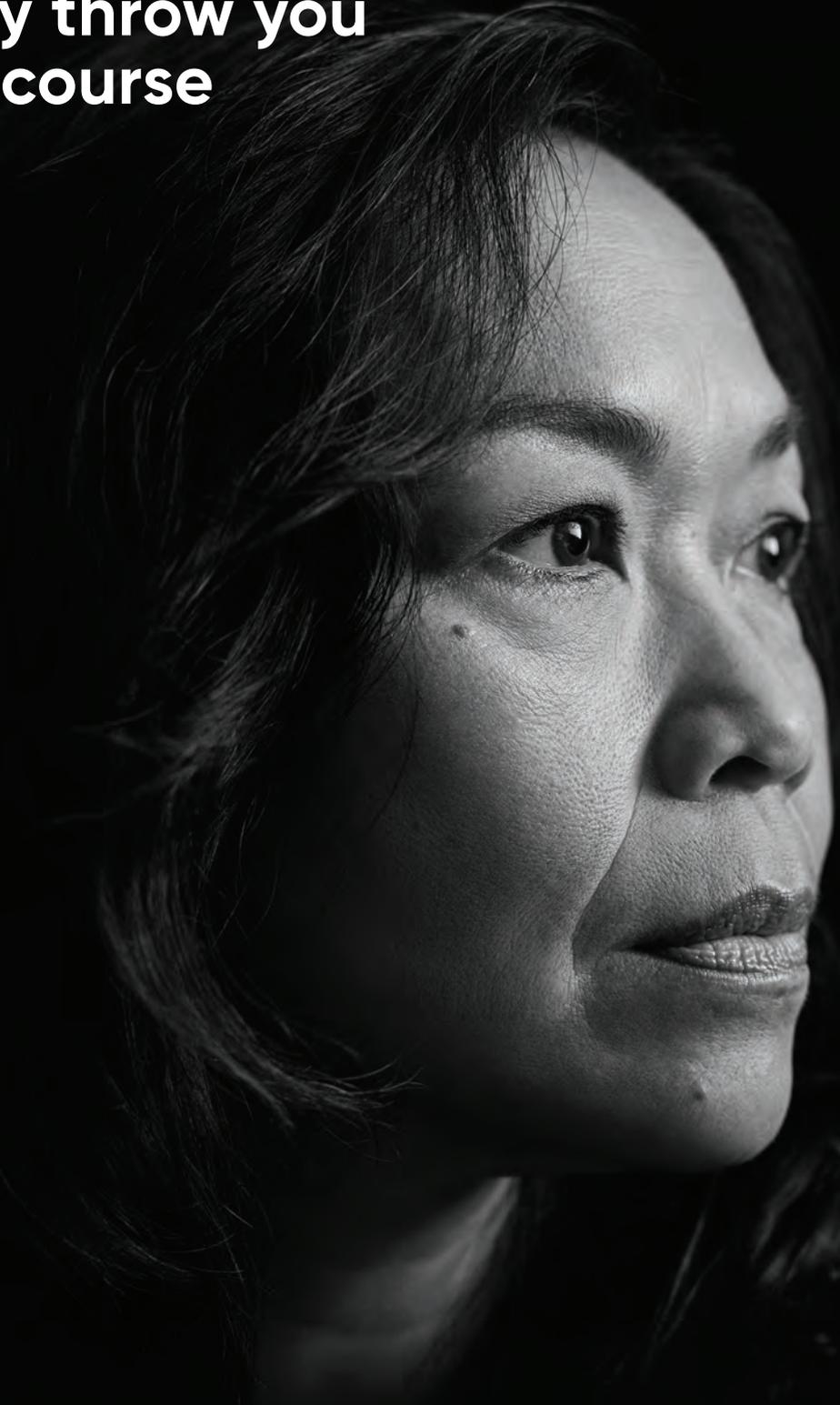
Take an active role in learning about Ph+ CML

The more you know about your disease, the better you may be able to communicate with your doctor. In addition to reviewing this brochure, **see page 45** to find contact information for a wide range of advocacy groups that support patients with Ph+ CML.

Learn more at
www.scemblix.com



A gene mutation may throw you off course



Some patients with Ph+ CML in chronic phase can develop what's known as a gene mutation. A mutation is a change in the DNA of a cell.

Mutations may cause drug resistance

One of the goals of treatment for Ph+ CML in chronic phase is to see the number of leukemic cells in the blood go down. That may not happen for some people.

If the number of leukemic cells in your body starts going up instead of decreasing, your doctor may want to see if you have become resistant to your medication. This is often called "drug resistance." It occurs when cancer cells are not responding to a medication.

There are 2 types of drug resistance:

- ▼ **Lack of response, also called primary drug resistance:** The body **does not respond** to a medication
- ▼ **Secondary drug resistance:** Over time, the body **stops responding** to a medication

Testing for a mutation in the *BCR-ABL1* gene

In Ph+ CML in chronic phase, one of the causes of resistance is a mutation in the *BCR-ABL1* gene.

To determine if you have a mutation, your doctor may order a *BCR-ABL1* kinase domain mutation analysis. This test looks for mutations in the *BCR-ABL1* gene that may cause certain tyrosine kinase inhibitors (TKIs) that treat Ph+ CML in chronic phase to stop working.

Identifying the T315I gene mutation

There are a number of different gene mutations that can occur in Ph+ CML in chronic phase, including a mutation called T315I. The only way to determine if you have a mutation is to undergo a *BCR-ABL1* kinase domain mutation analysis. If this test shows that you have developed the T315I mutation, your doctor may consider whether to change your medication.

To learn about a treatment for those who have Ph+ CML in chronic phase with the T315I mutation, **see pages 22–25**.



Can you become resistant to your medication?

Over time, some people may stop responding to their medication for Ph+ CML in chronic phase. This may be caused by a gene mutation. If you aren't seeing the results you had hoped for, ask your doctor if you should be tested for a gene mutation.

Learn more at www.scemblix.com



Side effects or drug resistance can make for a rocky journey

Some patients struggle with unmanageable side effects

For some people, the journey with Ph+ CML in chronic phase can have its ups and downs. That can be because **side effects** become unmanageable, which can make it difficult to stay on track with treatment.

Once you start on medication, it's important to maintain an open conversation with your doctor. If you're having trouble managing your side effects, don't stay silent.

While some people deal with side effects, others may experience **drug resistance**. This is when your body does not respond to a medication or may stop responding to a medication.

Work closely with your doctor to set treatment goals and understand key milestones.



Did you know?

More than 1 of every 2 patients (up to 55%) with Ph+ CML in chronic phase who had been treated with 2 prior tyrosine kinase inhibitors (TKIs) could not tolerate the side effects of one of their previous medications.*

*Specific to a clinical study where 60 patients with Ph+ CML in chronic phase or Ph+ CML in accelerated phase were treated with 2 prior TKIs.

