ICLUSIG®
(ponatinib) tablets
45mg / 30mg / 15mg / 10mg

FOR PATIENTS WHO CANNOT RECEIVE OTHER TKIs OR HAVE T315I POSITIVE Ph+ ALL

ICLUSIG could be your next step in treating Ph+ ALL

Not an actual patient

What is ICLUSIG?

ICLUSIG is a prescription medicine used to treat adults who have:

- Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL)
  - in combination with chemotherapy in newly diagnosed Ph+ ALL
  - alone in adults with Ph+ ALL who cannot receive any other kinase inhibitor medicines or who have a specific type of abnormal gene (T315I-positive) Ph+ ALL

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

ICLUSIG in combination with chemotherapy in newly diagnosed adult patients with Ph+ ALL was approved based on patient responses at 3 months of therapy. There is an ongoing study to confirm results.

Please see Important Safety Information on pages 10-13 and 18-21 and read the Medication Guide in the accompanying full Prescribing Information.

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Why your doctor may recommend ICLUSIG

Sometimes during treatment for **Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL)** your disease might progress. If this happens, your doctor may consider changing parts of your treatment plan. One of the options they may consider is ICLUSIG® (ponatinib).

ICLUSIG is a **tyrosine kinase inhibitor (TKI)** medication (sometimes referred to as a kinase inhibitor) that may help people with Ph+ ALL lower their blood counts.

You might have questions about starting a new treatment. How does it work? How do I take it? How will my doctor and I know if it's working? Keep reading to find out more. Talk to your doctor about whether ICLUSIG could be the right next step for you.

Images throughout this brochure are not of actual patients.

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ICLUSIG can cause serious side effects, including:

Blood clots or blockage in your blood vessels (arteries and veins). Blood clots or blockage in your blood vessels may lead to heart attack, stroke, or death. You may need emergency surgery or treatment in a hospital.

Heart problems. ICLUSIG can cause heart problems, including heart failure, which can be serious and may lead to death.

Liver problems. ICLUSIG can cause liver problems, including liver failure, which can be severe and may lead to death.

See **"What is the most important information I should know about ICLUSIG® (ponatinib)?"** on pages 10-13 for more information.

Please see Important Safety Information on pages 10-13 and 18-21 and read the Medication Guide in the accompanying full Prescribing Information.

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Overview of Ph+ ALL

As you may know, Ph+ ALL stands for:

Ph+	**Philadelphia chromosome**-positive
A	**Acute** (the cancer grows quickly)
L	**Lymphoblastic** (the cancer affects young white blood cells called lymphoblasts)
L	**Leukemia**

Ph+ ALL (or Philadelphia-positive ALL) is a type of blood cancer that grows quickly. It starts in young white blood cells called **lymphoblasts** or **blast cells**.

In people with Ph+ ALL, a change, or **mutation**, in their **DNA** creates the "Philadelphia" (Ph) chromosome. When the Ph chromosome is present in cells, a protein known as **BCR-ABL1** is produced. This protein activates the **bone marrow** to make too many lymphoblasts, which leads to leukemia.

Treating Ph+ ALL

Doctors treat Ph+ ALL with **chemotherapy**, **corticosteroids**, and **TKIs**. People with more advanced stages of the disease may receive other treatments as well. Your doctor will determine the treatment that is right for you.

Learn more about ICLUSIG® (ponatinib), including how it works and how it may help, on pages 16-19.

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Monitoring your response to treatment for Ph+ ALL

Throughout treatment, your doctor will monitor how well your body is responding. To do this, your doctor may perform 2 types of tests.

CYTOGENETIC TESTING

Cytogenetic testing helps detect the presence of altered chromosomes (such as the Philadelphia chromosome) in the body.

MOLECULAR TESTING

Molecular testing measures the levels of BCR-ABL1 in in the body. One type of molecular test is called **qPCR**, and it can be used to determine how well treatment is working.

