



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.

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



Savings options for those who have been prescribed SCEMBLIX

Learn about co-pay savings for patients on SCEMBLIX and how new patients starting on SCEMBLIX can receive a free 30-day trial.

See pages 40-41.

SCEMBLIX CONNEX

Get education and information by joining SCEMBLIX Connex

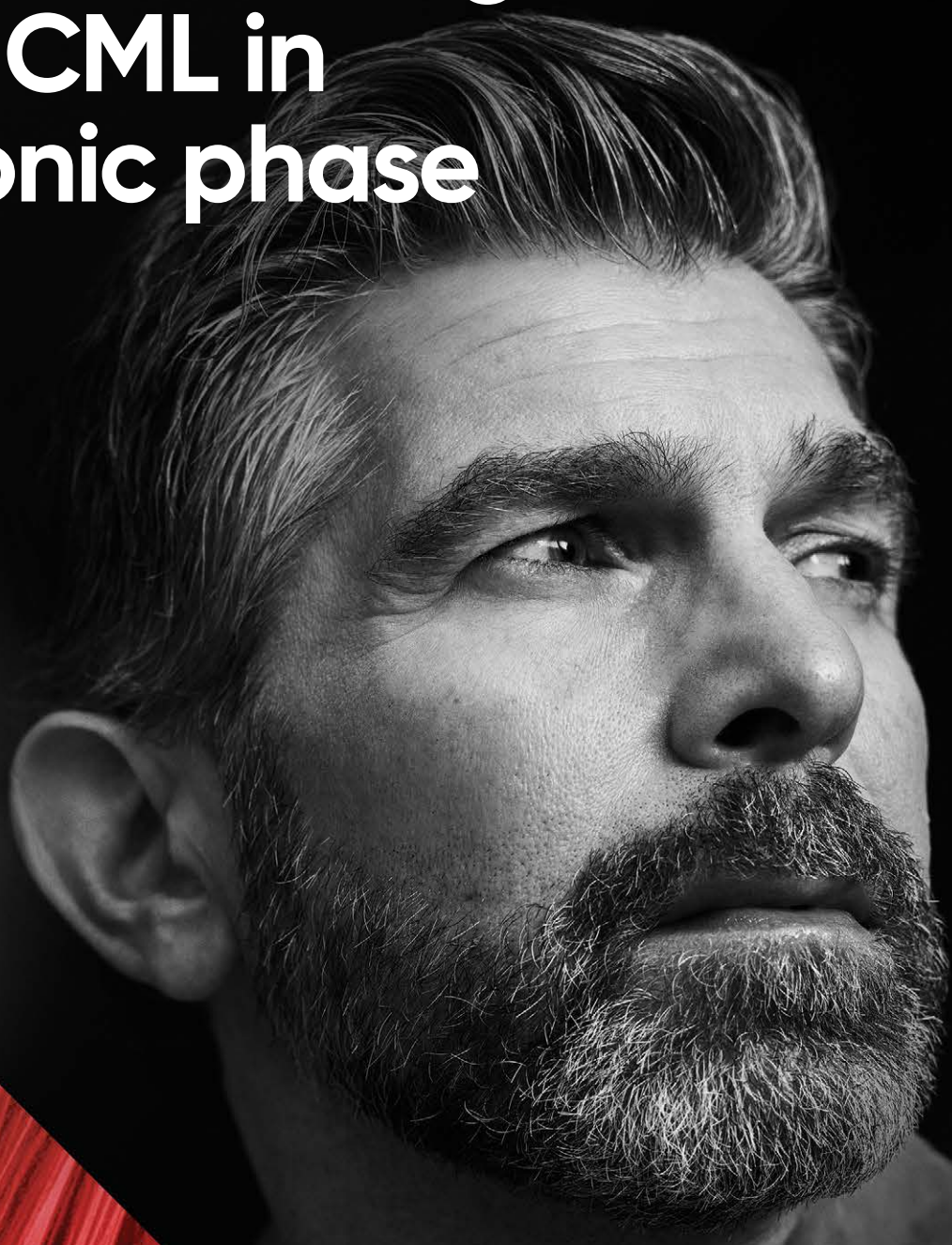
If you want to learn more about SCEMBLIX, sign up for support from SCEMBLIX Connex. You'll receive educational information about your disease and the medication. See page 43.

