



#### **INDICATION**

TABRECTA is a prescription medicine used to treat adults with a kind of lung cancer called non-small cell lung cancer (NSCLC) that:

- has spread to other parts of the body (metastatic), and
- whose tumors have an abnormal mesenchymal-epithelial transition (MET) gene. Your health care provider will perform a test to make sure that TABRECTA is right for you.

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

#### IMPORTANT SAFETY INFORMATION

**TABRECTA** may cause serious side effects. Tell your health care provider right away if you get any of the following:

- **Lung or breathing problems**. TABRECTA may cause inflammation of the lungs that can cause death. Tell your health care provider right away if you develop any new or worsening symptoms, including:
  - o cough
  - o fever
  - trouble breathing or shortness of breath

"My treatment is specific for my type of lung cancer."

METex14, Meet Doug

### Welcome to TABRECTA

You took a test to find out what type of lung cancer you have, and the results showed that your tumors have an abnormality in your mesenchymal-epithelial transition (MET) gene called *MET* exon 14 skipping (*MET*ex14). That's why your doctor has prescribed TABRECTA® (capmatinib) tablets for your metastatic non-small cell lung cancer (mNSCLC). Treatment will now be part of your daily routine. Use this booklet to learn what you can expect from TABRECTA, including potential treatment results and side effect information.

#### **IMPORTANT SAFETY INFORMATION (continued)**

- Liver problems. TABRECTA may cause abnormal liver blood test results. Your health care provider will do blood tests to check your liver function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs or symptoms of liver problems, including the following:
  - o your skin or the white part of your eyes turns yellow (jaundice)
  - dark or "tea-colored" urine
  - light-colored stools (bowel movements)
  - o confusion
  - o loss of appetite for several days or longer
  - o nausea and vomiting
  - o pain, aching, or tenderness on the right side of your stomach area (abdomen)
    - weakness
  - swelling in your stomach area

#### **IMPORTANT SAFETY INFORMATION (continued)**

- Pancreas problems. TABRECTA may cause changes in your blood amylase or lipase levels that may indicate a problem with your pancreas. Your health care provider will do blood tests to check your pancreatic function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs and symptoms of pancreas problems, including:
  - o upper stomach (abdominal) pain that may spread to your back and get worse with eating
  - weight loss
  - o nausea
  - vomiting

## What is TABRECTA? (ta brek' tah)

- TABRECTA® (capmatinib) tablets is a prescription medicine used to treat adults with a kind of lung cancer called non-small cell lung cancer (NSCLC) that:
- has spread to other parts of the body (metastatic), and
- whose tumors have an abnormality in their MET gene. Your health care provider will perform a test to make sure that TABRECTA is right for you.

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



MET exon 14 skipping (METex14)

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## Understanding **NSCLC**

NSCLC is not just 1 disease, but many types of disease with specific genetic differences. Certain people may have noninherited gene mutations that can cause their cancer cells to grow and multiply.

#### METex14 IS CAUSED BY MUTATIONS IN THE MET GENE

- Gene changes (mutations) have been linked to cancer growth in mNSCLC
- Certain noninherited gene mutations can cause METex14, which is an abnormal change in a gene that makes a protein called MET
- METex14 has been linked to cancer growth in mNSCLC
- METex14 can be detected by an FDA-approved comprehensive biomarker test
- For people with mNSCLC with *MET*ex14, there is an option to take the first FDA-approved targeted therapy, TABRECTA® (capmatinib) tablets

#### IMPORTANT SAFETY INFORMATION (continued)

- Allergic reactions. TABRECTA can cause an allergic reaction. Stop taking TABRECTA and tell your health care provider right away if you get any signs and symptoms of an allergic reaction, including:
  - fever
  - chills
  - itchina
  - ∘ rash
  - dizziness or feeling faint
  - nausea
  - vomiting
- Risk of sensitivity to sunlight (photosensitivity). Your skin may be sensitive to the sun (photosensitivity) during treatment with TABRECTA. Use sunscreen or wear clothes that cover your skin during your treatment with TABRECTA to limit direct sunlight exposure



About
TABRECTA®
(capmatinib)
tablets

TABRECTA® (capmatinib) tablets is the first treatment FDA approved to specifically treat people with mNSCLC who have *MET*ex14. Explore the following information about TABRECTA, including clinically proven treatment results.



