



# DISCOVER YOUR PATH AHEAD

WITH ORAL EXKIVITY® (mobocertinib)

FOR PATIENTS WITH **EGFR EXON20 INSERTION**–POSITIVE  
METASTATIC NON-SMALL CELL LUNG CANCER (NSCLC)  
AFTER CHEMOTHERAPY THAT CONTAINS PLATINUM

## What is EXKIVITY?

EXKIVITY is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC):

- that has spread to other parts of the body (metastatic) and cannot be removed by surgery, **and**
- has a certain abnormal epidermal growth factor receptor (EGFR) gene, **and**
- whose disease has worsened while on or after chemotherapy that contains platinum

Your healthcare provider will perform a test to make sure that EXKIVITY is right for you. It is not known if EXKIVITY is safe and effective in children. EXKIVITY is approved based on a medical study that measured how many people responded to treatment and for how long. There are ongoing studies to confirm its continued approval.

## IMPORTANT SAFETY INFORMATION

### What is the most important information I should know about EXKIVITY?

**EXKIVITY may cause serious side effects, including changes in the electrical activity of your heart called QTc prolongation and Torsades de Pointes. QTc prolongation can cause irregular heartbeats that can be life-threatening and may lead to death.** Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolytes before starting treatment and during treatment with EXKIVITY. Tell your healthcare provider right away if you feel dizzy, lightheaded, faint or have an irregular heartbeat.

Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the Patient Information in the accompanying full Prescribing Information.

 **EXKIVITY**®  
mobocertinib  
40 mg capsules

# Contents

NSCLC Overview .....	4
EGFR Exon20 Insertion Mutations Explained .....	6
How EXKIVITY® (mobocertinib) Works .....	7
Study Results .....	8
Important Safety Information .....	10
Taking EXKIVITY .....	14
Managing Side Effects .....	16
Support .....	20
Glossary .....	23

# Welcome to Treatment With EXKIVITY

EXKIVITY is the first oral therapy designed just for **your type of lung cancer:** metastatic lung cancer that's caused by an **epidermal growth factor receptor (EGFR) Exon20 insertion** mutation.

This brochure is designed just for you. It will guide you through **all the information** you'll need to know during treatment with EXKIVITY.

Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).

 **EXKIVITY**<sup>®</sup>  
mobocertinib  
40 mg capsules

# What Is NSCLC?

You may have heard your doctor call your type of lung cancer non-small cell lung cancer or *NSCLC*. But what is that?

**There are 2 main types of lung cancer:**

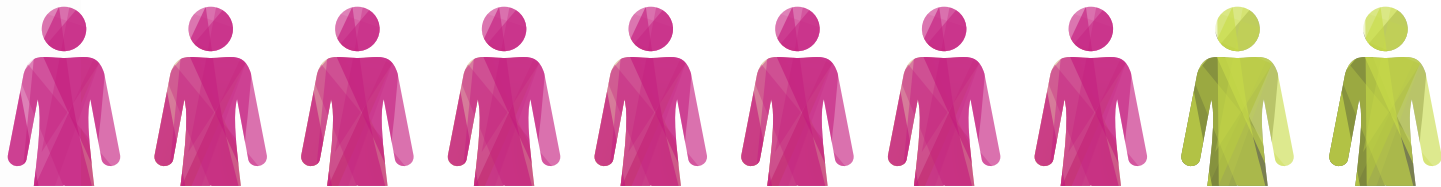


**Non-small cell lung cancer  
(NSCLC)**



**Small cell lung cancer  
(SCLC)**

Most people with lung cancer (about 8 in 10) have NSCLC, **the same type as you**



Another word you may have heard is *metastatic*. This means that the cancer has spread from the lungs to other parts of the body (for example, to the bone, liver, or brain). This is sometimes called Stage IV cancer.

# What Causes NSCLC?

When people think of lung cancer, they often assume it was caused by smoking. However, in some cases of NSCLC, a genetic change—or *mutation*—in the cell's genes causes the cell to function improperly and grow more quickly, which may lead to cancer.

## Testing for Mutations Can Help Identify the Ideal Therapy for You

At some point during your diagnosis, you may have had a biopsy. A biopsy is a medical procedure where a small part of your tumor is removed so it can be tested.

