TREATING ADVANCED BASAL CELL CARCINOMA

Inside: What you should know about Erivedge

Indication
Erivedge® (vismodegib) capsule is a prescription medicine used to treat adults with a type of skin cancer, called basal cell carcinoma, that has spread to other parts of the body or that has come back after surgery or that your healthcare provider decides cannot be treated with surgery or radiation.

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

Serious Side Effects
Erivedge can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects.

Please see the Important Safety Information on pages 12-16. Please see accompanying full Prescribing Information for additional Important Safety Information, including serious side effects, and the Medication Guide.
Find out how Erivedge may help your advanced basal cell carcinoma

Not an actual patient. Artist depiction of a lesion.

IN THIS BOOKLET

This booklet will help you learn what to expect from treatment with Erivedge® (vismodegib) capsule.

5 Why Erivedge may be right for you
6 About Erivedge
8 How Erivedge is designed to work
10 How Erivedge may help
12 Important safety information
18 How to take Erivedge
20 How to get Erivedge

This booklet is for educational purposes only and is not intended to provide medical advice or replace the medical advice of your doctor or other healthcare provider, who should always be your primary source of information about your health, diagnosis, and treatment.

Please see accompanying full Prescribing Information for additional Important Safety Information, including serious side effects, and the Medication Guide. Please see the Important Safety Information on pages 12-16.
“My doctor told me that surgery and radiation were not appropriate treatments for my advanced basal cell carcinoma.”

— Mitch, Erivedge patient
Loves reading and photography

WHY ERIVEDGE MAY BE RIGHT FOR YOU

If you have advanced basal cell carcinoma and surgery or radiation are not treatment options, then you and your doctor or other healthcare provider may decide that Erivedge® (vismodegib) capsule is the right treatment for you.

So what is basal cell carcinoma (BCC)? BCC is the most common type of skin cancer. It starts in the top layer of the skin. If it’s found early, most BCC can be removed with surgery.

Sometimes, BCC becomes more serious and can be called advanced BCC. When BCC is advanced, it’s either locally advanced or metastatic.

LEARN MORE ABOUT ERIVEDGE

Visit Erivedge.com

BCC is locally advanced if 1 or more of the following is true:

- It has grown large or deep below the surface, and surgery or radiation are not appropriate
- It’s on a part of the body, such as the face or ear, where treatment may severely change the way you look or cause functional damage
- It has come back after surgery, or cannot be treated with either surgery or radiation

BCC is metastatic if:

- It has spread to other parts of the body, such as the lymph nodes, lungs, or bones

Please see accompanying full Prescribing Information for additional Important Safety Information, including serious side effects, and the Medication Guide.

Please see the Important Safety Information on pages 12-16.
ABOUT ERIVEDGE

What you should know:

Erivedge® (vismodegib) capsule is a prescription medicine used to treat adults with a type of skin cancer, called basal cell carcinoma, that has spread to other parts of the body or that has come back after surgery or that your healthcare provider decides cannot be treated with surgery or radiation.

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

Erivedge is the first medicine approved by the Food and Drug Administration (FDA) to treat advanced basal cell carcinoma (BCC).

Erivedge is a pill that you can take by mouth once a day for your advanced BCC.

How long should you take Erivedge?
Learn more on page 18.

“Erivedge is the first oral treatment available for patients with advanced basal cell carcinoma.”

— Snehal Amin, MD
Dermatologist and Mohs Surgeon

Please see the Important Safety Information on pages 12-16.

Please see accompanying full Prescribing Information for additional Important Safety Information, including serious side effects, and the Medication Guide.
HOW ERIVEDGE IS DESIGNED TO WORK

Before starting treatment, it’s important to understand how Erivedge® (vismodegib) capsule may work inside the body.

Problems with a signal found in certain cells of the body can cause basal cell carcinoma (BCC) to grow.

Interrupting the signal may slow down the growth of BCC (based on laboratory studies).

Since Erivedge works inside the body, there are also risks you should be aware of.

Learn more about side effects on page 16.

Please see the Important Safety Information on pages 12-16.

Please see accompanying full Prescribing Information for additional Important Safety Information, including serious side effects, and the Medication Guide.
HOW ERIVEDGE MAY HELP

Erivedge® (vismodegib) capsule may cause your advanced basal cell carcinoma (BCC) to shrink, or it may help control your disease.

In a clinical study, 96 adults took Erivedge for their advanced BCC (63 had locally advanced BCC and 33 had metastatic BCC).

Results at 6 months of Erivedge treatment:

For locally advanced BCC patients:

43% (27 patients) SAW THEIR BCC SHRINK 
Out of those, 13 patients saw no visible sign of cancer.

For metastatic BCC patients:

30% (10 patients) SAW THEIR BCC SHRINK 
No patients in this group saw their cancer completely disappear.

How long patients saw improvement:

Half of the patients who responded to Erivedge saw improvement for less than 7.6 months, and half saw improvement for more than 7.6 months.

For patients who responded, the length of improvement ranged from:

- 1 to 13 months for locally advanced BCC patients
- 2 to 11 months for metastatic BCC patients

Keep in mind that everyone’s results are different. Erivedge can cause side effects, some of which can be serious.

Talk to your doctor or other healthcare provider about both the benefits and risks of Erivedge.

How long should you take Erivedge?

Learn more on page 18.

Please see accompanying full Prescribing Information for additional Important Safety Information, including serious side effects, and the Medication Guide.

Please see the Important Safety Information on pages 12-16.
IMPORTANT SAFETY INFORMATION

What is the most important information I should know about Erivedge® (vismodegib) capsule?

