

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 16-19 and the <u>Patient Information</u> in the accompanying full <u>Prescribing Information</u>.



What to Know About Being a Care Partner

You have been given this brochure because a loved one has been prescribed EXKIVITY® (mobocertinib)— the first oral therapy for metastatic non-small cell lung cancer, or NSCLC, caused by an epidermal growth factor receptor (EGFR) Exon20 insertion mutation. This brochure is **designed to help** you navigate challenges that may lie ahead as you and your loved one begin the treatment journey together.

How you can help your loved one

Emotional support through **good communication** is one of the most important parts of your role as a care partner. Being there to listen and empathize can sometimes be the kindest and most helpful gesture.

How you can help yourself

People often find comfort in sharing experiences and working together during difficult times. There are support groups and associations that **can offer you help**.

How this brochure can help

This brochure will help you **better understand** your loved one's cancer diagnosis and will provide tips on how to support them. Sections include:

- An overview of NSCLC with an EGFR Exon20 insertion mutation
- Treatment with EXKIVITY
- Tips for supporting your loved one and yourself
- Ways to connect with support groups and care partner communities

EGFR Exon20 Insertions: What They Mean

A rare non-small cell lung cancer diagnosis

Your loved one has NSCLC, which is one of the most common types of lung cancer. However, your loved one has a rare gene mutation called an **EGFR Exon20 insertion** mutation. 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.

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



About EXKIVITY® (mobocertinib)

What is EXKIVITY and who is it for?

EXKIVITY is the first oral therapy designed just for **the type of lung cancer your loved one has**—metastatic lung cancer that's caused by an **epidermal growth factor receptor** (*EGFR*) **Exon20** *insertion* mutation. EXKIVITY is prescribed for people who have previously been treated with a specific type of chemotherapy that contains platinum (eg, cisplatin or carboplatin).

What are the serious side effects I should be aware of?

- Changes in the electrical activity of the heart: tell your loved one's healthcare team right away if he/she feels dizzy, lightheaded, faint or has an irregular heartbeat.
- Lung problems: tell your loved one's healthcare team right away if he/she develops any new or worsening symptoms, including trouble breathing or shortness of breath, cough, chest pain, or fever
- **Heart problems, including heart failure**: tell your loved one's healthcare team right away if he/she has any signs or symptoms of a heart problem, including feeling like his/her heart is pounding or racing, shortness of breath, chest pain, swelling of his/her ankles and feet, or feeling faint
- **Diarrhea**: tell your loved one's healthcare team right away if he/she has any loose stools or has stools more often than is normal

What are the most common side effects of EXKIVITY?

Like all drugs, EXKIVITY can cause side effects. The most common side effects seen in the EXKIVITY clinical study included:

- Diarrhea
- Nausea
- Vomiting

- Infection of skin around nails
- Dry skin

- Rash
- Mouth sores
- Decreased appetite
- Tiredness

• Muscle or bone pain



Not every person will experience the same side effects, and for some people, some side effects may be more severe than others. If your loved one experiences any side effects, make sure the healthcare team is told right away. Addressing side effects as soon as possible may help them get the most out of treatment.

What should I know about diarrhea with EXKIVITY?

Diarrhea is a common side effect and 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 recommended that your loved one have an **antidiarrheal medicine (such as loperamide) at home** so he/she can treat diarrhea promptly when it happens. Their healthcare team is likely to instruct your loved one to take the antidiarrheal **at the first sign** of loose or poorly formed stools. However, they should **talk to their doctor** before taking any medication.



If your loved one experiences bowel movements more frequently than normal or if they cannot control their diarrhea after 24 hours, encourage them to call their doctor or someone on their care team immediately.

What should I know about skin reactions with EXKIVITY?

Some people taking EXKIVITY experienced skin reactions, but they were mostly mild or moderate. Common symptoms of rash were itchy, dry, or swollen red skin, and red, inflamed, scaly skin. When taking EXKIVITY, your loved one should consider limiting sun exposure, and keeping skin soft with alcohol- and perfume-free skin creams



If your loved one experiences any of these skin reactions, encourage him/her to inform their doctor or someone on their care team right away.



You Are Part of the Care Team



One aspect of being a care partner may include helping your loved one work with their healthcare team. Understanding the roles and responsibilities each team member holds will help you decide where to go for answers to your questions.

Some members of the healthcare team may include:

Oncologists

Specialize in the diagnosis and treatment of cancer. **Medical oncologists** use therapies and drugs to treat cancer. **Surgical oncologists** perform surgery to remove the cancer. **Radiation oncologists** use radiation to eliminate the tumor.

Oncology Nurses and Nurse Navigators

Prepare and administer treatments and provide supportive care for people with cancer. Sometimes, your healthcare team may include a nurse navigator, who serves as the main point of contact at the doctor's office and updates every member of the team with the latest information.

Pathologists

Examine cancer cells and tissues under a microscope. They help determine the type of cancer and how fast it is growing.

Specialty Pharmacists

Provide your loved one with his or her medicines. They may offer reminders on prescription refills and help manage side effects.

Dietitians or Nutritionists

Provide your loved one with information about nutrition, food, and diet. They may help answer questions about some side effects like diarrhea.



Get all your questions answered

Ask the healthcare team to explain if something is not clear.



Being There for Your Loved One

It's not always easy to find the right words, but **letting your loved one know** you care about them is one of the most powerful ways to show support. Sometimes the treatment journey may be difficult, but **together** you can find a way—**being there** to listen can sometimes be just as important.