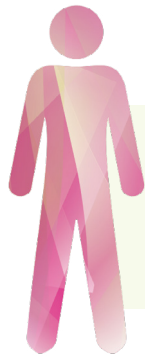
Your doctor may have used this biopsy to see if your NSCLC was caused by a specific gene mutation. Identifying your particular gene mutation can help you and your doctor choose specific treatment options—or *targeted therapies*—that are more likely to effectively treat your disease.

**Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).**

 **EXKIVITY<sup>®</sup>**  
mobocertinib  
40 mg capsules

# A Rare Mutation, but You're Not Alone

Your lung cancer is caused by a rare gene mutation called an **EGFR Exon20 insertion**. This mutation occurs in about **2%** of people with NSCLC.



**AROUND 2,000–4,000 PEOPLE**

are diagnosed with NSCLC caused by an **EGFR Exon20** insertion mutation **each year** in the US.

## Treating EGFR Exon20 Insertion Mutations

The treatment of EGFR Exon20 insertion mutations is advancing and more treatment options are now available. **This is a time of hope.**

**EXKIVITY® (mobocertinib) is helping to change the treatment story for people like you.**

**EXKIVITY may cause serious side effects**, including changes in the electrical activity of your heart, lung problems, heart problems, including heart failure, and diarrhea.

# Designed Just for Your Specific Mutation

Now, **for the first time**, there's an oral therapy that targets **EGFR Exon20 insertion** mutations for people who have been on chemotherapy—**EXKIVITY**.

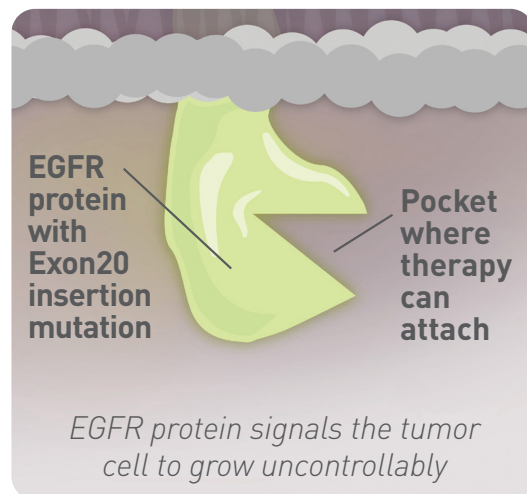
EXKIVITY is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC):

- that has spread to other parts of the body (metastatic) and cannot be removed by surgery, **and**
- has a certain abnormal epidermal growth factor receptor (EGFR) gene, **and**
- whose disease has worsened while on or after chemotherapy that contains platinum

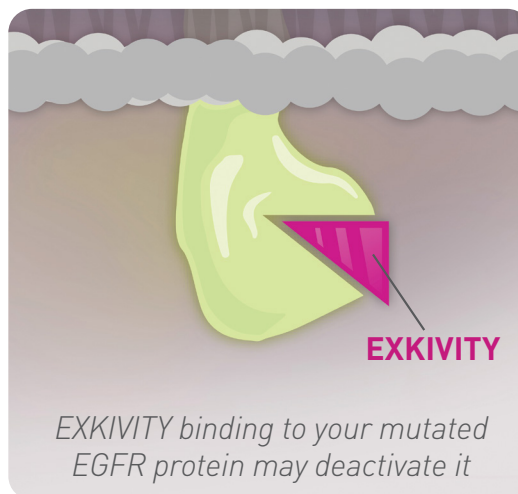
## How EXKIVITY works

EXKIVITY is **the only oral therapy designed** to bind to EGFR proteins with **Exon20 insertion mutations**.

### Without EXKIVITY



### With EXKIVITY



Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).

 **EXKIVITY**<sup>®</sup>  
mobocertinib  
40 mg capsules

# Studied in People Like You

The risks and benefits of EXKIVITY® (mobocertinib) were studied in 114 adults with metastatic NSCLC who had **EGFR Exon20 insertion** mutations. All people had been previously treated with chemotherapy containing platinum.