Erivedge can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects.

For females who can become pregnant:

- You should talk with your healthcare provider about the risks of Erivedge to your unborn child.
- Your healthcare provider will do a pregnancy test before you start taking Erivedge.
- In order to avoid pregnancy, you should use birth control during treatment and for 7 months after your final dose of Erivedge. Talk with your healthcare provider about what birth control method is right for you during this time.
- Talk to your healthcare provider right away if you have unprotected sex or if you think that your birth control has failed.
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant.

For males:

- Erivedge is present in semen. Do not donate semen while you are taking Erivedge and for 3 months after your final dose.
- You should always use a condom, even if you have had a vasectomy, during sex with female partners who are pregnant or who are able to become pregnant, during treatment with Erivedge and for 3 months after your final dose to protect your female partner from being exposed to Erivedge.
- Tell your healthcare provider right away if your partner becomes pregnant or thinks she is pregnant while you are taking Erivedge.

(Important Safety Information continues on page 14.)
Exposure to Erivedge® (vismodegib) capsule during pregnancy:

If you think that you or your female partner may have been exposed to Erivedge during pregnancy, talk to your healthcare provider right away. If you become pregnant during treatment with Erivedge, you or your healthcare provider should report your pregnancy to Genentech at (888) 835-2555.

What should I tell my healthcare provider before taking Erivedge?

- If you are pregnant or plan to become pregnant
- If you are breastfeeding or plan to breastfeed. It is not known if Erivedge passes into your breast milk. You should not breastfeed during treatment and for 7 months after your final dose of Erivedge. Talk to your healthcare provider about the best way to feed your baby during this time
- About all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements

What should I avoid while taking Erivedge?

- Do not donate blood or blood products while you are taking Erivedge and for 7 months after your final dose
- Do not donate semen while you are taking Erivedge and for 3 months after your final dose

(Important Safety Information continues on page 16.)
IMPORTANT SAFETY INFORMATION (CONT’D)

What are the possible side effects of Erivedge® (vismodegib) capsule?

The most common side effects of Erivedge are:

- Muscle spasms
- Hair loss
- Change in how things taste or loss of taste
- Weight loss
- Tiredness
- Nausea
- Diarrhea
- Decreased appetite
- Constipation
- Joint pain
- Vomiting

Erivedge can cause absence of menstrual periods (amenorrhea) in females who are able to become pregnant. It is not known if amenorrhea is permanent. Talk to your healthcare provider if you have concerns about fertility.

These are not all of the possible side effects of Erivedge. Because everyone is different, it is not possible to predict what side effects any one person will have or how severe they may be. Call your doctor for medical advice about side effects.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Have questions about side effects? Write them down and share them with your doctor or other healthcare provider.

Want some tips for common side effects?
Visit Erivedge.com to find some tips you can try for the most common side effects of Erivedge.
HOW TO TAKE ERIVEDGE

It’s very important to make sure you take Erivedge® (vismodegib) capsule exactly as your doctor or other healthcare provider tells you.

Here are a few things to remember:

• Take 1 capsule every day
• You can take it with or without food
• Be sure to swallow the capsule whole.
  Do not open or crush the capsule

If you happen to miss a dose:

• Skip the missed dose and take your next scheduled dose

How long you should take Erivedge:

Talk to your doctor or other healthcare provider about how long you should take Erivedge. It’s recommended that you continue taking Erivedge as long as it’s working for you and your side effects are tolerable.

In a clinical study of 96 adults with advanced basal cell carcinoma (BCC), half of the patients took Erivedge for more than 10 months, and half took Erivedge for less than 10 months. Patients stayed on Erivedge anywhere from 3 weeks to 19 months.

“...first thing in the morning as part of my daily routine.”
— Nancy, Erivedge clinical trial patient
Loves golfing and cooking

Please see the Important Safety Information on pages 12-16.
HOW TO GET ERIVEDGE

Here’s what you should know about getting your Erivedge® (vismodegib) capsule treatment:

- Erivedge is not available at your local drugstore
- You can get Erivedge from a specialty pharmacy
- A specialty pharmacy mails your medicine right to your home

Genentech, the maker of Erivedge, has developed a program called Erivedge Access Solutions® to help you get your Erivedge prescription filled. Regardless of your income or insurance status, Erivedge Access Solutions is here to help.

Contact Erivedge Access Solutions:
Call (888) 249-4918 from 9 AM to 8 PM ET, Monday through Friday, or visit www.genentech-access.com/erivedge/patients

How can I get Erivedge?

Follow these steps to getting your prescription:

Your doctor or other healthcare provider will send in a prescription to a specialty pharmacy or Erivedge Access Solutions.

If your doctor or other healthcare provider chooses to use Erivedge Access Solutions to help you get your prescription filled, a representative may call you to discuss next steps for getting your medicine.*

The specialty pharmacy will call you to collect your co-pay, if applicable, and confirm delivery details. It is very important that you speak with the pharmacy representative.

Erivedge is delivered to your home. Someone must be home to sign for the delivery.

*If patient is uninsured, or insurer denies coverage, or simply denies prescription, patients may be eligible to receive free Erivedge through the Genentech® Access to Care Foundation (GATCF).
Can I get help paying for my medicine?

The following resources are available to provide financial assistance:

Privately insured patients:

Erivedge® (vismodegib) capsule Co-pay Card—The card reduces out-of-pocket costs for eligible patients.

Referrals to nonprofit foundations for co-pay assistance—As an additional resource, privately insured patients can be referred to the co-pay assistance foundation.* For more information, visit PanFoundation.org.