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

Understanding Ph+ CML in chronic phase

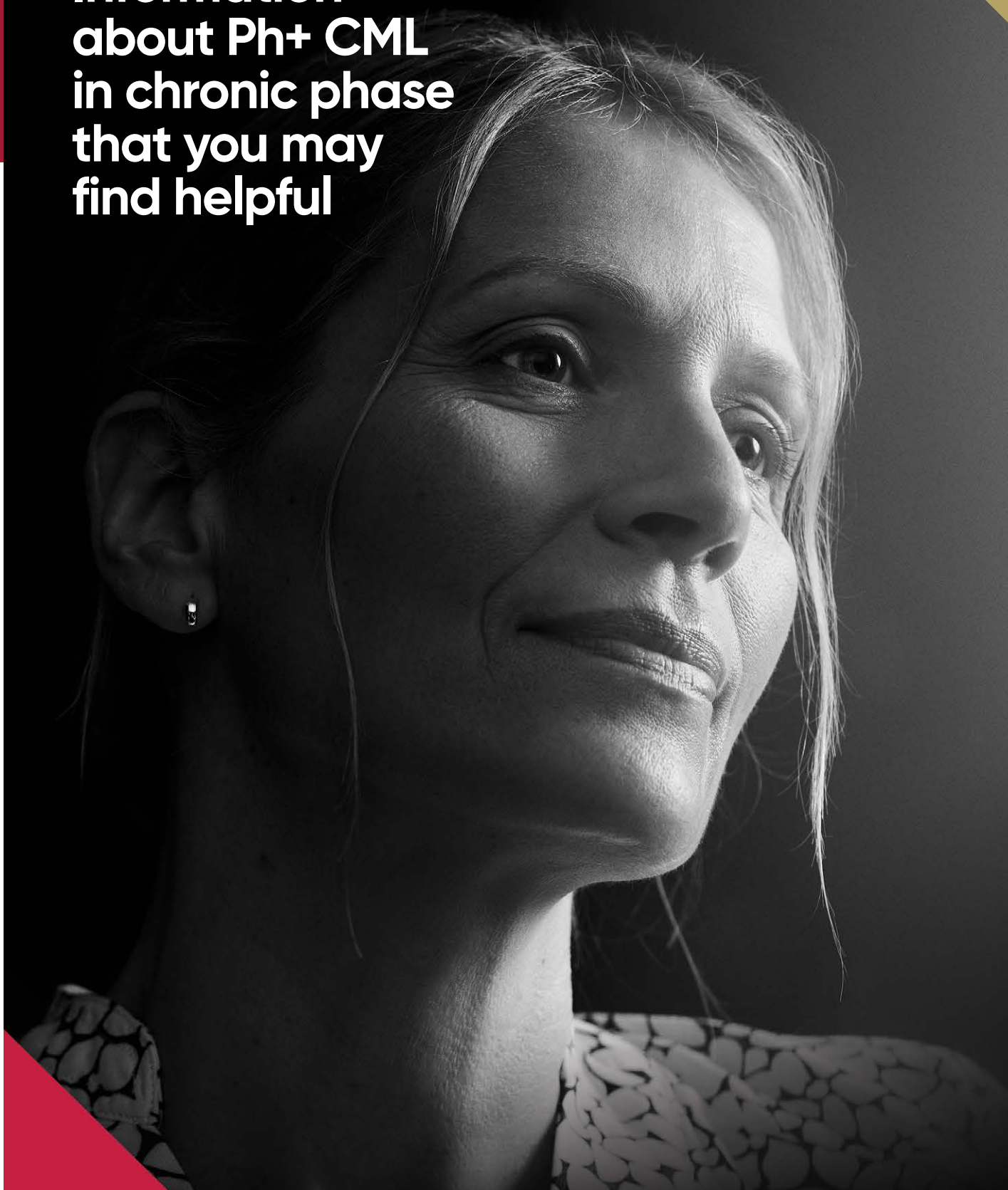


Learn about the disease, mutations, and milestones

This section provides:

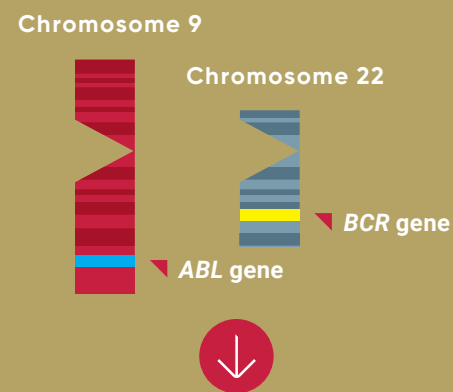
- ▼ A brief overview of Ph+ CML in chronic phase
- ▼ Information about drug resistance and mutations
- ▼ Background on treatment goals that you can discuss with your doctor