## In the study:

- All people received the recommended dosing regimen of 160 mg of EXKIVITY orally once daily
- Ages ranged from 27 years old to 84 years old
- Two-thirds were female
- Most had never smoked (71%)
- People were from all around the world: 53 from the United States, 6 from Europe, and 55 from the Asia Pacific region

## Clinical results with EXKIVITY

EXKIVITY **shrank tumors by about a third** or more for approximately

**3 in 10** people

with a median length of response of

**17.5 months**

- Meaning, half of the people who responded to EXKIVITY did so for 17.5 months or longer, and half responded for less than 17.5 months
- Approximately 60% of the people who responded to EXKIVITY did so for 6 months or longer

In this study, it was likely that the majority of people who responded to EXKIVITY saw a response that lasted anywhere between 7.4 months and 20.3 months.

**The most common side effects** seen in the EXKIVITY clinical study included diarrhea, rash, nausea, mouth sores, vomiting, decreased appetite, infection of skin around nails, tiredness, dry skin, and muscle or bone pain.

Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).

 **EXKIVITY**<sup>®</sup>  
mobocertinib  
40 mg capsules

# Important Safety Information for EXKIVITY® (mobocertinib)

## What is the most important information I should know about EXKIVITY?

**EXKIVITY may cause serious side effects, including changes in the electrical activity of your heart called QTc prolongation and Torsades de Pointes. QTc prolongation can cause irregular heartbeats that can be life-threatening and may lead to death.** Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolytes before starting treatment and during treatment with EXKIVITY. Tell your healthcare provider right away if you feel dizzy, lightheaded, faint, or have an irregular heartbeat.

## EXKIVITY may cause serious side effects, including:

- **Lung problems.** EXKIVITY may cause severe lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you develop any new or worsening symptoms, including trouble breathing or shortness of breath, cough, chest pain, or fever.
- **Heart problems, including heart failure.** EXKIVITY may cause heart problems that may lead to death. Your healthcare provider should check your heart function before you start and during treatment with EXKIVITY. Tell your healthcare provider right away if you have any signs or symptoms of a heart problem, including feeling like your heart is pounding or racing, shortness of breath, chest pain, swelling of your ankles and feet, or feeling faint.
- **Diarrhea.** Diarrhea is common during treatment with EXKIVITY and may sometimes be severe. Diarrhea can cause you to lose too much body fluid (dehydration) and kidney problems. Your healthcare provider may tell you to start drinking more fluids and electrolytes to replace body salts or start taking your antidiarrheal medicines. Tell your healthcare provider right away if you have any loose stools or have stools more often than is normal for you.

The most common side effects of EXKIVITY include diarrhea, rash, nausea, mouth sores, vomiting, decreased appetite, infection of skin around nails, tiredness, dry skin, muscle or bone pain. EXKIVITY may affect fertility in females and males, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

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

**Continued on next page >**

**Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).**

 **EXKIVITY<sup>®</sup>**  
mobocertinib  
40 mg capsules

# Important Safety Information (Cont'd)

**Before taking EXKIVITY, tell your healthcare provider about all your medical conditions, including if you:**

- have heart problems, including a condition called long QTc syndrome
- have problems with your electrolytes, such as sodium, potassium, calcium or magnesium
- have lung or breathing problems other than lung cancer
- are pregnant or plan to become pregnant. EXKIVITY can harm your unborn baby.

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

- Your healthcare provider should do a pregnancy test before you start treatment with EXKIVITY. You should use an effective form of non-hormonal birth control during treatment and for **1 month** after your last dose of EXKIVITY. Birth control pills (oral contraceptives) and other hormonal forms of birth control may not work as well during treatment with EXKIVITY. Talk to your healthcare provider about birth control methods that might be right for you during this time. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with EXKIVITY.

## **Males who have female partners who are able to become pregnant:**

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

**Tell your healthcare provider about all the medicines you take,** including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. Tell your healthcare provider if you take medicines for heart problems. EXKIVITY and other medicines may affect each other causing serious side effects.