Publicly insured patients:

Referrals to nonprofit foundations for co-pay assistance—Publicly insured patients can be referred to the co-pay assistance foundation.* For more information, visit PanFoundation.org. To apply, your patient will need to provide his or her most recent income documentation, insurance information, and the name of his or her doctor.

Facing an insurance coverage delay:

Sure Start™—If your insurance does not approve your Erivedge within 7 days, you may be eligible to receive Erivedge for free. Sure Start supplies Erivedge 14 days at a time for up to 3 months.

Uninsured:

The Genentech® Access to Care Foundation—If you are uninsured, or your insurer denies coverage or simply denies your prescription, you may be eligible to receive free Erivedge through the Genentech Access to Care Foundation (GATCF).*

*Genentech does not influence or control the operations of these Co-pay Assistance Foundations, but Erivedge Access Solutions can assist patients in navigating the process of seeking co-pay assistance by making an appropriate referral based on a patient’s diagnosis and by assisting with the application process. We cannot guarantee co-pay assistance once a patient has been referred by Erivedge Access Solutions. The Co-pay Assistance Foundations to which we refer patients have their own criteria for patient eligibility, including financial eligibility.

†GATCF helps eligible patients who meet specific medical and financial criteria receive Erivedge free of charge. GATCF provides free medicine to eligible patients who are uninsured, rendered uninsured by payer denial or underinsured. To qualify, patients meet specific financial and medical criteria.
FREQUENTLY ASKED QUESTIONS DURING TREATMENT

Here is a list of some questions to go over with your doctor or other healthcare provider. You can also refer to it throughout your treatment.

0 How do I take Erivedge?
A: Take 1 capsule every day. Be sure to swallow the capsule whole. Do not open or crush the capsule.

0 Can I take Erivedge with meals?
A: Yes, you can take it with or without food.

0 Are there any drug interactions with Erivedge?
A: Tell your doctor or other healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Are there any support programs that can help me?

There are programs available that can help you during treatment:

Erivedge Cares is a free educational support program designed to help you start on Erivedge® (vismodegib) capsule and provide you with useful information during treatment. Visit Erivedge.com to join today.

- Remember, the Erivedge Cares program is for educational purposes only and is not intended to provide medical advice or replace the medical advice of your doctor or other healthcare provider, who should always be your primary source of information about your health, diagnosis, and treatment.

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Please see the Important Safety Information on pages 12-16.
**Q** How long should I take Erivedge® (vismodegib) capsule?

**A:** Everyone is different, so you will need to discuss this with your doctor or other healthcare provider. It’s recommended that you continue taking Erivedge as long as it’s working for you and your side effects are tolerable. In a clinical study, half of the patients took Erivedge for more than 10 months and half took Erivedge for less than 10 months. Patients stayed on Erivedge anywhere from 3 weeks to 19 months.

**Q** What if I forget to take my pill?

**A:** If you happen to miss a dose, skip the missed dose and take your next scheduled dose.

**Q** What lifestyle changes should I expect to make during treatment?

**A:** Everyone is different, so you should speak to your doctor or other healthcare provider about your lifestyle and any potential changes.

**Q** Can I exercise while taking Erivedge?

**A:** Be sure to talk to your doctor or other healthcare provider before starting treatment to determine an exercise plan that is most appropriate for you.

**Q** What if I can’t tolerate the side effects?

**A:** You should discuss any side effects with your doctor or other healthcare provider. But if you experience side effects that are severe, it’s important to let your doctor or other healthcare provider know right away.

**Q** What if I have other questions?

**A:** Talk to your doctor or other healthcare provider with any questions you may have. You can also talk to registered nurses at the Erivedge Patient Support Line 24 hours a day, 7 days a week, who may be able to answer your questions. Just call (855) 7-ERIVEDGE (or 855-737-4833).

The Erivedge Patient Support Line is for educational purposes only and is not intended to provide medical advice or replace the medical advice of your doctor or healthcare provider, who should always be your primary source of information about your health, diagnosis, and treatment.

Please see accompanying full Prescribing Information for additional Important Safety Information, including serious side effects, and the Medication Guide.
Indication
Erivedge® (vismodegib) capsule is a prescription medicine used to treat adults with a type of skin cancer, called basal cell carcinoma, that has spread to other parts of the body or that has come back after surgery or that your healthcare provider decides cannot be treated with surgery or radiation.

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For more information about Erivedge® (vismodegib) capsule, visit Erivedge.com
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HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ERIVEDGE safely and effectively. See full prescribing information for ERIVEDGE.

ERIVEDGE® (vismodegib) capsule for oral use
Initial U.S. Approval: 2012

WARNING: EMBRYO-FETAL TOXICITY
See full prescribing information for complete boxed warning. ERIVEDGE can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. ERIVEDGE is embryotoxic, fetotoxic, and teratogenic in animals. Teratogenic effects included severe midline defects, missing digits, and other reversible malformations.

Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating ERIVEDGE therapy. Advise females of reproductive potential to use effective contraception during and after ERIVEDGE therapy. Advise males of the potential risk of ERIVEDGE exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential. Advise pregnant women of the potential risks to a fetus. (5.1, 5.3, 8.1, 8.3)

INDICATIONS AND USAGE
ERIVEDGE® (vismodegib) capsule is a hedgehog pathway inhibitor indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation. (1)

DOSAGE AND ADMINISTRATION
The recommended dose is 150 mg orally once daily. (2)

DOSAGE FORMS AND STRENGTHS
150 mg capsules. (3)

CONTRAINDICATIONS
None.