Common treatment goals

You'll want to ask your doctor about treatment goals that may be within your reach. Some common goals include:

- ▼ Reducing the number of leukemic cells in your body
- ▼ Lowering the amount of BCR-ABL protein in your body; your doctor may refer to this as a molecular response

Measuring response

To help determine if you are responding to your medication, your doctor will have you go for blood tests on a regular basis. Your results can help your doctor determine whether you are reaching treatment milestones.

Of course, not every patient will reach the following treatment milestones.

Treatment milestones

Blood tests will be used by your doctor to measure your response to treatment. Your doctor will consider your starting point (also called a baseline) as *BCR-ABL1* 100%. This means that 100 out of 100 cells have the *BCR-ABL1* gene.

Milestones your doctor may discuss:

Complete cytogenetic response (CCyR)

A cytogenetic response measures your chromosomes.

- ▼ Tests show there are no Ph+ cells in the bone marrow
- ▼ This means that the amount of *BCR-ABL1* is $\leq 1\%$ of all the cells in your blood
- ▼ Think of that as 1 out of every 100 cells having the *BCR-ABL1* gene compared with baseline

Major molecular response (MMR)

- ▼ Tests show that the amount of *BCR-ABL1* in the blood is $\leq 0.1\%$
- ▼ Think of that as 1 out of every 1000 cells having the *BCR-ABL1* gene compared with baseline

What if you're not reaching your milestones?

If you're not responding to your medication, it's important to be your own advocate and talk with your doctor. A good starting point is to ask about your blood tests and what your results mean.

Based on your blood work, your doctor may decide it's time to switch to another medication. It's also possible that you may have developed a gene mutation, which your doctor can determine by ordering a *BCR-ABL1* kinase domain mutation analysis.

To learn about an FDA-approved treatment option, review the following pages.



Speak up about side effects

If side effects of your current medication have become bothersome, talk with your doctor. Make your doctor aware and see if it's time to consider another option.

About SCEMBLIX

Approved Uses for SCEMBLIX

SCEMBLIX is a prescription medicine used to treat adults with:

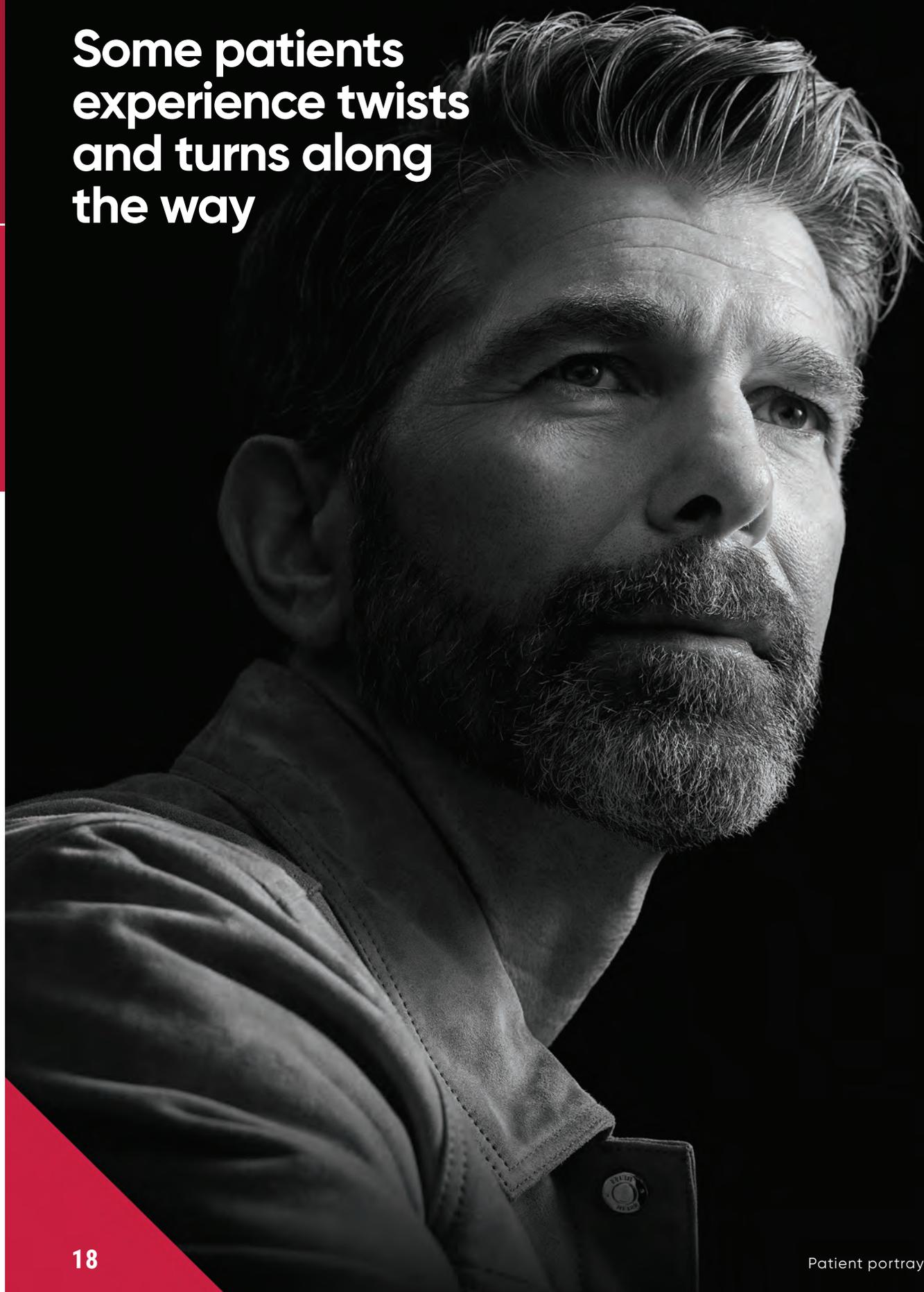
- ▶ Philadelphia chromosome – positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs)
- ▶ Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

 **SCEMBLIX**[®]
(asciminib) 20 mg, 40 mg tablets

Some patients experience twists and turns along the way



Has your doctor had to switch you from one tyrosine kinase inhibitor (TKI) for Ph+ CML in chronic phase to another? And another? And perhaps yet another still?

Your doctor may have made the switch because you did not respond to treatment. Or side effects became unmanageable. If this sounds all-too-familiar, it may be time to ask your doctor about SCEMBLIX.

Who is SCEMBLIX for?