## How should I take EXKIVITY?

- Take EXKIVITY exactly as your healthcare provider tells you to take it.
- Take your prescribed dose of EXKIVITY 1 time each day.
- Take EXKIVITY with or without food.
- Swallow EXKIVITY capsules whole. Do not open, chew, or dissolve the contents of the capsules.
- **Do not** change your dose or stop taking EXKIVITY unless your healthcare provider tells you to.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with EXKIVITY if you develop certain side effects.
- If you miss a dose of EXKIVITY, and it has been more than 6 hours, skip the dose and take your next dose at your regularly scheduled time the next day.
- If you vomit a dose of EXKIVITY, do not take an extra dose. Take your next dose at your regularly scheduled time the next day.

## What should I avoid while taking EXKIVITY?

- Avoid eating grapefruit or drinking grapefruit juice during treatment with EXKIVITY. Grapefruit may increase the amount of EXKIVITY in your blood.

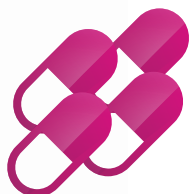
Please see [Patient Information](#) in the accompanying EXKIVITY (mobocertinib) full [Prescribing Information](#).

Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).

 **EXKIVITY**<sup>®</sup>  
mobocertinib  
40 mg capsules

# Taking EXKIVITY® (mobocertinib)

## 4 pills, once daily



Take EXKIVITY **exactly as your healthcare provider** tells you to take it. The recommended dosing for EXKIVITY is 4 pills all taken at the same time once a day.



You can take EXKIVITY at any time as long as it's the **same time every day**. You can take EXKIVITY with or without food. Just choose a time that is **convenient for you**.

### Things to remember

- ✓ **Swallow EXKIVITY capsules whole.** Do not open, chew, or dissolve the contents of the capsules
- ✓ **Do not change your dose or stop taking EXKIVITY** unless your healthcare provider tells you to
- ✓ Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with EXKIVITY if you develop certain side effects
- ✓ If you miss a dose of EXKIVITY, and it has been more than 6 hours, skip the dose and take your next dose at your regularly scheduled time the next day
- ✓ If you vomit after a dose of EXKIVITY, do not take an extra dose. Take your next dose at your regularly scheduled time the next day
- ✓ Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolytes before starting and during treatment with EXKIVITY

## Tips for taking your medication daily

Taking EXKIVITY every day is important. These tips may help you stay on track.



**Set an alarm** to remind you to take your medication at the same time every day.



If you're normally in the same place when you take EXKIVITY, keep your **pill box or medication bottle** there to help remind you.



Use a **calendar** to keep track, and mark each day with an X after you've taken your medication.



**Ask a friend**, family member, or caregiver to check in with you and remind you to take your medication.



Be sure to take your medication with you when you **travel**. If you are traveling by air, keep your medication in your carry-on bag. If you do leave it at home, call your healthcare provider right away. Your healthcare team may be able to get a new supply of EXKIVITY to you at your new location through a nearby pharmacy.



**Avoid eating grapefruit or drinking grapefruit juice** during treatment with EXKIVITY. Grapefruit may increase the amount of EXKIVITY in your blood.

Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).

 **EXKIVITY**<sup>®</sup>  
mobocertinib  
40 mg capsules

# Understanding Side Effects

EXKIVITY® (mobocertinib) may cause side effects. Not every person will experience the same side effects, and for some people, some side effects may be more severe than others. **You and your healthcare team should monitor for side effects** and work together to manage them early so you can **get the most out of treatment**.

## Possible serious side effects you should be aware of:



### Changes in the electrical activity of your heart

In some people, EXKIVITY can affect the electrical activity of the heart, causing irregular heartbeats. This can be life-threatening and may lead to death. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolytes before you start EXKIVITY and during treatment. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint, or have an irregular heartbeat.



### Lung problems

EXKIVITY may cause severe lung problems that may lead to death. It may be hard to tell lung problems from your lung cancer symptoms so tell your healthcare team right away if you develop any new or worsening symptoms, including trouble breathing or shortness of breath, cough, chest pain, or fever.



### Heart problems, including heart failure

EXKIVITY may cause heart problems, including heart failure. Your healthcare provider should check your heart function before you start EXKIVITY and during treatment. Tell your healthcare provider right away if you have any signs or symptoms of a heart problem, including feeling like your heart is pounding or racing, shortness of breath, chest pain, swelling of your ankles and feet, or feeling faint.