## Who is **TABRECTA for?**

- TABRECTA is used to treat adults with NSCLC that:
  - has spread to other parts of the body (metastatic), and
  - whose tumors have an abnormality in their MET gene. Your health care provider will perform a test to make sure that TABRECTA is right for you.

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



## How does **TABRECTA work?**

 TABRECTA works by blocking the activity of proteins made by METex14 that can cause your cancer to grow

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- TABRECTA affects both cancer cells and healthy cells
- Although TABRECTA has been studied in people with NSCLC, how TABRECTA works has been demonstrated only in laboratory studies

#### **IMPORTANT SAFETY INFORMATION (continued)**

Before you take TABRECTA, tell your health care provider about all your medical conditions, including if you:

- have or have had lung or breathing problems other than your lung cancer
- have or have had liver problems
- have or have had pancreatic problems
- are pregnant or plan to become pregnant. TABRECTA can harm your unborn baby **Females** who are able to become pregnant:
  - Your health care provider should do a pregnancy test before you start your treatment with TABRECTA
  - You should use effective birth control during treatment and for 1 week after your last dose of TABRECTA. Talk to your health care provider about birth control choices that might be right for you during this time
  - Tell your health care provider right away if you become pregnant or think you may be pregnant during treatment with TABRECTA

### TABRECTA was shown to help shrink or slow the growth of tumors

In a clinical trial, TABRECTA® (capmatinib) tablets was studied in 2 different groups of people with *MET*ex14: those taking TABRECTA as their first treatment and those previously treated before taking TABRECTA.

The overall response rate measures the size or number of tumors people have. This includes people whose tumors became smaller or fewer in number (which is called a partial response), and people whose tumors disappeared completely (which is called a complete response). A complete response is not the same thing as a cure.

Duration of response is the length of time that a tumor continues to respond to treatment without the cancer growing or spreading.

#### IMPORTANT SAFETY INFORMATION (continued)

Before you take TABRECTA, tell your health care provider about all your medical conditions, including if you (continued):

**Males** who have female partners who can become pregnant:

- You should use effective birth control during treatment and for 1 week after your last dose of TABRECTA
- are breastfeeding or plan to breastfeed. It is not known if TABRECTA passes into your breast milk.
   Do not breastfeed during treatment and for 1 week after your last dose of TABRECTA

**Tell your health care provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### PROVEN CLINICAL TRIAL RESULTS

## For people taking TABRECTA as their **first treatment**

#### Overall response rate

Nearly **7 in 10 people** had their tumors **shrink or disappear** 

\$ \$ \$ \$ \$ \$ **68%** 

Among people taking TABRECTA as their first treatment, 68% of 60 people achieved a response with TABRECTA. Of these responders, 5% had a complete response and 63% had a partial response.

#### **Duration of response**

#### Response lasted more than **1 year**:

The median (or midpoint) duration of response for people taking TABRECTA as their first treatment was 16.6 months. This means that half of the people who responded to treatment continued to respond for longer than 16.6 months and half responded for less than 16.6 months.

### **TABRECTA** was shown to help shrink or slow the growth of tumors

The overall response rate measures the size or number of tumors people have. This includes people whose tumors became smaller or fewer in number (which is called a partial response), and people whose tumors disappeared completely (which is called a complete response). A complete response is not the same thing as a cure.

Duration of response is the length of time that a tumor continues to respond to treatment without the cancer growing or spreading.

#### IMPORTANT SAFETY INFORMATION (continued)

The most common side effects of TABRECTA® (capmatinib) tablets include:

- swelling of your hands or feet
- nausea
- muscle or bone pain
- tiredness and weakness
- vomiting

- trouble breathing
- cough
- loss of appetite
- changes in certain blood tests

Your health care provider may change your dose, temporarily stop, or permanently stop treatment with TABRECTA if you develop certain side effects.