SCEMBLIX is a prescription medicine used to treat adults with Ph+ CML in chronic phase, previously treated with 2 or more TKIs.

It is not known if SCEMBLIX is safe and effective in children.

Struggling with drug resistance or unmanageable side effects?

For some people, the journey with Ph+ CML in chronic phase can have its ups and downs. That can be for a number of reasons:

- ▼ **Your body does not respond** to a medication, which is known as primary drug resistance
- ▼ **Your body stops responding** to a medication, referred to as secondary drug resistance
- ▼ **Side effects become unmanageable**, which can make it difficult to stay on track

Don't keep concerns to yourself

If you're not seeing results from your current medication, speak up and let your doctor know.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

SCEMBLIX may cause serious side effects, including:

- ▼ **Pancreas problems:** SCEMBLIX may increase enzymes in your blood called amylase and lipase, which may be a sign of pancreatitis. Your doctor may do blood tests monthly or as needed during treatment with SCEMBLIX to check for problems with your pancreas. Tell your doctor right away if you have sudden stomach-area pain or discomfort, nausea, or vomiting



How many TKIs have you taken?

If you've taken 2, 3, 4 or more medications for Ph+ CML in chronic phase and are experiencing drug resistance or unmanageable side effects, it may be time to ask your doctor about SCEMBLIX. The medication is thought to work by binding to a different site on the abnormal protein than other medications that treat Ph+ CML in chronic phase. To learn more, see the clinical results on **pages 20–21**.

Download the Doctor Discussion Guide at www.scemblix-resources.com



Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

SCEMBLIX[®]
(asciminib) 20 mg, 40 mg tablets

More patients achieved MMR with SCEMBLIX than with Bosulif

Nearly twice as many patients achieved a major molecular response (MMR) at 24 weeks

SCEMBLIX is the first treatment for Ph+ CML in chronic phase to show superior efficacy, such as response rates, vs Bosulif® (bosutinib)* in a clinical trial.

In a clinical study among those who did not respond to or did not tolerate 2 or more prior TKIs for Ph+ CML in chronic phase:

- Nearly twice as many patients achieved MMR with SCEMBLIX at 24 weeks than with Bosulif. The results were 25% for SCEMBLIX (40 of 157 patients) vs 13% for Bosulif (10 of 76 patients)

In the same clinical study among patients with Ph+ CML in chronic phase who were previously treated with 2 or more TKIs:

- More than twice as many patients achieved MMR with SCEMBLIX at nearly 2 years (96 weeks) than with Bosulif. The results were 38% for SCEMBLIX (59 of 157 patients) vs 16% for Bosulif (12 of 76 patients)

Nearly **4 out of 10** patients achieved MMR at 96 weeks with SCEMBLIX

In this clinical trial, the most common side effects reported (≥20%) with SCEMBLIX were nose/throat infections; pain in the muscles, bones, or joints; headache; and tiredness.

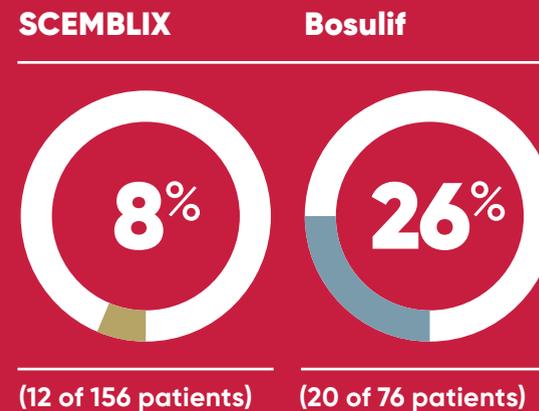
Nearly 2x as many patients achieved MMR at 24 weeks with SCEMBLIX than with Bosulif

* Bosulif is a registered trademark of Pfizer Inc.

Three times fewer SCEMBLIX patients stopped treatment due to side effects

More patients taking SCEMBLIX were able to continue their treatment than those taking Bosulif. After nearly 2 years (96 weeks), 26% of patients taking Bosulif (20 of 76 patients) had to stop taking their medication due to side effects compared to only 8% of those taking SCEMBLIX (12 of 156 patients).

Those who had to stop treatment at nearly 2 years due to side effects



How SCEMBLIX works

SCEMBLIX is the first and only TKI that is thought to bind to a different site within the abnormal protein that causes Ph+ CML in chronic phase. Your doctor may call this the myristoyl pocket. Learn more at www.scemblix.com

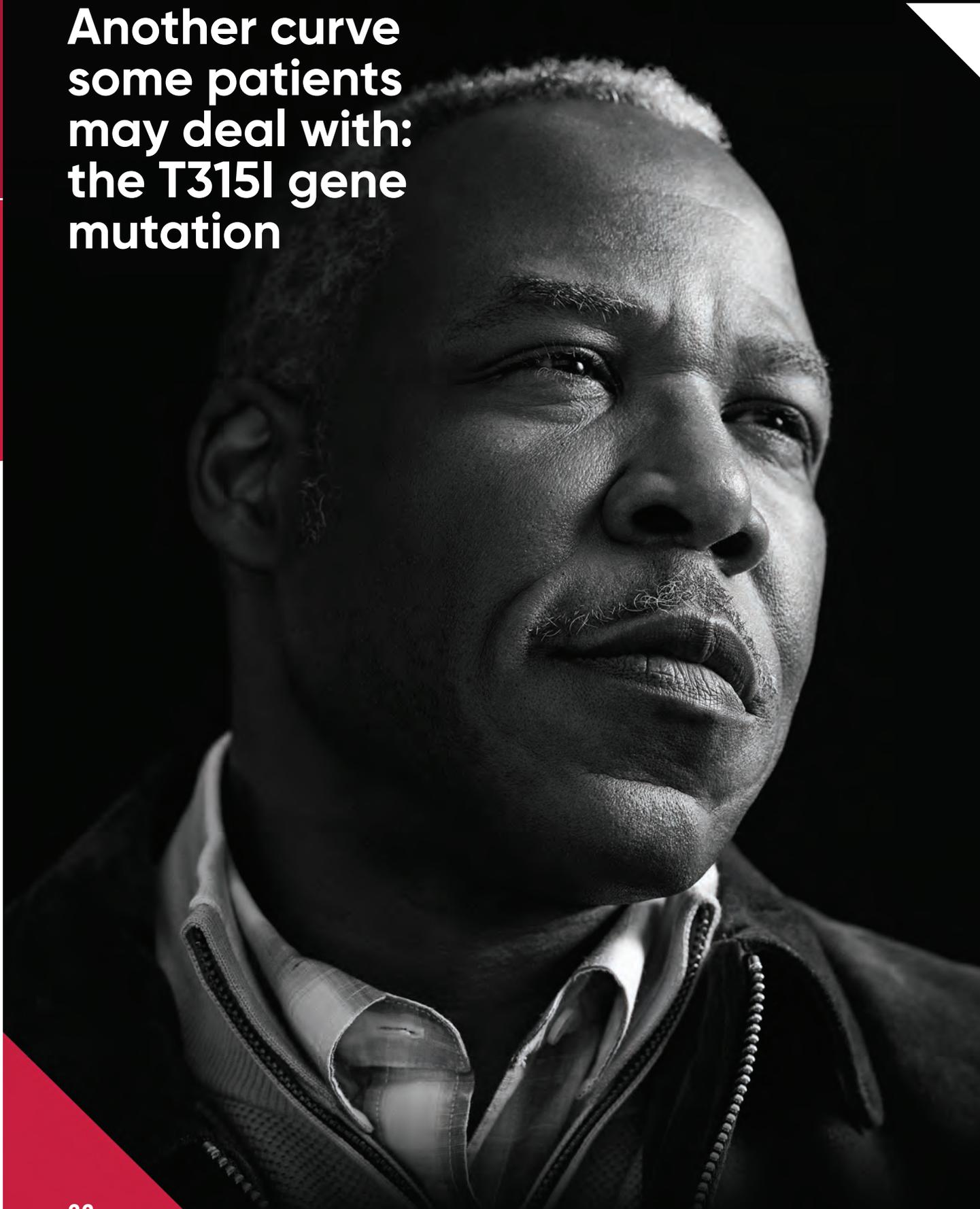
Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