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

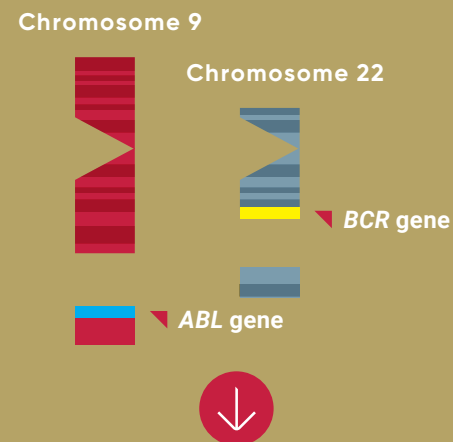


A swap between chromosomes 9 and 22 creates the Ph chromosome

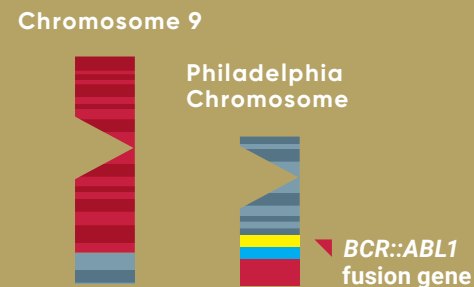
Normal Chromosomes



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

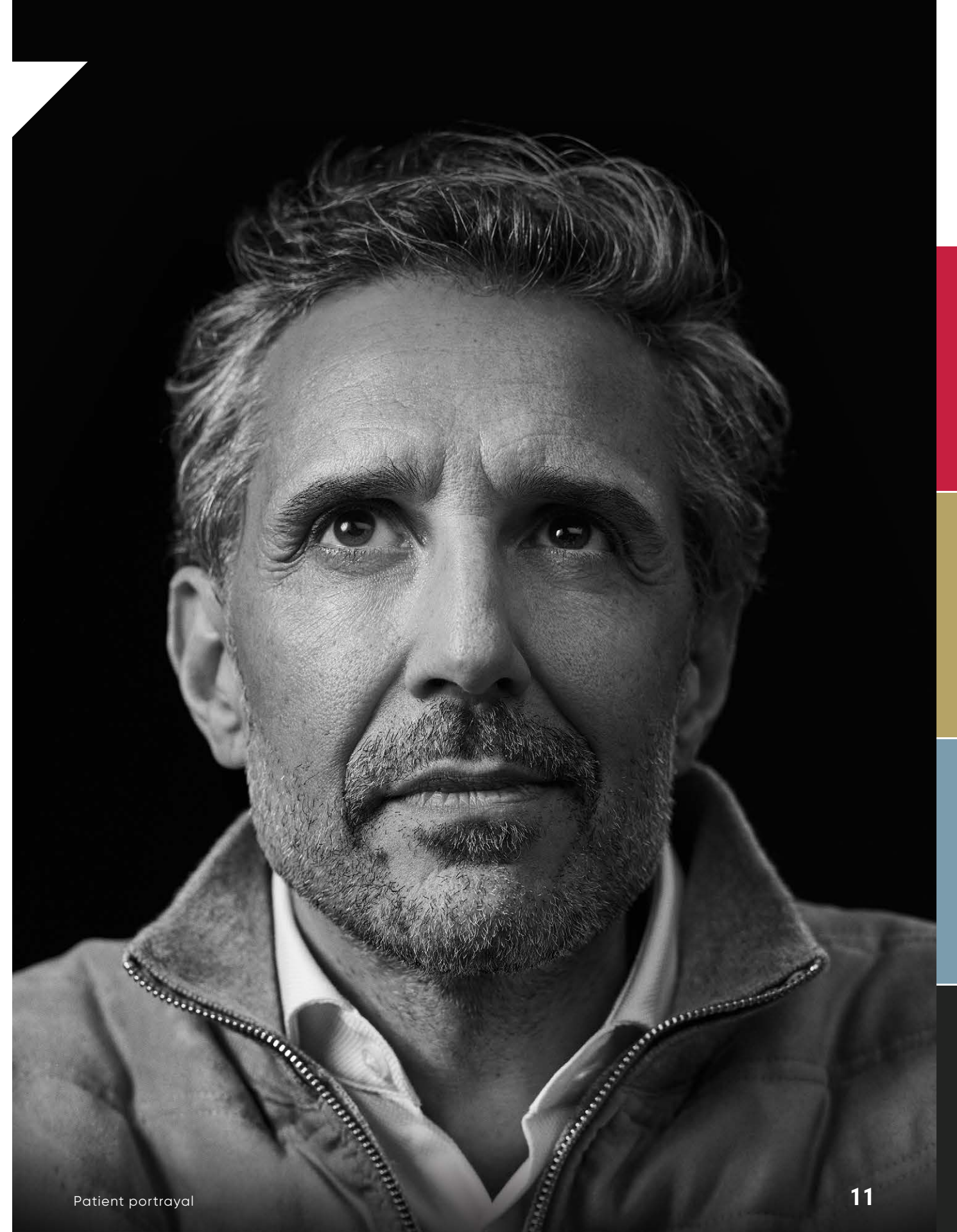
If you haven't responded to 2 or more medications for Ph+ CML in chronic phase, **see pages 18–21.**



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.sceblx.com



Patient portrayal

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.scmblx.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)

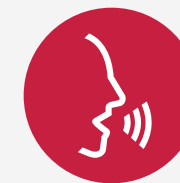
- ▼ Tests show that the amount of *BCR-ABL1* in the blood is $\leq 0.1\%$
- ▼ Think of that as 1 out of every 1000 cells having the *BCR-ABL1* gene compared with baseline