Engage more deeply in conversation

Asking your loved one **how they are feeling** and **empathizing** with them lets them know you really care about how they are doing. It is preferable to ask open-ended questions, such as "How are you feeling?" instead of "Do you feel ok?" This will lead to an **open dialogue** built on mutual understanding.

Be open about your feelings

It's normal to feel frustrated or stressed. A life-changing experience can impact everyone's sense of well-being. Share your fears and worries, while also letting each other know how much you care.

Show that you are together on this journey

Let your loved one know that **you're there for them** any time they want your support. Take cues from your loved one about how they like to communicate.

Focus on things you enjoy together

It's important to **reinforce your connection** with your loved one. This can mean anything from watching a movie together or going out for a walk to playing a board game or looking through old photo albums.

See encouraging but real

Telling your loved one to "always stay positive" can make it seem as though their feelings are being ignored. Similarly, try to avoid saying that you know how they must feel. No one can fully understand the emotions a loved one with cancer is experiencing.



Be there for your loved one

Tell your loved one: I'm here for you. I care about you.



Taking Care of Yourself

Dealing with a cancer diagnosis in someone you love can take a toll. But remember that even though you are caring for your loved one, it is still important that you **take care of yourself**. It will allow you to take better care of your loved one.

Know your strengths and limits

Take an honest look at the number of tasks you can take on, and which tasks can be delegated. **You can always ask for help.**

Accept help from others

Many people will want to help you. **Make a list** of daily tasks so that you can be very clear about what you need when help arrives.

List your weekly tasks

List all the things you plan to accomplish on a weekly basis and how much time you're spending on each one. Scratch off the ones that aren't important. This will **keep things more manageable** and give you more time for the things you really want and need to do.

Find comfort

Take some time each day, even if it's just for a few minutes, to **do something for yourself**. Those extra moments can help relax your mind from the demands of caregiving and recharge you to take on the rest of the day.

✓ Join a support group

Talking about your feelings or trading advice with others who share your experience as a care partner can **help you cope** and realize that you are not alone. See page 13 of this brochure for a list of support groups.

Write in a journal

Keeping a journal can help you express your thoughts and feelings. You can write about your worries and stresses, or you can write about things that make you feel good. This may help **improve your mood**.

Learn more about EGFR Exon20 insertion-positive metastatic lung cancer

When you better understand your loved one's diagnosis, you may feel more **confident and in control**. Speak up to your loved one's healthcare team when you feel you need to know something.



Look for the positive

It's not always easy to adjust to your role as a care partner. **Looking for the good** in life can help you and those around you to feel better. Think about something you find rewarding about caregiving or reflect on something else that is positive in your daily life.



Have Your Questions Ready

Before each doctor visit, write down a list of questions you or your loved one would like to ask. Be sure to put the most important questions at the top. Ask the doctor to explain if an answer to your question was unclear or if you would like more information.



Questions you may want to ask:

- What can my loved one do to prepare for treatment?
- What are the side effects of treatment?
- Are there any side effects we should call you about right away?
- Beyond treating the cancer, what can be done to treat symptoms and side effects?
- Will my loved one be able to work, exercise, and perform usual activities?
- What support services are available to my loved one?
- How can we reach you on nights, holidays, or weekends?

Where to Go for More Information

A cancer diagnosis is an intense, emotional experience for both the patient and their care partners. Talking with friends, family, and other cancer patients can **help you deal with these emotions**. Joining a support group and talking about your experience may also be helpful.

The organizations below can help you find a community ready to support you.

CancerCare

cancercare.org/caregiving [800] 813-4673

National Alliance for Caregiving (NAC)

<u>caregiving.org</u> (301) 718-8444

Caregiver Action Network (CAN)

caregiveraction.org (202) 454-3970

Family Caregiver Alliance (FCA)/ National Center on Caregiving

<u>caregiver.org</u> (800) 445-8106

The organizations below may **help you learn more** about your loved one's particular type of lung cancer.

The Exon 20 Group

exon20group.org (602) 618-0183 Lung Cancer

Foundation of America

lcfamerica.org

(507) 354-1361

GO₂ Foundation for Lung Cancer

go2foundation.org (800) 298-2436 **Lung Cancer Research Foundation**

<u>lungcancerresearchfoundation.org</u> (212) 588-1580

EGFR Resisters

of your healthcare providers.

<u>egfrcancer.org</u>

LUNGevity Foundation

lungevity.org (312) 407-6100

National Lung
Cancer Roundtable

nlcrt.org

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

Please read the Important Safety Information including information for the Boxed Warning on pages 16-19 and the Patient Information in the accompanying full Prescribing Information.



We're Here to Help



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

Takeda Oncology Here2Assist:

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



ACCESS SUPPORT: Once your loved one is enrolled, Takeda Oncology Here2Assist case managers can work with them and their healthcare provider to determine their coverage options and provide additional support throughout your loved one's treatment.



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



HELPFUL RESOURCES: Takeda Oncology Here2Assist Program case managers can provide information about additional resources that may help address day-to-day concerns associated with your loved one's 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. Let's Talk. We're available Monday-Friday, 8AM-8PM ET.

^{*}Patients will need to enroll in the texting program to receive text messages.

Notes:	



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 >



Important Safety Information (continued)

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 <u>Patient Information</u> in the accompanying EXKIVITY (mobocertinib) full <u>Prescribing Information</u>.



DISCOVER THE PATH AHEAD TOGETHER WITH EXKIVITY® (mobocertinib)

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

Please read the Important Safety Information including information for the Boxed Warning on pages 16-19 and the <u>Patient Information</u> in the accompanying full <u>Prescribing Information</u>.