WARNINGS AND PRECAUTIONS
• Blood donation: Advise patients not to donate blood or blood products while receiving ERIVEDGE and for 7 months after the final dose of ERIVEDGE. (5.2)
• Semen donation: Advise males not to donate semen during and for 3 months after therapy (5.3, 8.3)

ADVERSE REACTIONS
The most common adverse reactions (incidence of ≥ 10%) are muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgia, vomiting, and ageusia.

To report SUSPECTED ADVERSE REACTIONS, contact Genentech, Inc. at 1-888-835-2555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS
• Lactation: Breastfeeding not recommended. (8.2)
• Females and Males of Reproductive Potential: May cause amenorrhea in females. (8.3)

See Section 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling (Medication Guide).

Revised: 05/2015
FULL PRESCRIBING INFORMATION: CONTENTS*
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FULL PRESCRIBING INFORMATION

WARNING: EMBRYO-FETAL TOXICITY

ERIVEDGE can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. ERIVEDGE is embryotoxic, fetotoxic, and teratogenic in animals. Teratogenic effects included severe midline defects, missing digits, and other irreversible malformations.

Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating ERIVEDGE therapy. Advise females of reproductive potential to use effective contraception during and after ERIVEDGE therapy. Advise males of the potential risk of ERIVEDGE exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential. Advise pregnant women of the potential risks to a fetus. [See Warnings and Precautions (5.1, 5.3), Use in Specific Populations (8.1, 8.3)].

1 INDICATIONS AND USAGE
ERIVEDGE capsule is indicated for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation.

2 DOSAGE AND ADMINISTRATION
The recommended dose of ERIVEDGE is 150 mg taken orally once daily until disease progression or until unacceptable toxicity [see Clinical Studies (14)].

ERIVEDGE may be taken with or without food. Swallow capsules whole. Do not open or crush capsules.

If a dose of ERIVEDGE is missed, do not make up that dose; resume dosing with the next scheduled dose.

3 DOSAGE FORMS AND STRENGTHS
ERIVEDGE (vismodegib) capsules, 150 mg. The capsule has a pink opaque body and a grey opaque cap, with “150 mg” printed on the capsule body and “VISMO” printed on the capsule cap in black ink.

4 CONTRAINDICATIONS
None.

5 WARNINGS AND PRECAUTIONS
5.1 Embryo-Fetal Toxicity
Based on its mechanism of action, ERIVEDGE can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. In animal reproduction studies, vismodegib was embryotoxic, fetotoxic, and teratogenic at maternal exposures lower than the human exposures at the recommended dose of 150 mg/day.

Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating ERIVEDGE therapy. Advise females of reproductive potential to use effective contraception during therapy with ERIVEDGE and for 7 months after the final dose. Advise male patients to use condoms, even after a vasectomy, to avoid potential drug exposure in pregnant partners and female
partners of reproductive potential during therapy and for 3 months after the final dose of ERIVEDGE. Advise pregnant women of the potential risk to a fetus [see Use in Specific Populations (8.1, 8.3) and Clinical Pharmacology (12.1)].

5.2 Blood Donation
Advise patients not to donate blood or blood products while receiving ERIVEDGE and for 7 months after the final dose of ERIVEDGE.

5.3 Semen Donation
Vismodegib is present in semen. It is not known if the amount of vismodegib in semen can cause embryo-fetal harm. Advise male patients not to donate semen during and for 3 months after the final dose of ERIVEDGE [see Use in Specific Populations (8.1, 8.3)].

6 ADVERSE REACTIONS
6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

ERIVEDGE capsule was administered as monotherapy at doses ≥ 150 mg orally daily in four open-label, uncontrolled, dose-ranging or fixed single dose clinical trials enrolling a total of 138 patients with advanced basal cell carcinoma (BCC). The median age of these patients was 61 years (range 21 to 101), 100% were White (including Hispanics), and 64% were male. The median duration of treatment was approximately 10 months (305 days; range 0.7 to 36 months); 111 patients received ERIVEDGE for 6 months or longer.

The most common adverse reactions (≥ 10%) were muscle spasms, alopecia, dysgeusia, weight loss, fatigue, nausea, diarrhea, decreased appetite, constipation, arthralgias, vomiting, and ageusia (Table 1).
Table 1: Adverse Reactions Occurring in ≥ 10% of Advanced BCC Patients

<table>
<thead>
<tr>
<th>MedDRA Preferred Term²</th>
<th>All aBCC¹ Patients (N = 138)</th>
<th>All Grades³ (%)</th>
<th>Grade 3 (%)</th>
<th>Grade 4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gastrointestinal disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>42 (30.4%)</td>
<td>1 (0.7%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>40 (29.0%)</td>
<td>1 (0.7%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Constipation</td>
<td>29 (21.0%)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Vomiting</td>
<td>19 (13.8%)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>General disorders and administration site conditions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>55 (39.9%)</td>
<td>7 (5.1%)</td>
<td>1 (0.7%)</td>
<td>-</td>
</tr>
<tr>
<td><strong>Investigations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight loss</td>
<td>62 (44.9%)</td>
<td>10 (7.2%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Metabolism and nutrition disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>35 (25.4%)</td>
<td>3 (2.2%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Musculoskeletal and connective tissue disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle spasms</td>
<td>99 (71.7%)</td>
<td>5 (3.6%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Arthralgias</td>
<td>22 (15.9%)</td>
<td>1 (0.7%)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dysgeusia</td>
<td>76 (55.1%)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Ageusia</td>
<td>15 (10.9%)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alopecia</td>
<td>88 (63.8%)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

¹aBCC = Advanced Basal Cell Carcinoma.
²MedDRA = Medical Dictionary for Regulatory Activities.
³Grading according to NCI-CTCAE v3.0.