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:

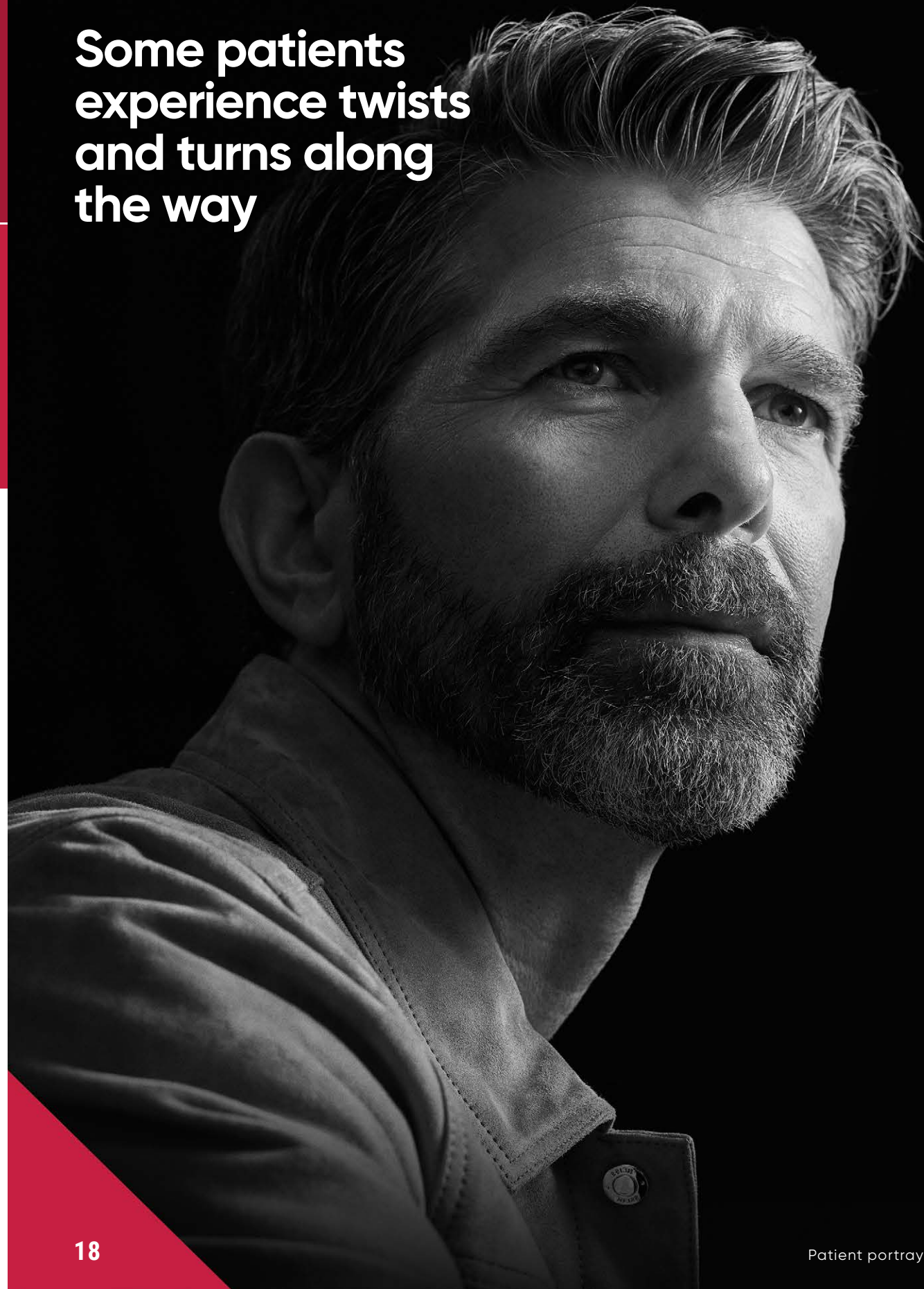
- ▶ Philadelphia chromosome – positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with 2 or more tyrosine kinase inhibitors (TKIs)
- ▶ Ph+ CML in CP with the T315I mutation

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)

Nearly 2x

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

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 ($\geq 20\%$) with SCEMBLIX were nose/throat infections; pain in the muscles, bones, or joints; headache; and tiredness.

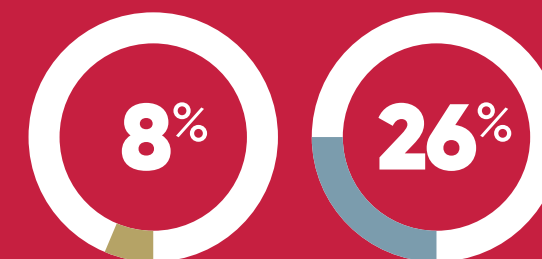
Three times fewer SCEMBLIX patients stopped treatment due to side effects

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

SCEMBLIX

Bosulif



(12 of 156 patients)

(20 of 76 patients)



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.