### Diarrhea

Diarrhea is common with EXKIVITY and may sometimes be severe. Diarrhea can cause you to lose too much body fluid (dehydration) and kidney problems. Tell your healthcare provider right away if you have any loose stools or have stools more often than is normal for you.

# How to Manage Diarrhea if It Occurs

## ANTICIPATE

- Diarrhea should be treated **right away**
- It typically **occurs within 5 days** but can occur as soon as 24 hours after starting EXKIVITY. It can continue to occur at any point during therapy
- It is most often **mild to moderate**
- It is recommended that you have an **antidiarrheal medicine (such as loperamide) at home** so you can treat diarrhea promptly when it happens
- **Talk to your healthcare team** before taking any medication

## ADDRESS

- Your healthcare team is likely to instruct you to take an antidiarrheal medicine at first sign of loose or poorly formed stool
- **Tell your healthcare team immediately** if you have any loose stools or if your bowel movements become more frequent than normal
- **Stay hydrated:** drink enough liquids (about 8 to 10 cups) every day to replace lost fluids and electrolytes
- **Eat simply:** eat smaller, more frequent meals of plain foods such as bananas, rice, applesauce, and toast. Avoid fatty and high-fiber foods

Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).

# How to Manage Skin Reactions if They Occur

Some people taking EXKIVITY® (mobocertinib) experienced skin reactions, but they were mostly mild or moderate. They included rash, dry skin, and nail inflammation. Common symptoms of rash were itchy, dry, or swollen red skin, and red, inflamed, scaly skin.

If you experience any of these skin reactions, be sure to talk to your healthcare team right away. Your team may refer you to a dermatologist. If your rash is severe, they may reduce, withhold, or permanently discontinue your dose of EXKIVITY.



## **Limit sun exposure**

Sunburn can make rash symptoms worse. Avoid too much time in the sun, use sunscreen, and protect your skin with a hat and long sleeves.



## **Keep skin soft**

Use an alcohol- and perfume-free skin cream often. Avoid hot showers and products that dry your skin.



## **Talk to your healthcare team**

Speak up if rash makes it hard for you to carry out normal daily activities.

## **The importance of speaking up**

Sometimes people worry about mentioning side effects to their doctors or nurses—they don't want to bother them, or they're scared of being taken off their medication.

If you have any side effect that interferes with daily life or that does not go away, **tell your healthcare team right away**. Addressing side effects as soon as possible may **keep them** from getting worse.



Images throughout are not of actual patients.

Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the Patient Information in the accompanying full Prescribing Information.

 **EXKIVITY**<sup>®</sup>  
mobocertinib  
40 mg capsules

# Patient Support Program



From finding financial assistance that may be right for you to understanding your disease, Takeda Oncology Here2Assist™ can provide the information you need throughout your treatment.

## Takeda Oncology Here2Assist:

- ▶ Works with your insurance company to help you get started on your medication
- ▶ Identifies available financial assistance that may be right for you
- ▶ May help get you started on treatment if there is a delay in insurance coverage determination
- ▶ Conducts regular follow-up calls with you
- ▶ Connects you to additional support services and resources
- ▶ Identifies specialty pharmacies to help fill and ship your prescriptions appropriately
- ▶ Sends you status updates and reminders via text messages\*
- ▶ Connects you with nurse navigators to support your product education journey



**ACCESS SUPPORT:** Once you're enrolled, Takeda Oncology Here2Assist case managers can work with you and your healthcare provider to determine your coverage options, and provide additional support throughout your treatment.



**FINANCIAL ASSISTANCE:** If you need assistance affording your medication, Takeda Oncology Here2Assist can help identify financial assistance programs that may be able to help you with the cost of your treatment.



**HELPFUL RESOURCES:** Takeda Oncology Here2Assist case managers can provide information about additional resources that may help address day-to-day concerns associated with your treatment.

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](http://www.Here2Assist.com). **Let's Talk.** We're available Monday-Friday, 8AM-8PM ET.

\*Patients will need to enroll in the texting program to receive text messages.

# Emotional Support



A cancer diagnosis is an emotional experience. Talking with friends, family, and other people can help you cope with these emotions.