**Amenorrhea:**
In clinical trials, a total of 3 of 10 pre-menopausal women developed amenorrhea while receiving ERIVEDGE [see Non-Clinical Toxicology (13.1)].

**Laboratory Abnormalities:**
Treatment-emergent Grade 3 laboratory abnormalities observed in clinical trials were hyponatremia in 6 patients (4%), hypokalemia in 2 patients (1%), and azotemia in 3 patients (2%).

7 **DRUG INTERACTIONS**
Clinically relevant pharmacokinetic interactions are not expected between vismodegib and a substrate, inducer or inhibitor of cytochrome 450 enzymes or an inhibitor of P-glycoprotein (P-gp) or between vismodegib and gastric pH elevating agents [see Clinical Pharmacology (12.3)].
8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action and animal reproduction studies, ERIVEDGE can cause fetal harm when administered to a pregnant woman [see Clinical Pharmacology (12.1)]. In animal reproduction studies, oral administration of vismodegib during organogenesis at doses below the recommended human dose resulted in embryotoxicity, fetotoxicity, and teratogenicity in rats [see Data]. There are no human data on the use of ERIVEDGE in pregnant women. Advise pregnant women of the potential risk to a fetus. Report pregnancies to Genentech at 1-888-835-2555.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

In an embryo-fetal developmental toxicity study, pregnant rats were administered vismodegib orally at doses of 10, 60, or 300 mg/kg/day during the period of organogenesis. Pre- and post-implantation loss were increased at doses of ≥ 60 mg/kg/day (approximately ≥ 2 times the systemic exposure (AUC) in patients at the recommended human dose), which included early resorption of 100% of the fetuses. A dose of 10 mg/kg/day (approximately 0.2 times the AUC in patients at the recommended dose) resulted in malformations (including missing and/or fused digits, open perineum and craniofacial anomalies) and retardations or variations (including dilated renal pelvis, dilated ureter, and incompletely or unossified sternal elements, centra of vertebrae, or proximal phalanges and claws).

8.2 Lactation

No data are available regarding the presence of vismodegib in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Because of the potential for serious adverse reactions in breastfed infants from ERIVEDGE, advise a nursing woman that breastfeeding is not recommended during therapy and for 7 months after the final dose.

8.3 Females and Males of Reproductive Potential

Pregnancy Testing

Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating ERIVEDGE therapy.

Contraception

Females

Based on its mechanism of action and animal data, ERIVEDGE can cause fetal harm when administered to a pregnant woman [see Use in Specific Populations (8.1)]. Advise females of reproductive potential to use effective contraception during therapy and for 7 months after the final dose of ERIVEDGE.

Males

Vismodegib is present in semen [see Clinical Pharmacology (12.3)]. It is not known if the amount of vismodegib in semen can cause embryo-fetal harm. Advise male patients to use condoms, even after a vasectomy, to avoid drug exposure to pregnant partners and female partners of reproductive potential during therapy with and for 3 months after the final dose of ERIVEDGE. Advise males of the potential risk to an embryo or fetus if a female partner of reproductive potential is exposed to
ERIVEDGE. Advise males not to donate semen during therapy with and for 3 months after the final dose of ERIVEDGE.

_Infertility_

_Females_

Amenorrhea can occur in females of reproductive potential. Reversibility of amenorrhea is unknown [see _Adverse Reactions (6)_.]

**8.4 Pediatric Use**

The safety and effectiveness of ERIVEDGE capsule have not been established in pediatric patients. In repeat-dose toxicity studies in rats, administration of oral vismodegib resulted in toxicities in bone and teeth. Effects on bone consisted of closure of the epiphyseal growth plate when oral vismodegib was administered for 26 weeks at ≥ 50 mg/kg/day (approximately ≥ 0.4 times the systemic exposure (AUC) in patients at the recommended human dose). Abnormalities in growing incisor teeth (including degeneration/necrosis of odontoblasts, formation of fluid-filled cysts in the dental pulp, ossification of the root canal, and hemorrhage resulting in breakage or loss of teeth) were observed after administration of oral vismodegib at ≥ 15 mg/kg/day (approximately ≥ 0.2 times the AUC in patients at the recommended human dose).

**8.5 Geriatric Use**

Clinical studies of ERIVEDGE capsule did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger patients.

**8.6 Hepatic Impairment**

No dose adjustment is required in patients with hepatic impairment [see _Clinical Pharmacology (12.3)_.]

**8.7 Renal Impairment**

No dose adjustment is required in patients with renal impairment [see _Clinical Pharmacology (12.3)_.]

**10 OVERDOSAGE**

There is no information on overdosage in humans. In clinical trials, ERIVEDGE capsule was administered at 540 mg orally once daily; exposure did not increase between 150 mg and 540 mg daily.

**11 DESCRIPTION**

Vismodegib is an inhibitor of the hedgehog (Hh) signaling pathway, which is described chemically as 2-Chloro-N-(4-chloro-3-(pyridin-2-yl)phenyl)-4-(methylsulfonyl)benzamide. The molecular formula is C₁₉H₁₄Cl₂N₂O₃S. The molecular weight is 421.30 g/mol and the structural formula is:

![Structural formula of Vismodegib](image-url)
Vismodegib is a crystalline free base with a pKa (pyridinium cation) of 3.8, appearing as a white to tan powder. The solubility of vismodegib is pH dependent with 0.1 µg/mL at pH 7 and 0.99 mg/mL at pH 1. The partition coefficient (log P) is 2.7.