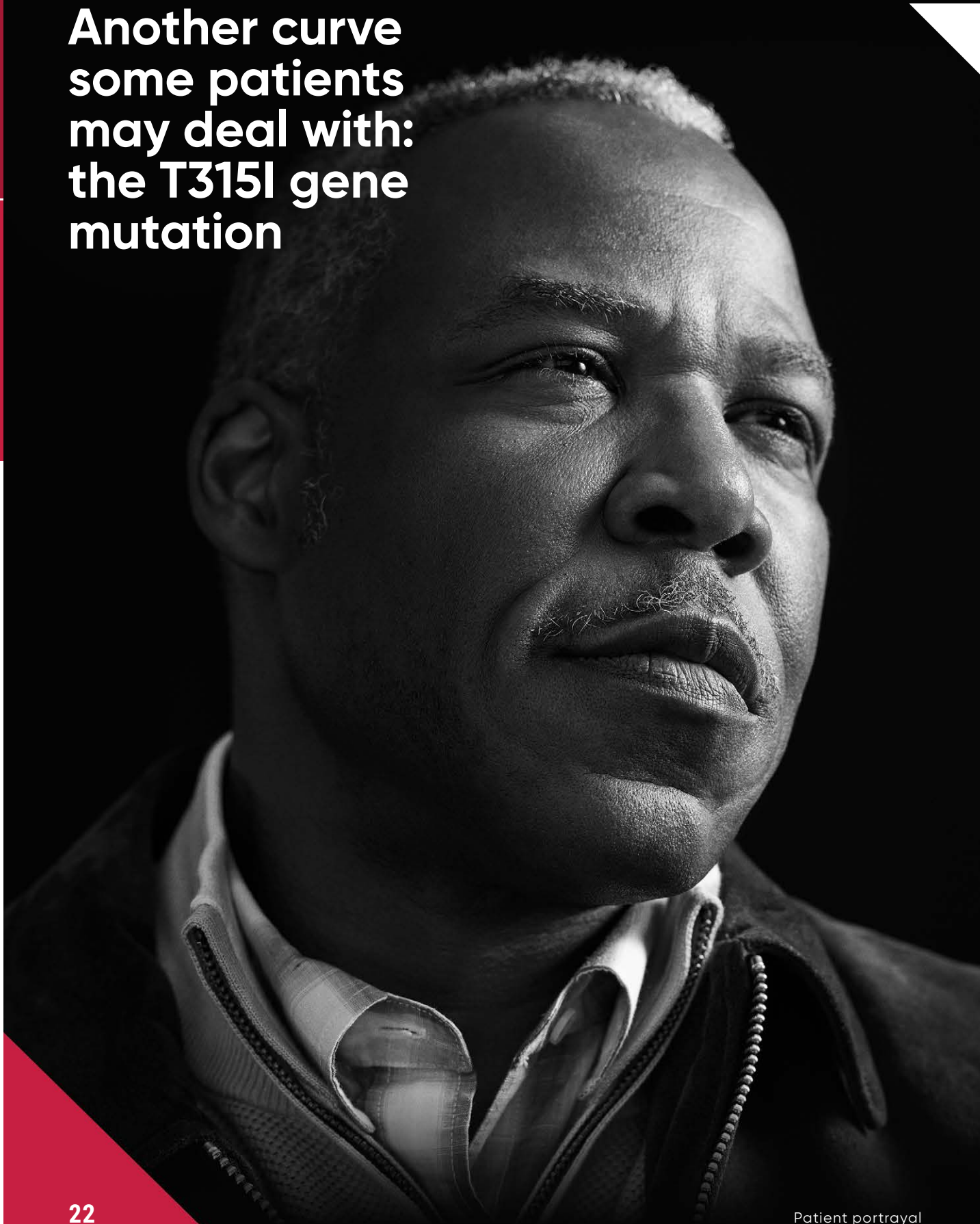
IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

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

* Bosulif is a registered trademark of Pfizer Inc.

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



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

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



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

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

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.

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

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.

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.

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

It is important to take SCEMBLIX 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 SCEMBLIX because you can't eat for at least 2 hours before you take the medication and 1 hour after your dose.

Take SCEMBLIX every day as prescribed

Your doctor will want you to take SCEMBLIX 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 SCEMBLIX. Swallow SCEMBLIX tablets whole. Do not break, crush, or chew SCEMBLIX tablets.