These are not all the possible side effects of TABRECTA. 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 click here for full Prescribing Information for TABRECTA, including Patient Information.

#### PROVEN CLINICAL TRIAL RESULTS

### For people taking TABRECTA after taking another medicine

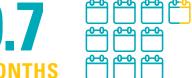
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#### Overall response rate

More than 4 in 10 people had their tumors shrink or disappear

Among people who were previously treated, 44% of 100 people achieved a response with TABRECTA. Of these responders, 0 people had a complete response and 44% had a partial response.

#### **Duration of response**



The median (or midpoint) duration of response for people who were previously treated was 9.7 months. This means that half of the people who responded to treatment continued to respond for longer than 9.7 months and half responded for less than 9.7 months.

#### **Summary of Important Information for TABRECTA**

#### What is TABRECTA?

TABRECTA® (capmatinib) tablets is a prescription medicine used to treat adults with a kind of lung cancer called non-small cell lung cancer (NSCLC) that:

- has spread to other parts of the body (metastatic), and
- whose tumors have an abnormal mesenchymal-epithelial transition (MET) gene. Your health care provider will perform a test to make sure that TABRECTA is right for you.

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

#### What are the possible side effects of TABRECTA?

TABRECTA may cause serious side effects. Tell your health care provider right away if you experience any of the following:

- Lung or breathing problems. TABRECTA may cause inflammation of the lungs that can cause death. Tell your health care provider right away if you develop any new or worsening symptoms, including:
  - cough
  - fever
  - trouble breathing or shortness of breath
- Liver problems. TABRECTA may cause abnormal liver blood test results. Your health care provider will do blood tests to check your liver function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs or symptoms of liver problems, including:
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or "tea-colored" urine
  - light-colored stools (bowel movements)
  - confusion

- loss of appetite for several days or longer
- nausea and vomiting
- o pain, aching, or tenderness on the right side of your stomach area (abdomen)
- weakness
- swelling in your stomach area
- Pancreas problems. TABRECTA may cause changes in your blood amylase or lipase levels that may indicate a problem with your pancreas. Your health care provider will do blood tests to check your pancreatic function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs and symptoms of pancreas problems, including:
  - o upper stomach (abdominal) pain that may spread to your back and get worse with eating
  - weight loss
  - nausea
  - vomiting
- Allergic reactions. TABRECTA can cause an allergic reaction. Stop taking TABRECTA and tell your health care provider right away if you get any signs and symptoms of an allergic reaction, including:
  - fever
  - o chills
  - itching
  - o rash
  - dizziness or feeling faint
  - o nausea
  - vomitina

Risk of sensitivity to sunlight (photosensitivity). Your skin may be sensitive to the sun (photosensitivity) during treatment with TABRECTA. Use sunscreen or wear clothes that cover your skin during your treatment with TABRECTA to limit direct sunlight exposure

#### The most common side effects of TABRECTA include:

- swelling of your hands or feet
- nausea
- muscle or bone pain

- tiredness and weakness
- vomiting
- trouble breathing

- cough
- loss of appetite
- changes in certain blood tests

Your health care provider may change your dose, or temporarily or permanently stop treatment with TABRECTA, if you develop certain side effects.

These are not all the possible side effects of TABRECTA. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

#### What should I tell my health care provider before taking TABRECTA?

Before you take TABRECTA, tell your health care provider about all your medical conditions, including if you:

- have or have had lung or breathing problems other than your lung cancer
- have or have had liver problems
- have or have had pancreas problems
- are pregnant or plan to become pregnant. TABRECTA can harm your unborn baby

**Females** who are able to become pregnant:

- Your health care provider should do a pregnancy test before you start your treatment with TABRECTA
- You should use effective birth control during treatment and for 1 week after your last dose of TABRECTA. Talk to your health care provider about birth control choices that might be right for you during this time
- Tell your health care provider right away if you become pregnant or think you may be pregnant during treatment with TABRECTA

Males who have female partners who can become pregnant:

- o You should use effective birth control during treatment and for 1 week after your last dose of TABRECTA
- are breastfeeding or plan to breastfeed. It is not known if TABRECTA passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of TABRECTA

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### What should I avoid while taking TABRECTA?