Determining if your current treatment is working

When evaluating these test results, your doctor will look for:

Complete remission

The goal of treatment is complete remission, which means:

- Your **blood count** is normal
- Your disease symptoms are gone
- Your doctor cannot see any leukemia cells in a sample of your bone marrow using a microscope

Minimal residual disease (MRD)

Even if you have complete remission, there may still be a small number of leukemia cells left behind. This is called **minimal residual disease**. It can only be detected with sensitive laboratory tests.

BCR-ABL1

Your doctor may monitor the levels of BCR-ABL1 in your blood. BCR-ABL1 is a protein that helps make leukemia cells.

Understand what tests you are taking and what the results mean. Take notes during your appointments so you can keep track of important information.

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Why your doctor may change your treatment

Some people will need to change their TKI treatment over time. There are 2 main reasons why a person may need to change their TKI treatment—**resistance** and/or **intolerance**.

Resistance: If your Ph+ ALL no longer responds to a TKI treatment, this is called resistance. A number of factors can cause you to become resistant to treatment, including if your Ph+ ALL develops a mutation. Resistance is one reason your doctor may recommend a different TKI.

Intolerance: Another reason your doctor may recommend switching TKIs is intolerance to side effects caused by your current treatment.

If your doctor recommends switching treatments, ask whether ICLUSIG® (ponatinib) may be the right next step for you.

Mutations may affect treatments

In Ph+ ALL, changes called mutations can appear in the BCR-ABL1 protein during treatment with a TKI. Mutations may impact your condition and cause your treatment to stop working. So it's important for your doctor to test regularly for mutations.

If you develop a mutation while on your current TKI, your doctor may recommend that you switch to a different TKI that may work better against the mutation.

T315I is a type of mutation that can occur in Ph+ ALL. ICLUSIG was the first TKI to be approved to treat people with the T315I mutation.

ICLUSIG may also help adult patients who cannot take any other kinase inhibitor medicine for Ph+ ALL.

Please see Important Safety Information on pages 10-13 and 18-21 and read the Medication Guide in the accompanying full Prescribing Information.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ICLUSIG® (ponatinib)?

ICLUSIG can cause serious side effects, including:

Blood clots or blockage in your blood vessels (arteries and veins). Blood clots or blockage in your blood vessels may lead to heart attack, stroke, or death. A blood clot or blockage in your blood vessels can prevent proper blood flow to your heart, brain, bowels (intestines), legs, eyes, and other parts of your body. You may need emergency surgery or treatment in a hospital. Get medical help right away if you get any of the following symptoms:

- chest pain or pressure
- pain in your arms, legs, back, neck or jaw
- shortness of breath
- numbness or weakness on one side of your body
- leg swelling
- trouble talking
- headache
- dizziness
- severe stomach area pain
- decreased vision or loss of vision

Blood clots or blockage in your blood vessels can happen in people with or without risk factors for heart and blood vessel disease, including people 50 years of age or younger. The most common risk factors for these problems are a history of high blood pressure (hypertension), high cholesterol, and heart disease. Blood clots or blockages in your blood vessels happen more often in people as they get older, and in people with a history of decreased blood flow, high blood pressure, diabetes, or high cholesterol.

Heart problems. ICLUSIG can cause heart problems, including heart failure which can be serious and may lead to death. Heart failure means your heart does not pump blood well enough. ICLUSIG can also cause irregular, slow, or fast heartbeats and heart attack. Your healthcare provider will check you for heart problems during your treatment with ICLUSIG. Get medical help right away if you get any of the following symptoms: shortness of breath, chest pain, fast or irregular heartbeats, dizziness, or feel faint.

Liver problems. ICLUSIG can cause liver problems, including liver failure, which can be severe and may lead to death. Your healthcare provider will do blood tests before and during your treatment with ICLUSIG to check for liver problems. Get medical help right away if you get any of these symptoms of liver problems during treatment:

- yellowing of your skin or the white part of your eyes
- dark “tea-colored” urine
- sleepiness
- loss of appetite
- bleeding or bruising

See **“What are the possible side effects of ICLUSIG?”** on pages 13 and 18-21 for information about side effects.