SCEMBLIX may cause serious side effects, including:

- High blood pressure:** Your doctor may check your blood pressure and treat any high blood pressure during treatment with SCEMBLIX as needed. Tell your doctor if you develop elevated blood pressure or symptoms of high blood pressure including confusion, headaches, dizziness, chest pain, or shortness of breath
- Allergic reaction:** Stop taking SCEMBLIX and get medical help right away if you get any signs or symptoms of an allergic reaction, including:
 - trouble breathing or swallowing
 - swelling of the face, lips, or tongue
 - skin rash or flushing of your skin
 - feeling dizzy or faint
 - fever
 - fast heartbeat

Another curve some patients may deal with: the T315I gene mutation



Patient portrayal



Some people with Ph+ CML in chronic phase develop a gene mutation known as T315I. This mutation can cause resistance to some medications.

Who is SCEMBLIX for?

SCEMBLIX is a prescription medicine used to treat adults with Ph+ CML in chronic phase with the T315I mutation.

It is not known if SCEMBLIX is safe and effective in children.

Testing can identify if you have a gene mutation

If you're not responding to your current medication for Ph+ CML in chronic phase, you may want to ask your doctor if you should be tested for what's called a gene mutation.

A gene mutation is a change in a cell's DNA. With Ph+ CML in chronic phase, a mutation may develop that prevents certain tyrosine kinase inhibitors (TKIs) from working. One of these mutations is called the T315I gene mutation.

To find out if you have the T315I mutation, your doctor will need to order a test called the *BCR-ABL1* kinase domain mutation analysis. This test can identify mutations in the *BCR-ABL1* gene that may cause you to become resistant to certain medications that treat Ph+ CML in chronic phase.

Your doctor may decide to have you tested for a gene mutation if you are:

- ▼ Not responding or no longer responding to a medication
- ▼ Unable to reach a certain treatment milestone

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

SCEMBLIX may cause serious side effects, including:

- ▼ **Heart and blood vessel (cardiovascular) problems:** SCEMBLIX may cause heart and blood vessel problems, including heart attack, stroke, blood clots, blockage of your arteries, heart failure, and abnormal heartbeat, which can be serious and may sometimes lead to death. These heart and blood vessel problems can happen in people with risk factors or a history of these problems, and/or previously treated with other TKI medicines. Your doctor may monitor you for heart and blood vessel problems and treat you as needed during treatment with SCEMBLIX. Tell your doctor or get medical help right away if you get:

- ▼ shortness of breath
- ▼ chest pain or pressure
- ▼ a feeling like your heart is beating too fast or you feel abnormal heartbeats
- ▼ swelling in your ankles or feet
- ▼ dizziness
- ▼ weight gain
- ▼ numbness or weakness on one side of your body
- ▼ decreased vision or loss of vision
- ▼ trouble talking
- ▼ pain in your arms, legs, back, neck, or jaw
- ▼ headache
- ▼ severe stomach-area pain

Learn more at
www.scemblix.com



Results among those with the T315I mutation



Results of a clinical trial

SCEMBLIX was studied among patients with Ph+ CML in chronic phase who have the T315I mutation. In a clinical trial:

- ▼ 42% of patients (out of 45 patients) with the T315I mutation achieved a major molecular response (MMR) by 24 weeks
- ▼ 49% of patients (out of 45 patients) achieved MMR by 96 weeks

Only your doctor can determine if you have the T315I mutation through a specific test. If it turns out that you have the T315I mutation, SCEMBLIX may be right for you.

More than
4 out of 10

patients achieved MMR by 24 weeks

In this clinical trial, the most common side effects reported ($\geq 20\%$) were pain in muscles, bones, or joints; tiredness; nausea; rash; and diarrhea.

Ask your doctor about SCEMBLIX

If you're not responding to your current medication for Ph+ CML in chronic phase, ask your doctor whether you should be tested for a gene mutation. If testing shows that you have the T315I mutation, you and your doctor should discuss if SCEMBLIX may be right for you.

To help you have a productive conversation with your doctor, see the Doctor Discussion Guide at www.scemblix-resources.com



The T315I gene mutation and resistance

If testing shows that you have developed the T315I mutation, this may affect the way you are responding to your current medication. Mutations can lead to drug resistance. If your doctor determines you have the T315I mutation, be sure to ask if SCEMBLIX may be a treatment option for you.

IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

The most common side effects of SCEMBLIX include:

- ▼ nose, throat, or sinus (upper respiratory tract) infections
- ▼ muscle, bone, or joint pain
- ▼ headache
- ▼ tiredness
- ▼ nausea
- ▼ rash
- ▼ diarrhea
- ▼ decreased blood platelet counts, white blood cell counts, and red blood cell counts
- ▼ increased blood fat (triglycerides) levels
- ▼ increased blood creatine kinase levels
- ▼ increased blood liver enzyme levels
- ▼ increased blood pancreas enzyme (amylase and lipase) levels
- ▼ increased blood uric acid levels

Your doctor may change your dose, temporarily stop, or permanently stop treatment with SCEMBLIX if you have certain side effects.

SCEMBLIX may cause fertility problems in females. This may affect your ability to have a child. Talk to your doctor if this is a concern for you.