Your skin may be sensitive to the sun (photosensitivity) during treatment with TABRECTA. Use sunscreen or wear clothes that cover your skin during your treatment with TABRECTA to limit direct sunlight exposure.

#### General information about the safe and effective use of TABRECTA

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

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 click here for full Prescribing Information for TABRECTA, including Patient Information.



# Taking TABRECTA® (capmatinib) tablets

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### Taking TABRECTA

Take TABRECTA® (capmatinib) tablets exactly as your health care provider tells you. TABRECTA is an oral tablet. The recommended dose of TABRECTA is 400 mg (two 200-mg tablets) twice daily. It's important to always follow your health care provider's directions when taking TABRECTA.

### How should I take TABRECTA?



Take TABRECTA twice a day



TABRECTA can be taken with or without food



Swallow TABRECTA tablets whole. Do not break, chew, or crush them

- Take TABRECTA 2 times a day with or without food
- Swallow TABRECTA tablets whole. Do not break, chew, or crush TABRECTA tablets
- Your health care provider may change your dose, temporarily stop, or permanently stop treatment with TABRECTA if you have certain side effects
- Do not change your dose or stop taking TABRECTA unless your health care provider tells you to
- If you miss or vomit a dose of TABRECTA,
   do not make up the dose. Take your next
   dose at your regularly scheduled time

## What should I avoid while taking TABRECTA?

Your skin may be sensitive to the sun (photosensitivity) during treatment with TABRECTA.



Limit direct sunlight exposure



Use sunscreen



Wear clothes that cover your skin

#### **IMPORTANT SAFETY INFORMATION**

**TABRECTA may cause serious side effects.** Tell your health care provider right away if you get any of the following:

- Lung or breathing problems. TABRECTA may cause inflammation of the lungs that can cause death. Tell your health care provider right away if you develop any new or worsening symptoms, including:
  - o cough
  - fever
  - trouble breathing or shortness of breath





## How should I store TABRECTA?

- Store TABRECTA® (capmatinib) tablets at room temperature between 68°F to 77°F (20°C to 25°C)
- Store TABRECTA in the original package with the drying agent (desiccant) cartridge
- Protect TABRECTA from moisture
- Throw away (discard) any unused TABRECTA you have left after 6 weeks of first opening the bottle
- Talk to your pharmacist for instructions on how to discard unused TABRECTA tablets

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

#### IMPORTANT SAFETY INFORMATION (continued)

- Liver problems. TABRECTA may cause abnormal liver blood test results. Your health care provider will do blood tests to check your liver function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs or symptoms of liver problems, including the following:
  - o your skin or the white part of your eyes turns yellow (jaundice)
  - o dark or "tea-colored" urine
  - light-colored stools (bowel movements)
  - confusion
  - o loss of appetite for several days or longer
  - nausea and vomiting
  - o pain, aching, or tenderness on the right side of your stomach area (abdomen)
  - weakness
  - o swelling in your stomach area



## What are the ingredients in TABRECTA?

**ACTIVE INGREDIENT:** capmatinib

**Inactive ingredients:** Tablet core: colloidal silicon dioxide; crospovidone; magnesium stearate; mannitol; microcrystalline cellulose; povidone; and sodium lauryl sulfate. Tablet coating (150 mg): ferric oxide, red; ferric oxide, yellow; ferrosoferric oxide; hypromellose; polyethylene glycol (PEG) 4000; talc; and titanium dioxide. Tablet coating (200 mg): ferric oxide, yellow; hypromellose; polyethylene glycol (PEG) 4000; talc; and titanium dioxide.

#### GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF TABRECTA

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



## Side **Effects**

### Side **Effects**

It's only natural to have concerns about potential side effects when starting a new treatment. TABRECTA® (capmatinib) tablets may have some side effects with which you're unfamiliar. Talk to your doctor about any side effects you're experiencing. If you develop certain serious side effects, your doctor may decrease your dose, have you take a break from treatment, or have you stop taking TABRECTA.

### What are the possible side effects of TABRECTA?

#### TABRECTA MAY CAUSE SERIOUS SIDE EFFECTS, INCLUDING:



LUNG OR BREATHING PROBLEMS. TABRECTA may cause inflammation of the lungs that can cause death. Tell your health care provider right away if you develop any new or worsening symptoms, including:

- cough
- fever
- trouble breathing or shortness of breath



LIVER PROBLEMS. TABRECTA may cause abnormal liver blood test results. Your health care provider will do blood tests to check your liver function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs and symptoms of liver problems, including:

- your skin or the white part of your eyes turns yellow (jaundice)
- dark or "tea-colored" urine
- light-colored stools (bowel movements)
- confusion
- loss of appetite for several days or longer swelling in your stomach area
- nausea and vomiting
- pain, aching, or tenderness on the right side of your stomach area (abdomen)
- weakness



PANCREAS PROBLEMS. TABRECTA may cause increases in your blood amylase and/or lipase levels that may indicate a problem with your pancreas. Your health care provider will do blood tests to check your pancreatic function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs and symptoms of pancreas problems, including:

- upper stomach (abdominal) pain that may spread to your back and get worse with eating
- weight loss
- nausea
- vomiting



ALLERGIC REACTIONS. TABRECTA can cause an allergic reaction. Stop taking TABRECTA and tell your health care provider right away if you get any signs and symptoms of an allergic reaction, including:

- fever
- chills
- itchina
- rash

- dizziness or feeling faint
- nausea
- vomiting



RISK OF SENSITIVITY TO SUNLIGHT (PHOTOSENSITIVITY). Your skin may be sensitive to the sun (photosensitivity) during treatment with TABRECTA. Use sunscreen or wear clothes that cover your skin during your treatment with TABRECTA to limit direct sunlight exposure

#### **IMPORTANT SAFETY INFORMATION (continued)**

- Pancreas problems. TABRECTA may cause changes in your blood amylase or lipase levels that may indicate a problem with your pancreas. Your health care provider will do blood tests to check your pancreatic function before you start treatment and during treatment with TABRECTA. Tell your health care provider right away if you develop any signs and symptoms of pancreas problems, including:
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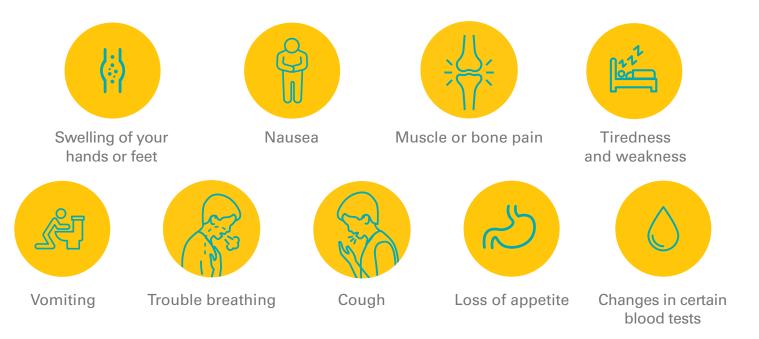
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vomiting

- o rash
- Risk of sensitivity to sunlight (photosensitivity). Your skin may be sensitive to the sun (photosensitivity) during treatment with TABRECTA. Use sunscreen or wear clothes that cover your skin during your treatment with TABRECTA to limit direct sunlight exposure

## What are the most common side effects of TABRECTA?

THE MOST COMMON SIDE EFFECTS OF TABRECTA® (capmatinib) tablets INCLUDE:



Your health care provider may change your dose, temporarily stop, or permanently stop treatment with TABRECTA if you develop certain side effects.