Each ERIVEDGE (vismodegib) capsule for oral administration contains 150 mg vismodegib and the following inactive ingredients: microcrystalline cellulose, lactose monohydrate, sodium lauryl sulfate, povidone, sodium starch glycolate, talc, and magnesium stearate (non-bovine). The capsule shell contains gelatin, titanium dioxide, red iron oxide, and black iron oxide. The black printing ink contains shellac and black iron oxide.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Vismodegib is an inhibitor of the Hedgehog pathway. Vismodegib binds to and inhibits Smoothened, a transmembrane protein involved in Hedgehog signal transduction.

12.2 Pharmacodynamics

Cardiac Electrophysiology

The QTc interval was not affected by therapeutic doses of ERIVEDGE in a thorough QTc trial.

12.3 Pharmacokinetics

Absorption

The single dose absolute bioavailability of vismodegib is 31.8%. Absorption is saturable as evidenced by the lack of dose proportional increase in exposure after a single dose of 270 mg or 540 mg vismodegib. ERIVEDGE capsule may be taken without regard to meals because the systemic exposure of vismodegib at steady state is not affected by food.

Distribution

The volume of distribution of vismodegib ranges from 16.4 to 26.6 L. Vismodegib plasma protein binding in patients is greater than 99%. Vismodegib binds to both human serum albumin and alpha-1-acid glycoprotein (AAG) and binding to AAG is saturable.

In a pharmacokinetic study, male patients (n=3) had an average concentration of vismodegib in semen on day 8 that was 6.5% of the average steady state concentration (C_{ss}) observed in plasma.

Metabolism

Greater than 98% of the total circulating drug-related components are the parent drug. Metabolic pathways of vismodegib in humans include oxidation, glucuronidation, and pyridine ring cleavage. The two most abundant oxidative metabolites recovered in feces are produced in vitro by recombinant CYP2C9 and CYP3A4/5.

Elimination

Vismodegib and its metabolites are eliminated primarily by the hepatic route with 82% of the administered dose recovered in the feces and 4.4% recovered in urine. The estimated elimination half-life (t_{1/2}) of vismodegib is 4 days after continuous once-daily dosing and 12 days after a single dose.

Specific Populations

Hepatic Impairment: In a dedicated clinical study, the mean systemic exposure (AUC_{0-24hr}) of vismodegib was increased by 24% in patients with mild (n=8), 31% in patients with moderate (n=6) and decreased 14% in patients with severe (n=3) hepatic impairment when compared to patients with normal hepatic function (n=9) after 8 days of daily ERIVEDGE administration. The NCI Organ Dysfunction Working Group criteria for hepatic impairment were used in the study. Mild hepatic impairment was defined as normal total bilirubin and aspartate transaminase (AST) > upper limit of
normal (ULN) or total bilirubin > 1.0 to 1.5 times ULN, moderate hepatic impairment as total bilirubin > 1.5 to 3.0 times ULN, and severe hepatic impairment as total bilirubin > 3.0 to 10.0 times ULN.

Renal Impairment: Renal excretion of vismodegib after oral administration of ERIVEDGE is low (<5%). The population pharmacokinetic analysis suggested no clinically relevant effect of renal impairment on the systemic exposure of vismodegib, based on pharmacokinetic data from patients with mild (CLcr 50 to 79 mL/min, n=58), and moderate (CLcr 30 to 49 mL/min, n=16) renal impairment.

Weight, Age, and Sex: The results of a population pharmacokinetic analysis suggested no clinically relevant effect of weight (range: 41-140 kg), age (range: 26-89 years), and sex on the systemic exposure of vismodegib.

Drug Interaction Studies
Effect of Drugs on Vismodegib: Coadministration of ERIVEDGE with fluconazole (a moderate CYP2C9 inhibitor and moderate CYP3A4 inhibitor) increased mean AUC₀–₂₄hr and steady-state concentrations of vismodegib by 1.3-fold in healthy subjects. A strong inhibitor of CYP3A4 and P-gp (itraconazole) or a proton pump inhibitor (rabeprazole) had no effect on the steady-state systemic exposure of vismodegib when coadministered with ERIVEDGE in healthy subjects.

Effects of Vismodegib on Other Drugs: Results of a drug interaction study conducted in cancer patients demonstrated that the systemic exposure of rosiglitazone (a CYP2C8 substrate) or oral contraceptives (ethinyl estradiol and norethindrone) is not altered when either drug is coadministered with vismodegib.

In vitro studies suggest that vismodegib is an inhibitor of CYP2C8, CYP2C9, CYP2C19 and the transporter BCRP and that vismodegib is not an inducer of CYP1A2, CYP2B6, or CYP3A.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenicity studies with vismodegib have not been conducted. Pilomatricoma (a benign cutaneous neoplasm) was observed in rats administered oral vismodegib for 26 weeks at 100 mg/kg/day (approximately 0.8 times the systemic exposure (AUC) in patients at the recommended human dose).

Vismodegib was not mutagenic in the in vitro bacterial reverse mutation (Ames) assay and was not clastogenic in the in vitro human chromosomal aberration assay in human peripheral blood lymphocytes or in the in vivo rat bone marrow micronucleus assay.