Remember, it's normal to feel a wide range of emotions. It's normal for your feelings—even intense ones—to change daily, hourly, or even minute to minute.

Normal feelings may include:

- Feeling overwhelmed
- Denial and anger
- Fear and worry
- Sadness and depression
- Stress and anxiety
- Hope

Joining a support group or advocacy organization to talk about your experience may also be helpful. Meeting people who are going through something similar to you may help you understand your feelings and gain additional perspective. It may help reduce tension, anxiety, tiredness, and depression, and may help your overall feeling of well-being.

**Please read the Important Safety Information including information for the Boxed Warning on pages 10-13 and the [Patient Information](#) in the accompanying full [Prescribing Information](#).**

 **EXKIVITY<sup>®</sup>**  
mobocertinib  
40 mg capsules

# Where to Go for More Information

The organizations below can help you find more information and answers about **EGFR Exon20 insertion** mutations and metastatic lung cancer. They can also help you find a **community ready to help and support you**.

**The Exon 20 Group**

[exon20group.org](http://exon20group.org)

(602) 618-0183

**EGFR Resisters**

[egfrcancer.org](http://egfrcancer.org)

**LUNGeity Foundation**

[lungeity.org](http://lungeity.org)

(312) 407-6100

**National Lung  
Cancer Roundtable**

[nlcrt.org](http://nlcrt.org)

**GO<sub>2</sub> Foundation for Lung Cancer**

[go2foundation.org](http://go2foundation.org)

(800) 298-2436

**Lung Cancer Research Foundation**

[lungcancerresearchfoundation.org](http://lungcancerresearchfoundation.org)

(212) 588-1580

**Lung Cancer Foundation of America**

[lcfamerica.org](http://lcfamerica.org)

(507) 354-1361

**American Cancer Society**

[cancer.org/cancer/lung-cancer.html](http://cancer.org/cancer/lung-cancer.html)

(800) 227-2345

**CancerCare**

[cancercares.org/caregiving](http://cancercares.org/caregiving)

(800) 813-4673

**Cancer Support Community**

[cancersupportcommunity.org](http://cancersupportcommunity.org)

(888) 793-9355

**Patient Advocate Foundation**

[patientadvocate.org](http://patientadvocate.org)

(800) 532-5274

The manufacturer does not endorse these organizations. Takeda is not responsible for the content provided by any third-party organization. The online resources are provided for informational purposes only and are not meant to replace the medical advice of your healthcare providers.

# Glossary

**EGFR:** EGFR stands for epidermal growth factor receptor. It is a protein found on the surface of some cells. Normally, it helps control how cells grow and divide. If it becomes mutated, it can cause cells to grow out of control, which can cause cancer.

**Insertion:** An insertion mutation means a bit of DNA has accidentally been added to one of your genes. This insertion may cause the gene to no longer work properly.

**Metastatic:** If cancer is metastatic, that means it has spread from the place where it started to other parts of the body.

**Mutation:** A mutation is a change in the DNA of a cell. They can happen by mistake when cells are growing and dividing. They can also happen because of exposure to something that damages the DNA. Some mutations may lead to cancer, but others can be beneficial or have no effect.

**NSCLC:** Non-small cell lung cancer is a type of lung cancer named for how the cells look under a microscope. There are different subtypes. The main subtypes are squamous cell carcinoma, large cell carcinoma, and adenocarcinoma. These subtypes are named after the types of cells where the cancer starts.

**Targeted therapies:** A type of treatment that identifies and attacks specific types of cancer cells with less harm to normal cells. These targeted therapies block the actions of proteins on, or in, the cancer cells that control how the cell grows and divides.

# DISCOVER YOUR PATH AHEAD

Visit **EXKIVITY.com** for more information and resources

Please read the Important Safety Information including information for the Boxed Warning on pages 10–13 and the Patient Information in the accompanying full Prescribing Information.



ONCOLOGY

All trademarks are property of their respective owners.  
©2022 Takeda Pharmaceuticals U.S.A., Inc.  
All rights reserved. 03/22 USO-MOB-0062

 **EXKIVITY<sup>®</sup>**  
mobocertinib  
40 mg capsules