These are not all the possible side effects of SCEMBLIX. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

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.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

 **SCEMBLIX**[®]
(asciminib) 20 mg, 40 mg tablets

Taking SCEMBLIX and tracking your results



Establishing your routine, keeping up with lab tests

The following pages provide guidance on creating your dosing routine for SCEMBLIX and review the tests your doctor may order to see whether you are responding to treatment.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

SCEMBLIX[®]
(asciminib) 20 mg, 40 mg tablets

Something that's important to get straight: your dosing routine

It is important to take SCSEMBLIX exactly as prescribed by your doctor.

It is helpful to establish a routine for taking your medication that works with your schedule. That's especially important with SCSEMBLIX because you can't eat for at least 2 hours before you take the medication and 1 hour after your dose.

Take SCSEMBLIX every day as prescribed

Your doctor will want you to take SCSEMBLIX every day. You'll be prescribed either the 20 mg or 40 mg tablets. Your doctor will tell you how many times a day to take SCSEMBLIX. Swallow SCSEMBLIX tablets whole. Do not break, crush, or chew SCSEMBLIX tablets.

Do NOT take SCSEMBLIX with food

One of the most important things to know about SCSEMBLIX is that it should never be taken with food.

Do not eat for at least 2 hours before and 1 hour after you take SCSEMBLIX.

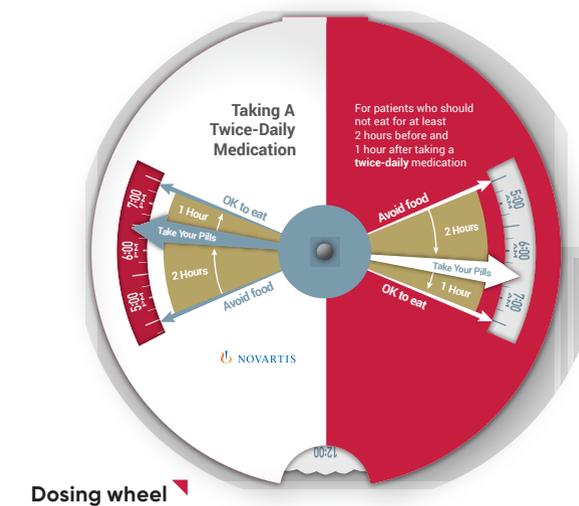
Why it's important to take SCSEMBLIX on an empty stomach

Food may change the way your body absorbs SCSEMBLIX. If the medication is taken with food, it can decrease the amount of SCSEMBLIX in your blood in an unpredictable way.

What if you miss a dose?

If you take SCSEMBLIX once daily and miss a dose by more than 12 hours, skip the missed dose. If you take SCSEMBLIX twice daily and miss a dose by more than 6 hours, skip the missed dose. Take your next dose at your regular scheduled time.

Use the dosing wheel to help create a routine



Dosing wheel

We've created a dosing wheel that can help you see when you should take SCSEMBLIX. There are 2 sides to the wheel, depending on whether your doctor has told you to take SCSEMBLIX once a day or twice a day. You can request a dosing wheel through a Novartis Patient Navigator. To learn how to sign up for the Patient Navigator Program, **see page 42.**

Once you have a dosing wheel, you can use the appropriate side of the wheel to help establish a regular routine for taking SCSEMBLIX as prescribed. Simply choose a time and the wheel will display when you should take SCSEMBLIX. It also shows you the hours you shouldn't eat before taking SCSEMBLIX—and when you can eat again.

Food and medication considerations

Certain medications may interact with SCSEMBLIX. Before starting on SCSEMBLIX, tell your doctor if you are taking any other medicines. This includes medicines prescribed by other doctors you see, as well as medicines, herbs, and supplements that you buy without a prescription.

For tips on how to make SCSEMBLIX part of your daily schedule, go to www.scemblix.com

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

IMPORTANT SAFETY INFORMATION for SCSEMBLIX (continued)

Before taking SCSEMBLIX, tell your doctor about all your medical conditions, including if you:

- ▼ have a history of inflammation of your pancreas (pancreatitis)
- ▼ have a history of heart problems or blood clots in your arteries and veins (types of blood vessels)
- ▼ are pregnant or plan to become pregnant. SCSEMBLIX can harm your unborn baby
 - ▽ Your doctor will do a pregnancy test before you start treatment with SCSEMBLIX
 - ▽ **Females** who are able to become pregnant should use effective birth control during treatment and for 1 week after your last dose of SCSEMBLIX. Talk to your doctor about birth control methods that may be right for you
 - ▽ Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with SCSEMBLIX
- ▼ are breastfeeding or plan to breastfeed. It is not known if SCSEMBLIX passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of SCSEMBLIX

Tell your doctor about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements. SCSEMBLIX and other medicines may affect each other and cause side effects.

Blood tests can help your doctor see if you're moving in the right direction

To see if you are responding to treatment with SCEMBLIX, your doctor will have you go for regular blood tests. Your blood counts should be checked every 2 weeks for the first 3 months and monthly after that.



Monitoring is a key part of treatment

When you have Ph+ CML in chronic phase, monitoring your blood is key. Your doctor will order tests to see if SCEMBLIX is working and to check for side effects.

Discuss your results

It's important to go for any blood tests your doctor prescribes. But you have to go a step further and make sure you discuss the results of your blood work with your doctor. This will help you understand what your results mean.

Tests your doctor may prescribe

- ▼ **Complete blood count (CBC):** The CBC with differential and chemistry profile counts the number of red blood cells, white blood cells, and platelets in the blood
- ▼ **Standard cytogenetic test:** Using a small sample of your bone marrow, this test measures the number of cells with the Ph chromosome
- ▼ **Fluorescence in situ hybridization (FISH) test:** This test uses fluorescent dyes and a fluorescent microscope to measure the number of cells with the Ph chromosome. Your doctor may order this test because a standard cytogenetic test may not detect all the leukemic cells in the blood

- ▼ **Quantitative polymerase chain reaction (qPCR or molecular) test:** qPCR testing is sensitive enough to detect the smallest amount of leukemic cells in the blood and bone marrow. Be sure to go to a lab that uses a standardized scale, called the International Scale, to measure your *BCR-ABL1* level.
- ▼ ***BCR-ABL1* kinase domain mutation analysis:** This test is used to look for mutations in the *BCR-ABL1* gene, which may cause certain medications to stop working. Your doctor will order this test to determine if you have a gene mutation, such as the T315I mutation

Keep track of your results

You and your doctor will want to see your *BCR-ABL1* level decrease over time. If this level starts to increase, your doctor may adjust your dose or consider another treatment option.