Studies to assess the potential of vismodegib to affect fertility have not been conducted; however, data from repeat-dose toxicity studies in rats and dogs indicate that male and female reproductive function and fertility may be impaired in patients receiving ERIVEDGE capsule. In a 26-week toxicity study in rats, a relative decrease in percent motile sperm was observed at ≥ 15 mg/kg/day (approximately ≥ 0.3 times the AUC in patients at the recommended human dose). In dogs, increased numbers of degenerating germ cells and hypospermia were observed in young animals administered oral vismodegib for 4 weeks at ≥ 50 mg/kg/day (approximately ≥ 2 times the AUC in patients at the recommended human dose). No corresponding findings were observed in sexually mature dogs at similar doses in 13-week and 26-week toxicity studies. A decrease in the number of corpora lutea was observed in female rats administered oral vismodegib for 26 weeks at 100 mg/kg/day (approximately 0.8 times the AUC in patients at the recommended human dose).

13.2 Animal Toxicology
Neurologic effects characterized as limb or body tremors or twitching were observed in rats administered oral vismodegib for 4 weeks or longer at ≥ 50 mg/kg/day (approximately ≥ 0.4 times
the AUC in patients at the recommended human dose). These observations resolved upon discontinuation of dosing and were not associated with microscopic findings.

14 CLINICAL STUDIES

A single, international, single-arm, multi-center, open-label, 2-cohort trial was conducted in 104 patients with either metastatic basal cell carcinoma (mBCC) \( n = 33 \) or locally advanced BCC (laBCC) \( n = 71 \). Patients with laBCC were required to have lesions that had recurred after radiotherapy, unless radiotherapy was contraindicated or inappropriate (e.g. Gorlin syndrome; limitations because of location of tumor or cumulative prior radiotherapy dose), and where the lesions were either unresectable or surgical resection would result in substantial deformity. Patients were to receive 150 mg vismodegib per day orally until disease progression or unacceptable toxicity.

The major efficacy outcome measure of the trial was objective response rate (ORR) as assessed by an independent review facility (IRF). In the mBCC cohort, tumor response was assessed according to the Response Evaluation Criteria in Solid Tumors (RECIST) version 1.0. In the laBCC cohort, tumor response evaluation included measurement of externally assessable tumor (including scar) and assessment for ulceration in photographs, radiographic assessment of target lesions (if appropriate), and tumor biopsy. An objective response in laBCC required at least one of the following criteria and absence of any criterion for disease progression: (1) \( \geq 30\% \) reduction in lesion size \[\text{sum of the longest diameter (SLD)}\] from baseline in target lesions by radiographic assessment; (2) \( \geq 30\% \) reduction in SLD from baseline in externally visible dimension of target lesions; (3) complete resolution of ulceration in all target lesions. Complete response was defined as objective response (as defined above) with no residual BCC on sampling tumor biopsy. Disease progression was defined as any of the following: (1) \( \geq 20\% \) increase in the SLD from nadir in target lesions (either by radiography or by externally visible dimension); (2) new ulceration of target lesions persisting without evidence of healing for at least 2 weeks; (3) new lesions by radiographic assessment or physical examination; (4) progression of non-target lesions by RECIST.

Of the 104 patients enrolled, 96 patients were evaluable for ORR. Twenty-one percent of patients carried a diagnosis of Gorlin syndrome. The median age of the efficacy evaluable population was 62 years (46\% were at least 65 years old), 61\% male and 100\% White. For the mBCC cohort \( n = 33 \), 97\% of patients had prior therapy including surgery (97\%), radiotherapy (58\%), and systemic therapies (30\%). For the laBCC cohort \( n = 63 \), 94\% of patients had prior therapies including surgery (89\%), radiotherapy (27\%), and systemic/topical therapies (11\%). The median duration of treatment was 10.2 months (range 0.7 to 18.7 months).

The key outcome measures are presented in Table 2, below.
Table 2:  Objective Response Rate: Efficacy-Evaluable Patients¹

<table>
<thead>
<tr>
<th></th>
<th>mBCC (n = 33)</th>
<th>laBCC (n = 63)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IRF²-Confirmed ORR, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 (30.3)</td>
<td>27 (42.9)</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(15.6, 48.2)</td>
<td>(30.5, 56.0)</td>
</tr>
<tr>
<td><strong>Complete response³</strong></td>
<td>0 (0.0)</td>
<td>13 (20.6)</td>
</tr>
<tr>
<td><strong>Partial response</strong></td>
<td>10 (30.3)</td>
<td>14 (22.2)</td>
</tr>
<tr>
<td><strong>Median Response Duration (months)</strong></td>
<td>7.6</td>
<td>7.6</td>
</tr>
<tr>
<td>(95% CI⁵)</td>
<td>(5.6, NE⁴)</td>
<td>(5.7, 9.7)</td>
</tr>
</tbody>
</table>

¹Patients who received at least one dose of ERIVEDGE with independent pathologist-confirmed diagnosis of BCC
²IRF = Independent Review Facility
³For laBCC, complete response was defined as objective response with no residual BCC on sampling tumor biopsy.
⁴NE = Not estimable
⁵CI = Confidence Interval

16  HOW SUPPLIED/STORAGE AND HANDLING
Each ERIVEDGE (vismodegib) capsule has a pink opaque body and a grey opaque cap with “150 mg” printed on the capsule body and “VISMO” printed on the capsule cap in black ink. ERIVEDGE capsules are available in bottles of 28 capsules (NDC 50242-140-01).

Store at room temperature 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].

17  PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Medication Guide).

Administration Instructions
• Advise patients to swallow ERIVEDGE capsules whole and not to crush or open the capsules.