Do NOT take SCEMBLIX with food

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

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

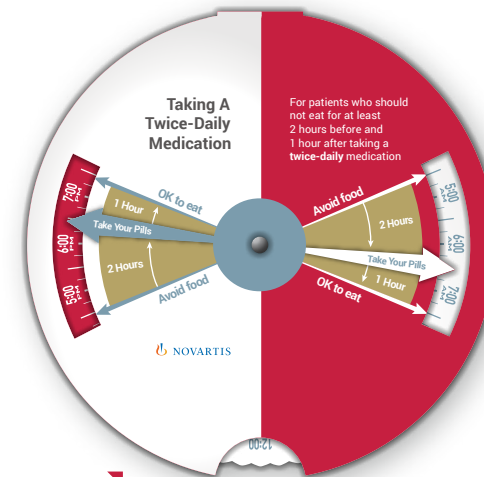
Why it's important to take SCEMBLIX on an empty stomach

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

What if you miss a dose?

If you take SCEMBLIX once daily and miss a dose by more than 12 hours, skip the missed dose. If you take SCEMBLIX 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 SCEMBLIX. There are 2 sides to the wheel, depending on whether your doctor has told you to take SCEMBLIX 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 SCEMBLIX as prescribed. Simply choose a time and the wheel will display when you should take SCEMBLIX. It also shows you the hours you shouldn't eat before taking SCEMBLIX—and when you can eat again.

Food and medication considerations

Certain medications may interact with SCEMBLIX. Before starting on SCEMBLIX, 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 SCEMBLIX part of your daily schedule, go to www.scemblix.com

IMPORTANT SAFETY INFORMATION for SCEMBLIX (continued)

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.

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

To see if you are responding to treatment with SCSEMBLIX, 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 SCSEMBLIX 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 SCSEMBLIX, 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 SCSEMBLIX.



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 SCSEMBLIX (continued)

SCSEMBLIX may cause serious side effects, including:

- ▼ **Low blood cell counts:** SCSEMBLIX 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 SCSEMBLIX. 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:** SCSEMBLIX 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 SCSEMBLIX 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.

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

Summary of Important Information for SCEMBLIX

About the Disease

About SCEMBLIX

Taking SCEMBLIX and Testing

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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(asciminib) 20 mg, 40 mg tablets

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.

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

Savings and support for those prescribed SCEMBLIX

Novartis Patient Support is here for you

To help you start, stay, and save on SCEMBLIX, get personalized support that includes:

- ▶ Financial support that can provide savings and other possible ways to afford your treatment
- ▶ Insurance support that helps you navigate the insurance process and understand your coverage
- ▶ Ongoing support that provides helpful resources and answers to your questions throughout your treatment

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

Novartis Patient Support

Here for you every step of the way

Once you've been prescribed SCEMBLIX, you or your loved one can sign up for Novartis Patient Support. You'll have a go-to team member who will reach out from the start and get to know you.

And once your health care provider has filed the paperwork with your insurance for you to start on SCEMBLIX, Novartis Patient Support can help with the rest.

3 ways to get started



Sign Up Online

Enter your information securely online at support.scemblix.com



Call 866-433-8000

Monday-Friday, 8:00 AM to 8:00 PM ET, excluding holidays. Your dedicated Novartis Patient Support team can then help you sign up.



Ask your provider

Your health care provider and/or their office staff can help you sign up.



Financial Support

Your support will be based on your unique financial situation.

What is Co-Pay Plus?

The Co-Pay Plus offer can help cover any out-of-pocket costs related to your SCEMBLIX prescription, including refills. If you have private insurance, you may be eligible.

\$0 Co-Pay Plus Offer*

Pay as little as \$0 with your Co-Pay Plus offer

- Eligible patients with private insurance may pay as little as \$0
- Have an annual benefit limit of \$15,000 per calendar year
- Your annual benefit limit automatically resets every year. There's no need to sign up again

TERMS AND CONDITIONS:

*Limitations apply. Valid only for those with private insurance. The Program includes the Co-Pay Plus offer, Plus Card (if applicable), and Rebate, with a combined annual limit up to \$15,000. Patient is responsible for any costs once limit is reached in a calendar year. Program not valid (i) under Medicare, Medicaid, TRICARE, VA, DoD, or any other federal or state health care program, (ii) where patient is not using insurance coverage at all, (iii) where the patient's insurance plan reimburses for the entire cost of the drug, or (iv) where product is not covered by patient's insurance. The value of this program is exclusively for the benefit of patients and is intended to be credited towards patient out-of-pocket obligations and maximums, including applicable co-payments, coinsurance, and deductibles. Program is not valid where prohibited by law. Patient may not seek reimbursement for the value received from this program from other parties, including any health insurance program or plan, flexible spending account, or health care savings account. Patient is responsible for complying with any applicable limitations and requirements of their health plan related to the use of the Program. Valid only in the United States and Puerto Rico. This Program is not health insurance. Program may not be combined with any third-party rebate, coupon, or offer. Proof of purchase may be required. Novartis reserves the right to rescind, revoke, or amend the Program and discontinue support at any time without notice.