Before you take ICLUSIG, tell your healthcare provider about all of your medical conditions, including if you:

- have a history of blood clots in your blood vessels (arteries or veins)

Be sure to tell your doctor about any side effects you have while taking ICLUSIG.

Please see additional Important Safety Information on pages 10-13 and 18-21 and read the Medication Guide in the accompanying full Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

- have heart problems, including heart failure, irregular heartbeats, and QT prolongation
- have diabetes
- have a history of high cholesterol
- have liver problems
- have had inflammation of your pancreas (pancreatitis)
- have high blood pressure
- have bleeding problems
- plan to have surgery or have had a recent surgery. You should stop taking ICLUSIG at least 1 week before planned surgery. See **"What are the possible side effects of ICLUSIG?"** on pages 13 and 18-21.
- are lactose (milk sugar) intolerant. ICLUSIG tablets contain lactose.
- eat grapefruit or drink grapefruit juice. See **"How should I take ICLUSIG?"** on page 13.
- are pregnant or plan to become pregnant. ICLUSIG can harm your unborn baby.
  - Your healthcare provider will do a pregnancy test before you start taking ICLUSIG.
  - **For females who can become pregnant:**
    - Use an effective form of birth control during treatment and for **3 weeks** after your last dose of ICLUSIG.
    - Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with ICLUSIG.
    - ICLUSIG may affect your ability to have children. Tell your healthcare provider if this is a concern for you.
- are breastfeeding or plan to breastfeed. It is not known if ICLUSIG passes into your breast milk. **Do not** breastfeed during treatment and for **1 week** after your last dose of ICLUSIG.

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. ICLUSIG and other medicines may affect each other causing side effects.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ICLUSIG?

- Take ICLUSIG exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking ICLUSIG unless your healthcare provider tells you.
- Swallow ICLUSIG tablets whole. Do not crush, break, cut, chew or dissolve ICLUSIG tablets.
- Take ICLUSIG with or without food.
- Do not eat grapefruit or drink grapefruit juice during treatment with ICLUSIG.
- If you miss a dose of ICLUSIG, take your next dose at your regularly scheduled time the next day. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much ICLUSIG, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of ICLUSIG?

ICLUSIG may cause serious side effects, including:

- See **"What is the most important information I should know about ICLUSIG?"** on pages 10-11.
- **High blood pressure (hypertension).** High blood pressure is common during treatment with ICLUSIG and can also be serious or severe. ICLUSIG can cause new or worsening high blood pressure. Your blood pressure should be checked regularly, and any high blood pressure should be treated during treatment with ICLUSIG. Tell your

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Understanding ICLUSIG and how it works

ICLUSIG is a prescription medicine used to treat adults who have:

- Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia (Ph+ ALL)
  - in combination with chemotherapy in newly diagnosed Ph+ ALL
  - alone in adults with Ph+ ALL who cannot receive any other kinase inhibitor medicines or who have a specific type of abnormal gene (T315I-positive) Ph+ ALL

ICLUSIG is not for use to treat people with newly diagnosed chronic phase CML.

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

ICLUSIG in combination with chemotherapy in newly diagnosed adult patients with Ph+ ALL was approved based on patient responses at 3 months of therapy. There is an ongoing study to confirm results.

ICLUSIG works by stopping the BCR-ABL1 protein

ICLUSIG helps to stop cancer-causing BCR-ABL1 proteins from creating Ph+ ALL cells. ICLUSIG has been shown to work even if these proteins have developed a type of mutation called the T315I mutation.

Talk to your doctor about whether ICLUSIG may be the next step in treating your Ph+ ALL.

Medication is only one part of your treatment. Don't be afraid to ask for help from friends and family when you feel you need it.

Please see Important Safety Information on pages 10-13 and 18-21 and read the Medication Guide in the accompanying full Prescribing Information.