Other tests you may need

During your treatment with SCEMBLIX, your doctor will conduct tests to check for side effects. Your doctor will periodically monitor your blood pressure. Your doctor will also check your blood cell counts (white blood cells, red blood cells, and platelets), and test for pancreatitis. Your doctor may also order a pregnancy test before you start treatment with SCEMBLIX.



Ask about your results

Your blood work is a key measure of how you are responding to treatment. So don't be shy. Discuss your results with your doctor, so you know what your numbers mean. Visit www.scemblix.com

IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

SCEMBLIX may cause serious side effects, including:

- ▼ **Low blood cell counts:** SCEMBLIX may cause low platelet counts (thrombocytopenia), low white blood cell counts (neutropenia), and low red blood cell counts (anemia). Your doctor will do blood tests to check your blood cell counts every 2 weeks for the first 3 months of treatment and then monthly or as needed during treatment with SCEMBLIX. Tell your doctor right away if you have unexpected bleeding or easy bruising, blood in your urine or stools, fever, or any signs of an infection
- ▼ **Pancreas problems:** SCEMBLIX may increase enzymes in your blood called amylase and lipase, which may be a sign of pancreatitis. Your doctor may do blood tests monthly or as needed during treatment with SCEMBLIX to check for problems with your pancreas. Tell your doctor right away if you have sudden stomach-area pain or discomfort, nausea, or vomiting

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

 **SCEMBLIX**[®]
(asciminib) 20 mg, 40 mg tablets

Summary of Important Information for SCEMBLIX

Important information you should know

Be sure to review the following pages to learn important information about SCEMBLIX, including possible side effects.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

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Summary of Important Information for SCEMBLIX

What is SCEMBLIX?

SCEMBLIX is a prescription medicine used to treat adults with:

- Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs)
- Ph+ CML in CP with the T315I mutation

It is not known if SCEMBLIX is safe and effective in children.

Before taking SCEMBLIX, tell your doctor about all your medical conditions, including if you:

- have a history of inflammation of your pancreas (pancreatitis)
- have a history of heart problems or blood clots in your arteries and veins (types of blood vessels)
- are pregnant or plan to become pregnant. SCEMBLIX can harm your unborn baby
 - Your doctor will do a pregnancy test before you start treatment with SCEMBLIX
 - Females** who are able to become pregnant should use effective birth control during treatment and for 1 week after your last dose of SCEMBLIX. Talk to your doctor about birth control methods that may be right for you
 - Tell your doctor right away if you become pregnant or think you may be pregnant during treatment with SCEMBLIX
- are breastfeeding or plan to breastfeed. It is not known if SCEMBLIX passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of SCEMBLIX

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. SCEMBLIX and other medicines may affect each other and cause side effects.

How should I take SCEMBLIX?

- Take SCEMBLIX exactly as your doctor tells you
- Take SCEMBLIX without food. **You should avoid eating** for at least 2 hours before and 1 hour after taking SCEMBLIX
- Swallow SCEMBLIX tablets whole. **Do not** break, crush, or chew SCEMBLIX tablets
- If you take SCEMBLIX **1 time a day** and miss a dose by more than 12 hours, skip the missed dose and take your next dose at your regular time
- If you take SCEMBLIX **2 times a day** and miss a dose by more than 6 hours, skip the missed dose and take your next dose at your regular time

What are the possible side effects of SCEMBLIX?

SCEMBLIX may cause serious side effects, including:

- Low blood cell counts:** SCEMBLIX may cause low platelet counts (thrombocytopenia), low white blood cell counts (neutropenia), and low red blood cell counts (anemia). Your doctor will do blood tests to check your blood cell counts every 2 weeks for the first 3 months of treatment and then monthly or as needed during treatment with SCEMBLIX. Tell your doctor right away if you have unexpected bleeding or easy bruising, blood in your urine or stools, fever, or any signs of an infection
- Pancreas problems:** SCEMBLIX may increase enzymes in your blood called amylase and lipase, which may be a sign of pancreatitis. Your doctor may do blood tests monthly or as needed during treatment with SCEMBLIX to check for problems with your pancreas. Tell your doctor right away if you have sudden stomach-area pain or discomfort, nausea, or vomiting

- High blood pressure:** Your doctor may check your blood pressure and treat any high blood pressure during treatment with SCEMBLIX as needed. Tell your doctor if you develop elevated blood pressure or symptoms of high blood pressure including confusion, headaches, dizziness, chest pain, or shortness of breath
- Allergic reaction:** Stop taking SCEMBLIX and get medical help right away if you get any signs or symptoms of an allergic reaction, including:
 - trouble breathing or swallowing
 - swelling of the face, lips, or tongue
 - skin rash or flushing of your skin
 - feeling dizzy or faint
 - fever
 - fast heartbeat
- Heart and blood vessel (cardiovascular) problems:** SCEMBLIX may cause heart and blood vessel problems, including heart attack, stroke, blood clots, blockage of your arteries, heart failure, and abnormal heartbeat, which can be serious and may sometimes lead to death. These heart and blood vessel problems can happen in people with risk factors or a history of these problems, and/or previously treated with other TKI medicines. Your doctor may monitor you for heart and blood vessel problems and treat you as needed during treatment with SCEMBLIX. Tell your doctor or get medical help right away if you get:
 - shortness of breath
 - chest pain or pressure
 - a feeling like your heart is beating too fast or you feel abnormal heartbeats
 - swelling in your ankles or feet
 - dizziness
 - weight gain
 - numbness or weakness on one side of your body
 - decreased vision or loss of vision
 - trouble talking
 - pain in your arms, legs, back, neck, or jaw
 - headache
 - severe stomach-area pain

Summary of Important Information for SCEMBLIX (continued)

The most common side effects of SCEMBLIX include:

- ▼ nose, throat, or sinus (upper respiratory tract) infections
- ▼ muscle, bone, or joint pain
- ▼ headache
- ▼ tiredness
- ▼ nausea
- ▼ rash
- ▼ diarrhea
- ▼ decreased blood platelet counts, white blood cell counts, and red blood cell counts
- ▼ increased blood fat (triglycerides) levels
- ▼ increased blood creatine kinase levels
- ▼ increased blood liver enzyme levels
- ▼ increased blood pancreas enzyme (amylase and lipase) levels
- ▼ increased blood uric acid levels

Your doctor may change your dose, temporarily stop, or permanently stop treatment with SCEMBLIX if you have certain side effects.

SCEMBLIX may cause fertility problems in females. This may affect your ability to have a child. Talk to your doctor if this is a concern for you.

These are not all the possible side effects of SCEMBLIX. For more information, ask your doctor or pharmacist. Call your doctor for medical advice about side effects.

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.

How should I store SCEMBLIX?