*No purchase required. This free trial is not health insurance. Void where prohibited by law. Product dispensed pursuant to terms and conditions of offer. Valid only in the US and Puerto Rico. Claims shall not be submitted to any public or private third-party payer or any federal or state health care program for reimbursement. Offer not valid if reproduced or submitted to any other payer. It is illegal for any person to sell, purchase or trade, or offer to sell, purchase or trade, or to counterfeit, this offer. Prescriber ID# is required on prescription. This is the property of Novartis Pharmaceuticals Corporation and must be returned upon request. Novartis Pharmaceuticals Corporation reserves the right to rescind, revoke, or amend offer without notice.

†Confirm your specialty pharmacy accepts this offer before filling your prescription.

What if I don't have insurance?

If you're experiencing financial hardship and/or have no third-party insurance coverage, we can help.

Charitable organizations like Novartis Patient Assistance Foundation (NPAF) may help provide access to Novartis medications.

To be eligible for NPAF, you must:

- Be a United States resident
- Meet certain income requirements
- Have limited or no prescription coverage

Visit PAP.novartis.com for a complete list of medications and income requirements. Get answers to your questions at 1-800-277-2254.

New to SCEMBLIX?

Get a 30-day Free Trial Offer for SCEMBLIX†

Your first month of SCEMBLIX will be free. You can start your treatment as soon as possible. It will even get shipped directly to your home.

Your Free Trial Offer for SCEMBLIX is:

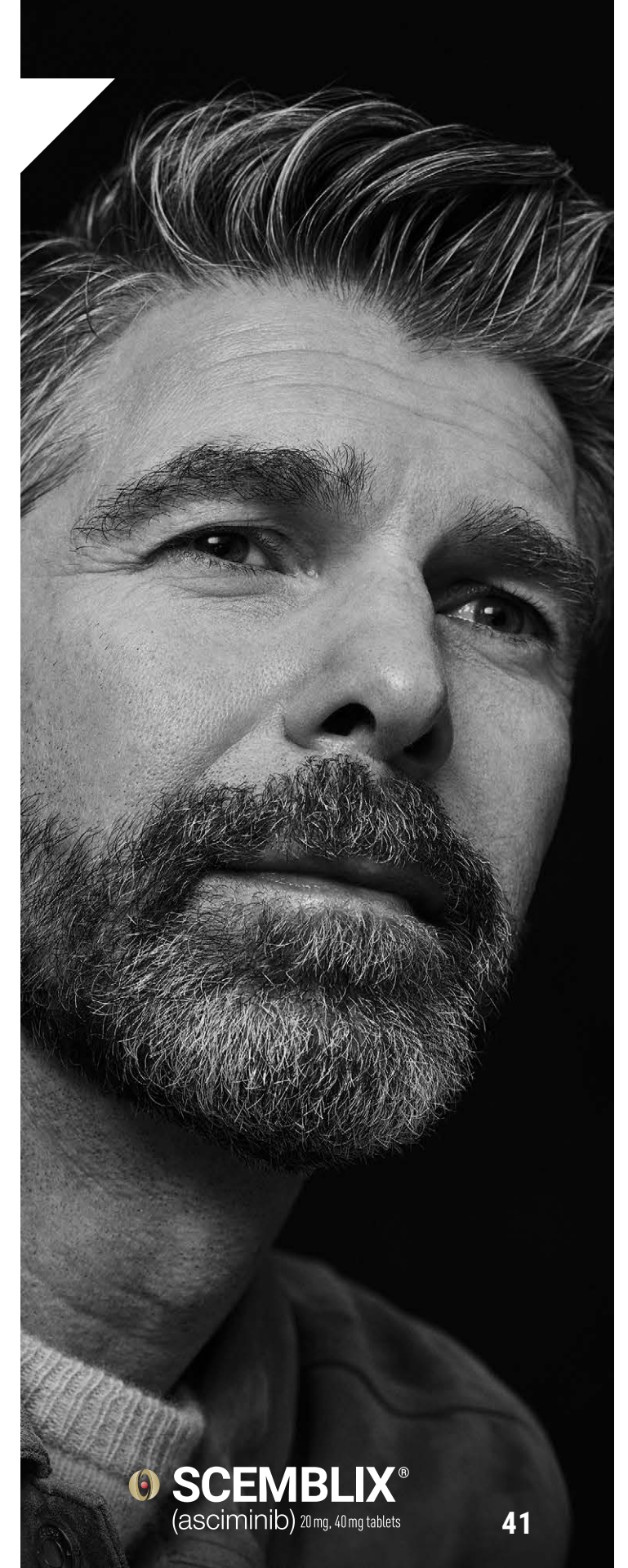
- Good for a 30-day supply of your medication at no cost to you
- Available to all with a valid prescription†—regardless of insurance
- For one-time use only

Download the Free Trial Offer now www.scemblix.com



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

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Novartis Patient Support



Insurance Support

How can my Novartis Patient Support team help me navigate insurance coverage?

Getting you the medication you need is our number one priority.

Novartis Patient Support is here to help.