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How ICLUSIG may help

A study looked at the safety and effectiveness of ICLUSIG® (ponatinib) in Ph+ ALL. It included 32 people with Ph+ ALL who were resistant or intolerant to other TKI medicines.

The study looked at 2 types of treatment responses to see how well ICLUSIG was working:

COMPLETE HEMATOLOGIC RESPONSE (CHR):

This means blood cell counts go down to a normal amount.

MAJOR HEMATOLOGIC RESPONSE (MaHR):

In addition to blood cell counts going down to a normal amount, there is also no evidence of leukemia.

ICLUSIG WAS EFFECTIVE IN Ph+ ALL

34%
of patients
(11 out of 32 patients)
achieved **CHR** by 6 months

41%
of patients
(13 out of 32 patients)
achieved **MaHR** by 6 months

Every patient is different. Results may vary.

Remember, you and your doctor will consider side effects along with the potential benefits of ICLUSIG.

Talk to your doctor about these results to learn more about how ICLUSIG was studied and how it could be a part of your treatment plan.

Please see Important Safety Information on pages 10-13 and 18-21 and read the Medication Guide in the accompanying full Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

healthcare provider right away if you get confusion, headaches, dizziness, chest pain or shortness of breath.

- **Inflammation of the pancreas (pancreatitis).** Pancreatitis is common during treatment with ICLUSIG and can also be serious or severe. Tell your healthcare provider right away if you get any of the following symptoms: sudden stomach-area pain or discomfort, nausea, and vomiting. Your healthcare provider should do blood tests to check for pancreatitis during treatment with ICLUSIG.
- **Neuropathy.** ICLUSIG may cause damage to the nerves in your arms, brain, hands, legs, or feet (neuropathy). Tell your healthcare provider right away if you get any of these symptoms during treatment with ICLUSIG:
  - muscle weakness, tingling, burning, pain, discomfort or loss of feeling in your hands and feet
  - double vision and other problems with eyesight, trouble moving the eye, drooping of part of the face, sagging or drooping eyelids, or change in taste
- **Eye problems.** Serious eye problems that can lead to blindness or blurred vision may happen with ICLUSIG. Tell your healthcare provider right away if you get any of the following symptoms: bleeding in the eye, perceived flashes of light, light sensitivity, floaters, blurred vision, dry, inflamed, swollen, or itchy eyes, or eye pain. Your healthcare provider will monitor your vision before and during your treatment with ICLUSIG.
- **Bleeding.** Bleeding is common during treatment with ICLUSIG and can also be serious and may lead to death. Tell your healthcare provider right away if you get any signs of bleeding during treatment with ICLUSIG including:
  - vomiting blood or if your vomit looks like coffee-grounds
  - pink or brown urine
  - red or black (looks like tar) stools
  - coughing up blood or blood clots
  - unusual bleeding or bruising of your skin
  - menstrual bleeding that is heavier than normal
  - unusual vaginal bleeding
  - nose bleeds that happen often
  - drowsiness or difficulty being awakened
  - confusion
  - headache
  - change in speech
- **Fluid retention.** Your body may hold too much fluid (fluid retention) which can be serious and may lead to death. Tell your healthcare provider right away if you get any of these symptoms during treatment with ICLUSIG:
  - swelling of your hands, ankles, feet, face, or all over your body
  - weight gain
  - shortness of breath and cough
- **Irregular heartbeat.** ICLUSIG may cause an irregular heartbeat. Tell your healthcare provider right away if you experience loss of consciousness, fainting, dizziness, chest pain or palpitations.
- **Low blood cell counts.** ICLUSIG may cause low blood cell counts, which can be severe. Your healthcare provider will check your blood counts regularly during treatment with ICLUSIG. Tell your healthcare provider right away if you have a fever or any signs of an infection while taking ICLUSIG.
- **Tumor Lysis Syndrome (TLS).** TLS is caused by a fast breakdown of cancer cells. TLS can cause you to have kidney failure and the need for dialysis treatment, and an abnormal heartbeat. Your healthcare provider may do blood tests to check for TLS. Drink plenty of water during treatment with ICLUSIG to help reduce your risk of getting TLS. Call your healthcare provider or get emergency help right away if you get any of the following symptoms during treatment with ICLUSIG:
  - nausea and vomiting
  - weakness