Embryo-Fetal Toxicity
• Advise pregnant women of the potential risk to a fetus [see Warnings and Precautions (5.1) and Use in Specific Populations (8.1)].
• Advise females of reproductive potential to use effective contraception during therapy with and for 7 months after the final dose of ERIVEDGE [see Warnings and Precautions (5.1) and Use in Specific Populations (8.1, 8.3)].
• Advise males, even those with prior vasectomy, to use condoms to avoid potential drug exposure in both pregnant partners and female partners of reproductive potential during therapy with and for 3 months after the final dose of ERIVEDGE [see Warnings and Precautions (5.1) and Use in Specific Populations (8.1, 8.3)].
• Advise female patients and female partners of male patients to contact their healthcare provider with a known or suspected pregnancy. Report pregnancies to Genentech at 1-888-835-2555 [see Warnings and Precautions (5.1) and Use in Specific Populations (8.1, 8.3)].

Semen Donation

• Advise males not to donate semen during therapy with and for 3 months after the final dose of ERIVEDGE.

Lactation

• Advise women that breastfeeding is not recommended during therapy with ERIVEDGE and for 7 months after the final dose [see Use in Specific Populations (8.2)].

Blood Donation

• Advise patients not to donate blood or blood products while taking ERIVEDGE and for 7 months after the final dose of ERIVEDGE.

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ERIVEDGE® [vismodegib] capsule

Manufactured by:
Patheon, Inc.
Mississauga, Canada

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Distributed by:
Genentech USA, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080-4990
What is the most important information I should know about ERIVEDGE?

ERIVEDGE can cause your baby to die before it is born (be stillborn) or cause your baby to have severe birth defects.

For females who can become pregnant:
• You should talk with your healthcare provider about the risks of ERIVEDGE to your unborn child.
• Your healthcare provider will do a pregnancy test before you start taking ERIVEDGE.
• In order to avoid pregnancy, you should use birth control during treatment and for 7 months after your final dose of ERIVEDGE. Talk with your healthcare provider about what birth control method is right for you during this time.
• Talk to your healthcare provider right away if you have unprotected sex or if you think that your birth control has failed.
• Tell your healthcare provider right away if you become pregnant or think that you may be pregnant.

For males:
• ERIVEDGE is present in semen. Do not donate semen while you are taking ERIVEDGE and for 3 months after your final dose.
• You should always use a condom, even if you have had a vasectomy, during sex with female partners who are pregnant or who are able to become pregnant, during treatment with ERIVEDGE and for 3 months after your final dose to protect your female partner from being exposed to ERIVEDGE.
• Tell your healthcare provider right away if your partner becomes pregnant or thinks she is pregnant while you are taking ERIVEDGE.

Exposure to ERIVEDGE during pregnancy:
If you think that you or your female partner may have been exposed to ERIVEDGE during pregnancy, talk to your healthcare provider right away. If you become pregnant during treatment with ERIVEDGE, you or your healthcare provider should report your pregnancy to Genentech at 1-888-835-2555.

What is ERIVEDGE?
ERIVEDGE is a prescription medicine used to treat adults with a type of skin cancer, called basal cell carcinoma, that has spread to other parts of the body, or that has come back after surgery or that your healthcare provider decides cannot be treated with surgery or radiation.

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

What should I tell my healthcare provider before taking ERIVEDGE?
Before taking ERIVEDGE, tell your healthcare provider if you:
• are pregnant or plan to become pregnant. See “What is the most important information I should know about ERIVEDGE?”
• are breastfeeding or plan to breastfeed. It is not known if ERIVEDGE passes into your breast milk. You should not breastfeed during treatment and for 7 months after your final dose of ERIVEDGE. Talk to your healthcare provider about the best way to feed your baby during this time.

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

How should I take ERIVEDGE?
• Take ERIVEDGE exactly as your healthcare provider tells you.
• You can take ERIVEDGE with or without food.
• Swallow ERIVEDGE capsules whole. Do not open or crush the capsules.
• Take ERIVEDGE one time each day.
• If you miss a dose, skip the missed dose. Just take your next scheduled dose.

What should I avoid while taking ERIVEDGE?
• Do not donate blood or blood products while you are taking ERIVEDGE and for 7 months after your final dose.
• Do not donate semen while you are taking ERIVEDGE and for 3 months after your final dose.
What are the possible side effects of ERIVEDGE?
ERIVEDGE can cause serious side effects, including:
• See “What is the most important information I should know about ERIVEDGE?”
The most common side effects of ERIVEDGE are:
• muscle spasms
• hair loss
• change in how things taste or loss of taste
• weight loss
• tiredness
• nausea

ERIVEDGE can cause diarrhea, decreased appetite, constipation, joint pain, vomiting, absence of menstrual periods (amenorrhea) in females who are able to become pregnant. It is not known if amenorrhea is permanent. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of ERIVEDGE. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.
You may also report side effects to Genentech, Inc. at 1-888-835-2555.

How should I store ERIVEDGE?
• Store ERIVEDGE at room temperature between 68°F to 77°F (20°C to 25°C).
Keep ERIVEDGE and all medicines out of the reach of children.

General information about the safe and effective use of ERIVEDGE
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ERIVEDGE for a condition for which it was not prescribed. Do not give ERIVEDGE to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ERIVEDGE that is written for health professionals.

What are the ingredients in ERIVEDGE?
Active ingredient: vismodegib
Inactive ingredients: microcrystalline cellulose, lactose monohydrate, sodium lauryl sulfate, povidone, sodium starch glycolate, talc, magnesium stearate (non-bovine). The capsule shell contains gelatin, titanium dioxide, red iron oxide, and black iron oxide. The black printing ink contains shellac and black iron oxide.

Manufactured by: Patheon, Inc. Mississauga, Canada
Distributed by: Genentech USA, Inc. A Member of the Roche Group 1 DNA Way South San Francisco, CA 94080-4990
For more information, call 1-855-737-4833 or go to www.erivedge.com
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