- ▼ Store SCEMBLIX at room temperature between 68°F to 77°F (20°C to 25°C)
- ▼ Dispense and store SCEMBLIX in the original container to protect it from moisture

Keep SCEMBLIX and all medicines out of the reach of children.

General information about the safe and effective use of SCEMBLIX

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use SCEMBLIX for a condition for which it was not prescribed. Do not give SCEMBLIX to other people, even if they have the same symptoms you have. It may harm them. You can ask your doctor or pharmacist for more information about SCEMBLIX that is written for health care professionals.

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.

Patient portrayal

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.

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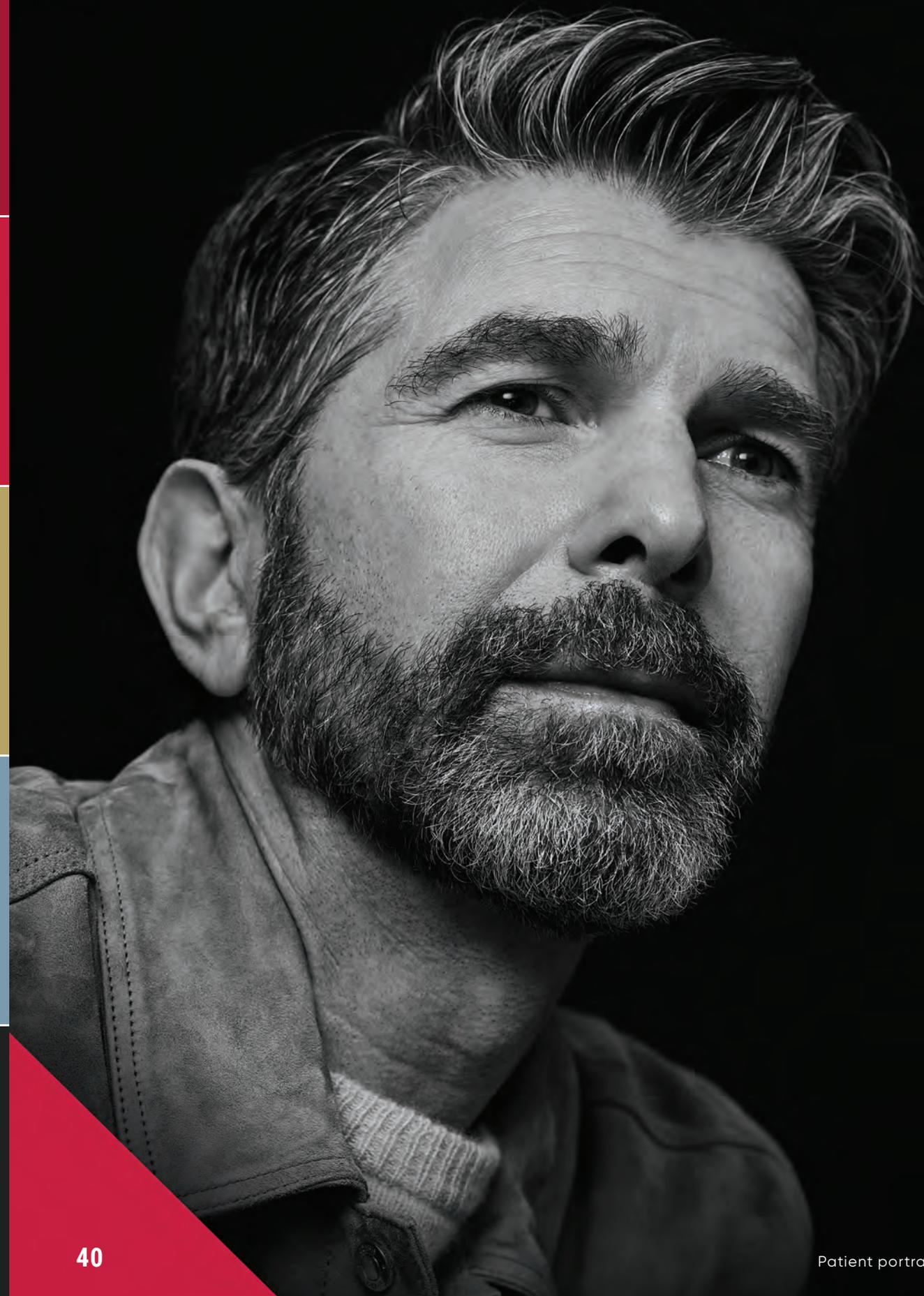
Savings and support for those prescribed SCEMBLIX

Financial resources and patient support services

To help you start and stay on SCEMBLIX, learn about resources that are available, including:

- ▶ Financial resources that can help eligible patients save on their medication
- ▶ A patient support program called SCEMBLIX Connex that provides educational information
- ▶ One-on-one support from a Novartis Patient Navigator

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.



Patient portrayal

Financial resources for patients starting on SCEMBLIX

Our Patient Assistance Now Oncology (PANO) program was created to assist you with accessing your Novartis medicine(s) – from insurance verification to financial assistance – all through a knowledgeable and supportive call center.



New to SCEMBLIX? Get a voucher for up to a 30-day free supply

If you have been prescribed SCEMBLIX, you may be eligible to receive up to a 30-day free supply, which will allow you to start your prescribed treatment quickly. Program rules may vary.

To learn more, call **1-800-282-7630** or visit **Patient.NovartisOncology.com**

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.



Co-pays as low as \$0*

You may be eligible for immediate co-pay savings on your next prescription of SCEMBLIX.

- Eligible patients with private insurance may pay \$0 per month
- Novartis will pay the remaining co-pay, up to \$15,000 per calendar year, per product*

To find out if you are eligible for the Novartis Oncology Universal Co-pay Program, call **1-877-577-7756** or visit the website at **Copay.NovartisOncology.com**

***Limitations apply.** This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice. For full Terms and Conditions, visit **Copay.NovartisOncology.com** or call **1-877-577-7756**.

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Support to help you stay the course

If your doctor has prescribed SCEMBLIX, you can take advantage of support services that are designed to help you start—and stay—on your medication.