Please see additional Important Safety Information on pages 10-13 and 18-21 and read the Medication Guide in the accompanying full Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

  - swelling
  - shortness of breath
  - muscle cramps
  - seizures
- **Reversible Posterior Leukoencephalopathy Syndrome (RPLS – also known as Posterior Reversible Encephalopathy Syndrome).** ICLUSIG may trigger a condition called RPLS. Call your healthcare provider right away if you get headaches, seizures, confusion, changes in vision or problems thinking.
- **Wound healing problems.** Wound healing problems have happened in some people who take ICLUSIG. Tell your healthcare provider if you plan to have any surgery before or during treatment with ICLUSIG.
  - You should stop taking ICLUSIG at least 1 week before planned surgery.
  - Your healthcare provider should tell you when you may start taking ICLUSIG again after surgery.
- **A tear in your stomach or intestinal wall (perforation).** Tell your healthcare provider right away if you get:
  - severe pain in your stomach-area (abdomen)
  - swelling of the abdomen
  - high fever

The most common side effects of ICLUSIG when given alone include:

- skin rash
- joint pain
- stomach-area (abdomen) pain
- headache
- constipation
- dry skin
- tiredness
- swelling of your hands, ankles, feet, face, or all over your body (fluid retention and edema)
- fever
- nausea
- increase in lipase levels (a blood test done to check your pancreas)
- low hemoglobin in the blood (anemia)
- liver problems
- blood clots or blockage in blood vessels (arteries)
- low blood platelet counts
- low blood levels of white blood cells

The most common side effects of ICLUSIG when given with chemotherapy include:

- liver problems
- joint pain
- skin rash
- headache
- fever
- stomach-area (abdomen) pain
- constipation
- tiredness
- nausea
- mouth sores
- increase in lipase levels (a blood test done to check your pancreas)
- numbness, or tingling (pins and needles), pain, or weakness in the hands or feet
- fever due to low white blood cell counts (febrile neutropenia)
- swelling of your hands, ankles, feet, face, or all over your body (fluid retention and edema)
- vomiting
- irregular heartbeat
- low blood levels of white blood cells
- low blood platelet counts
- low hemoglobin in the blood (anemia)
- changes in liver function tests

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with ICLUSIG if you have certain side effects.

Tell your healthcare provider if you have any side effect that bothers you or does not go away.

These are not all of the possible side effects of ICLUSIG. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects.

To report SUSPECTED SIDE EFFECTS, contact Takeda at 1-844-817-6468 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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How to take ICLUSIG

ICLUSIG IS TAKEN

as one tablet

once a day

with or without food

The recommended starting dose of ICLUSIG® (ponatinib) is 45 mg orally once a day. Your doctor may stop ICLUSIG if you experience side effects or do not respond to treatment.

How should I take ICLUSIG?

- Take ICLUSIG exactly as your healthcare provider tells you to take it.
- Do not change your dose or stop taking ICLUSIG unless your healthcare provider tells you.
- Swallow ICLUSIG tablets whole. Do not crush, break, cut, chew or dissolve ICLUSIG tablets.
- Take ICLUSIG with or without food.
- Do not eat grapefruit or drink grapefruit juice during treatment with ICLUSIG.
- If you miss a dose of ICLUSIG, take your next dose at your regularly scheduled time the next day. Do not take 2 doses at the same time to make up for a missed dose.
- If you take too much ICLUSIG, call your healthcare provider or go to the nearest hospital emergency room right away.

It's important to take ICLUSIG as your doctor tells you in order to see potential results. Do not stop taking ICLUSIG unless your doctor instructs you to. Tell your doctor about any side effects you may experience.