You'll work with an experienced team member who can:

- ▼ Help you navigate the insurance process
- ▼ Work with your health care provider to manage insurance forms
- ▼ Assist you if there are changes to your insurance coverage



Ongoing Support

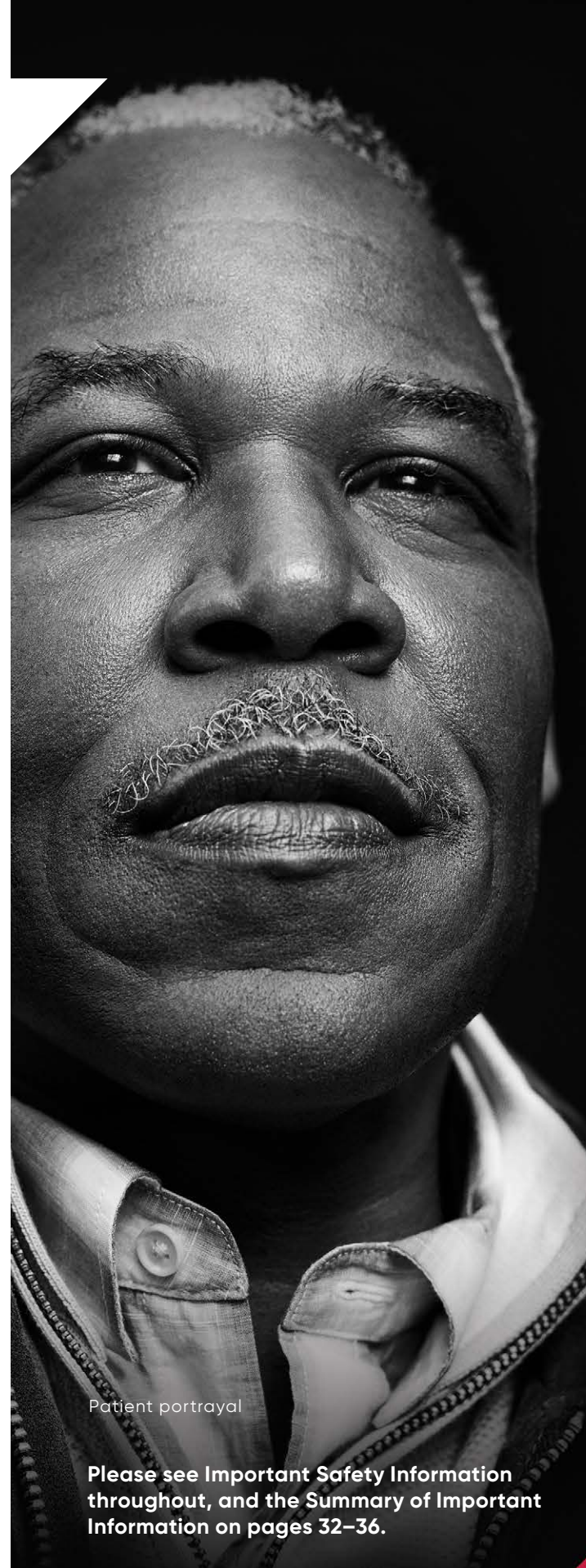
What if I need ongoing support after starting my treatment?

Your Novartis Patient Support team will be there for you.

Live, one-on-one support is just a phone call away.

- ▼ Guidance on your health plan coverage process
- ▼ Options for saving on your prescription
- ▼ Help with SCEMBLIX and your routine
- ▼ Educational resources
 - ▼ [Tips](#) for talking to your health care provider
 - ▼ [A welcome kit](#)
 - ▼ [A patient guide](#) to help with many of your questions
- ▼ [A list of supportive groups](#) that can link you to others with your condition

Novartis Patient Support doesn't replace medical guidance from your health care provider.



Patient portrayal

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

Considering SCEMBLIX?

If you're thinking about asking your doctor about SCEMBLIX, sign up for SCEMBLIX Connex.

This support program provides education about Ph+ CML in chronic phase and SCEMBLIX.

SCEMBLIX CONNEX

Don't go it alone: Join SCEMBLIX Connex

When you sign up, you'll receive:

- ▼ Educational information about your disease and the medication
- ▼ Information about financial resources that may help eligible patients save on treatment
- ▼ Materials designed to help you talk with your doctor about any side effects you may be experiencing from your current medication

To enroll, visit www.scemblix-connex.com

Resources to help you learn more about Ph+ CML

If you'd like to learn more about Ph+ CML, the organizations listed here 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.

The Leukemia & Lymphoma Society®
www.LLS.org
1-800-955-4572

The National CML Society
www.nationalcmlsociety.org

The Max Foundation
www.themaxfoundation.org/maxgps/
1-425-778-8660

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

Leukemia Research Foundation
<https://leukemiarf.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
1-202-347-8009

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.



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

Ask your doctor if SCEMBLIX is right for you.

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