SCEMBLIX CONNEX

Don't go it alone: Join SCEMBLIX Connex

Whether you're starting on SCEMBLIX or looking to learn more about the medication, you can sign up for the SCEMBLIX Connex patient support program. You'll receive:

- ▼ Educational information about your disease and the medication
- ▼ Information about financial resources that may help eligible patients save on treatment
- ▼ Materials that focus on the importance of staying on track with your medication, from taking it exactly as prescribed to keeping up with blood tests your doctor may order

To enroll, visit www.scemblix-support.com

Let a Patient Navigator be your guide

The Novartis Patient Navigator Program is staffed by a team of specialists who are available to support you during your treatment journey.* Once enrolled in the program, you will receive a series of phone calls from a specially trained navigator who will support and guide you through various aspects of initiating your prescribed medicine.†

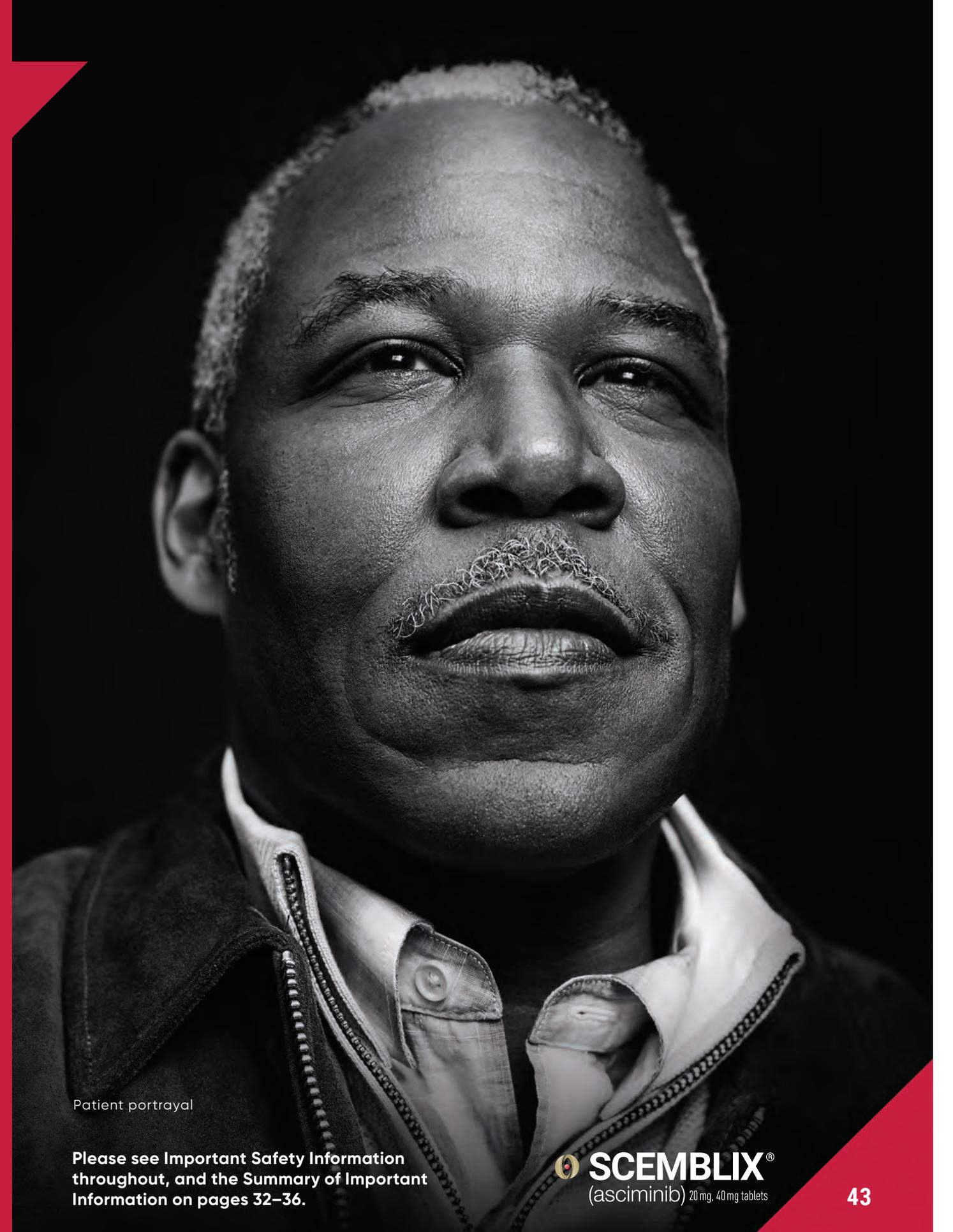
Novartis Patient Navigators:

- ▼ Educate on product features: for example, dosing and administration, side effects, and monitoring recommendations
- ▼ Provide information on lifestyle support during treatment
- ▼ Educate on the benefits investigation process: review the results and out-of-pocket responsibilities
- ▼ Provide access to disease education materials and guide patients to other Novartis resources where applicable

To enroll in the Patient Navigator Program, contact Patient Assistance Now Oncology (PANO) at **1-800-282-7630, prompt 3** or visit Patient.NovartisOncology.com

* The Novartis Patient Navigator Program is available for select Novartis Oncology products. Patient Navigator services do not involve the practice of nursing or provide clinical advice and counseling.

† Must be prescribed a Novartis Oncology medicine for an approved indication that is offered within the Patient Navigator Program.



Patient portrayal

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Resources to help you learn more about Ph+ CML

If you'd like to learn more about Ph+ CML, the organizations listed below may be helpful to you. Review the websites to learn more about the disease. You may also be able to connect with others who are living with Ph+ CML.

Leukemia & Lymphoma Society®

www.LLS.org
1-800-955-4572

The National CML Society

www.nationalcmlsociety.org
1-877-431-2573

The Max Foundation

www.themaxfoundation.org
1-888-462-9368

CancerCare®

www.cancercares.org
1-800-813-HOPE (1-800-813-4673)

Leukemia Research Foundation

www.allbloodcancers.org
1-847-424-0600

American Cancer Society®

www.cancer.org
1-800-ACS-2345 (1-800-227-2345)

National Cancer Institute's Cancer Information Service

www.cancer.gov/contact
1-800-4CANCER (1-800-422-6237)
Those with TTY equipment may call
1-800-322-8615

National Patient Advocate Foundation

www.npaf.org
1-800-532-5274

The organizations and websites listed on this page are maintained by third parties over whom Novartis Pharmaceuticals Corporation has no control. As such, Novartis Pharmaceuticals Corporation makes no representation as to the accuracy or any other aspect of the information supplied by these organizations or contained in these websites.

Please see Important Safety Information throughout, and the Summary of Important Information on pages 32–36.



Track your CML journey

You may find it helpful to track your treatment for CML, whether it's recording the results of blood tests, notes from speaking with your doctor, or simply how you're feeling. Some people prefer to use a journal to capture their thoughts. Others use one of the many tracker apps available. One of these apps is called Belong—Beating Cancer Together.

As a social network for managing and navigating cancer treatment, the Belong app connects patients with CML and caregivers. It's anonymous and free.

You can download the Belong app from Google Play or the App Store. To learn more, visit www.belong.life



HAS YOUR JOURNEY BEEN
**ANYTHING BUT A
STRAIGHT LINE?**

Ask your doctor if SCEMBLIX is right for you.

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