These are not all the possible side effects of TABRECTA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

#### **IMPORTANT SAFETY INFORMATION (continued)**

Before you take TABRECTA, tell your health care provider about all your medical conditions, including if you:

- have or have had lung or breathing problems other than your lung cancer
- have or have had liver problems
- have or have had pancreatic problems
- are pregnant or plan to become pregnant. TABRECTA can harm your unborn baby

# Talk to your doctor if you experience swelling of your hands or feet

Swelling of the hands or feet is a common side effect of TABRECTA.

If you experience swelling, be sure to reach out to your doctor. There are strategies your doctor may suggest to help potentially manage the swelling, which may include changing how you take TABRECTA.

YOUR DOCTOR MAY TRY THESE WAYS TO MANAGE THE SYMPTOMS OF SWELLING:







Compression stockings



Dietary salt modification



Make sure you reach out to your doctor to talk about these techniques before trying them at home.



## Patient Support

There's a lot of information to take in when starting treatment. You may have questions.

including information about insurance coverage and financial resources.

Here are some important details to help you get started on TABRECTA® (capmatinib) tablets,

Patient Support

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## Financial Resources & Access for TABRECTA

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.

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



#### NOVARTIS ONCOLOGY UNIVERSAL CO-PAY PROGRAM

You may be eligible for immediate co-pay savings on your TABRECTA prescription.

- 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 **Copay.NovartisOncology.com**.

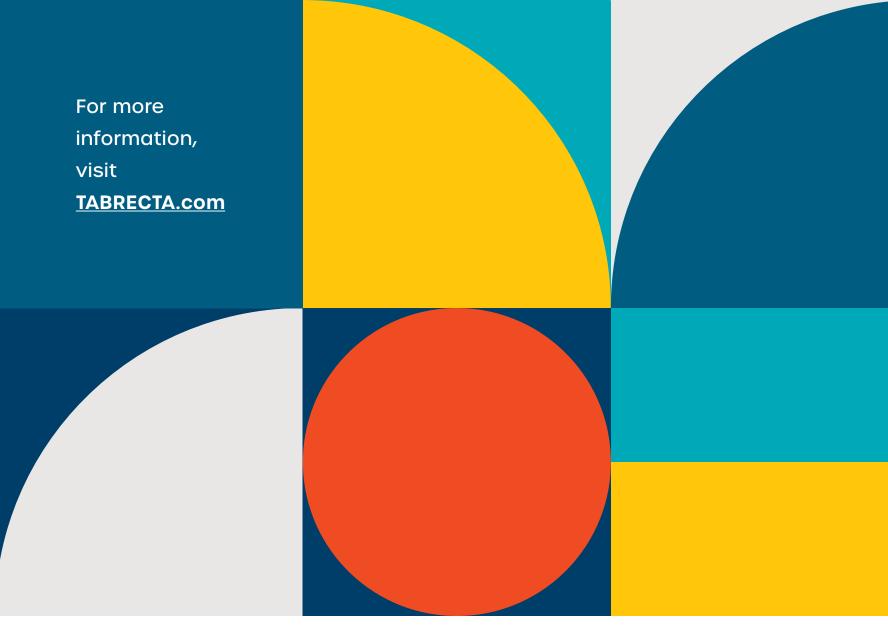
\*Limitations apply. This offer is only available to patients with private insurance. The program is not available for patients who are enrolled in Medicare, Medicaid, or any other federal or state health care program. Novartis reserves the right to rescind, revoke, or amend this program without notice.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



#### TABRECTA 14-DAY FREE TRIAL PROGRAM

With the TABRECTA 14-Day Free Trial Program, you can receive a free supply of TABRECTA for a US Food and Drug Administration (FDA)—approved indication. The supply can be shipped directly to your home or another convenient location so you can start treatment immediately. Program rules may vary.

Ask your health care provider to help you apply for the TABRECTA 14-Day Free Trial Program through PANO.



Please see Important Safety Information throughout. Please <u>click here</u> for the Summary of Important Information.



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