Talk to your doctor about ICLUSIG

It's normal to have questions about Ph+ ALL treatment. That's why it's important to work closely with your healthcare team and understand your treatment plan.

Talk to your doctor about the information you've read here. And be sure to ask questions like:

- Is ICLUSIG the right next step for me?
- How can ICLUSIG help control Ph+ ALL?
- What is the recommended dose of ICLUSIG?
- What are the side effects of ICLUSIG?

Working closely with your healthcare team can help you remain confident as you continue to take on Ph+ ALL.

Please see Important Safety Information on pages 10-13 and 18-21 and read the Medication Guide in the accompanying full Prescribing Information.

Glossary

BCR-ABL1: An abnormal protein that causes too many abnormal white blood cells (leukemia, or CML, cells) to be made. Sometimes referred to as BCR-ABL1^{IS}.

BCR-ABL1 mutations: Changes to the BCR-ABL1 protein that prevent certain TKIs from working.

Blast cell: An abnormal, immature blood cell. Also called a lymphoblast.

Bone marrow: Soft tissue in the center of bones where blood cells are made.

Chemotherapy: Medicines that kill cells, including fast-growing cancer cells and normal cells.

Complete hematologic response (CHR): Treatment response when blood cell counts decrease to normal.

Complete remission: When no leukemia cells are found in the bone marrow and all signs and symptoms of the cancer are gone.

Corticosteroids: Medicines used to reduce redness, swelling, and pain, but also to kill leukemia cells. They are also called steroids.

Cytogenetic testing: A test that looks for changes in chromosomes (the part of the cell that contains genetic information).

DNA: Deoxyribonucleic acid. The genetic information carried by cells.

Intolerance: When treatment with a drug must be stopped because of side effects.

Major hematologic response (MaHR): Treatment response that combines a complete hematologic response with another type of hematologic response called "no evidence of leukemia" (NEL).

Minimal residual disease (MRD): A very small number of cancer cells left in the body after treatment.

Molecular testing: A sensitive test that can measure very small amounts of BCR-ABL1 in the blood. One type of molecular test is a qPCR test.

Mutation: An abnormal change in the DNA of a cell, particularly common in cancer cells.

Mutation testing: Tests used to see if samples of DNA have changed, or mutated.

Philadelphia (Ph) chromosome: An abnormal chromosome that forms in Ph+ ALL. It contains the BCR-ABL1 gene.

Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL): A form of leukemia where the cells contain the abnormal Philadelphia chromosome.

qPCR (quantitative reverse transcriptase polymerase chain reaction): A very sensitive test that measures the number of cells in the blood or bone marrow that have the BCR-ABL1 gene.

Resistance (or resistant): When cancer does not respond to a treatment.

T315I: A type of BCR-ABL1 mutation that prevents cancer cells from responding to certain TKI treatments.

Tyrosine kinase inhibitor (TKI): A type of medicine that stops the growth of leukemia cells by blocking, or "inhibiting," BCR-ABL1.

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We're here for you throughout your treatment

Takeda Oncology Here2Assist

From helping you understand coverage options to identifying available financial assistance, Takeda Oncology Here2Assist® is committed to offering you comprehensive support throughout your treatment journey.

- Works with your insurance company to help you get started on your medication
- Identifies available financial assistance that may be right for you
- Connects you to additional support services and resources
- Identifies specialty pharmacies to help fill and ship your prescriptions appropriately
- Conducts regular follow-up calls with you

To learn more about Takeda Oncology Here2Assist, call to speak with a case manager at **1-844-817-6468**, Option 2, or visit **www.Here2Assist.com**.

Let's Talk. We're available Monday-Friday, 8AM-8PM ET.

To learn more about ICLUSIG® ponatinib, talk to your healthcare provider or visit ICLUSIG.com.

Please see Important Safety Information on pages 10-13 and 18-21 and read the Medication Guide in the accompanying full Prescribing Information.

ONCOLOGY