

ODOMZO[®]: A Tolerable Treatment Option for Locally Advanced Basal Cell Carcinoma (laBCC)^{1,*}

Promote open, informed conversations to address concerns, dispel myths, and enhance the ODOMZO experience for you, your staff, and your patients.

*95% of the most common adverse reactions (occurring in >10% of patients) were mild to moderate.

INDICATION

ODOMZO[®] (sonidegib) is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY

- ODOMZO can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. ODOMZO is embryotoxic, fetotoxic, and teratogenic in animals
- Verify the pregnancy status of females of reproductive potential prior to initiating therapy. Advise females of reproductive potential to use effective contraception during treatment with ODOMZO and for at least 20 months after the last dose
- Advise males of the potential risk of exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential during treatment with ODOMZO and for at least 8 months after the last dose

WARNINGS AND PRECAUTIONS

Most Common Adverse Reactions: The most common adverse reactions occurring in $\geq 10\%$ of patients were muscle spasms (54%), alopecia (53%), dysgeusia (46%), fatigue (41%), nausea (39%), musculoskeletal pain (32%), diarrhea (32%), decreased weight (30%), decreased appetite (23%), myalgia (19%), abdominal pain (18%), headache (15%), pain (14%), vomiting (11%), and pruritus (10%).

Please see additional Important Safety Information throughout, and accompanying full **Prescribing Information**, including **Boxed WARNING**.



Odomzo[®]
(sonidegib) capsules
200mg



Talking with your patients about ODOMZO®:

ODOMZO is a nonchemotherapeutic and effective treatment for laBCC.^{1,2}

WHAT IS ODOMZO®?

ODOMZO® (sonidegib) is a hedgehog inhibitor (HHI) used to treat adults with a type of skin cancer called locally advanced basal cell carcinoma (laBCC), for patients who are not candidates for surgery or radiation, or whose condition has recurred following surgery or radiation.¹

WHAT IS laBCC?

Basal cell carcinoma (BCC) is the most common type of skin cancer. It occurs in skin exposed to the sun, especially on the head and neck. Basal cells are located in the top layer of skin, called the epidermis. Abnormal, uncontrolled growth of basal cells leads to locally advanced basal cell carcinoma (laBCC), which is normally slow growing.³⁻⁶

WHAT IS A HEDGEHOG INHIBITOR (HHI)?¹

HHIs are called “targeted therapies” in the treatment of advanced basal cell skin cancer (including laBCC), but it’s important to know that not all HHIs are the same – they have different degrees of side effects.^{1,7}

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Embryo-fetal Toxicity: ODOMZO can cause embryo-fetal death or severe birth defects when administered to a pregnant woman. *Females of Reproductive Potential:* Verify pregnancy status prior to initiating ODOMZO. Advise females to use effective contraception and not to breastfeed, due to the potential for serious adverse reactions in breastfed infants, during treatment, and for at least 20 months after the last dose. Report pregnancies to Sun Pharmaceutical Industries, Inc. at 1-800-406-7984.

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What is ODOMZO®?

ODOMZO is not chemotherapy. It is a medicine that treats a type of skin cancer called locally advanced basal cell carcinoma (laBCC) that's been approved since 2015.

How does ODOMZO work?

It works differently than chemotherapy by blocking a pathway to stop the growth of cancer cells. ODOMZO has the ability to penetrate the tissue and target where the tumor resides.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

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Males: Advise males to use condoms, even after a vasectomy, and to not donate semen during treatment and for at least 8 months after the last dose to avoid potential drug exposure in pregnant females or females of reproductive potential.

Blood Donation: Advise patients not to donate blood or blood products while taking ODOMZO, and for at least 20 months after the last dose because their blood or blood products might be given to a female of reproductive potential.

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





ODOMZO[®] is an effective medication with manageable side effects that can support your patient's treatment plan.^{1,8}

WHAT ARE THE MOST COMMON SIDE EFFECTS OF ODOMZO[®]?

Some of the most common side effects in patients were muscle spasms, hair loss, changes in taste, fatigue, and nausea.¹

HOW MANAGEABLE ARE THE SIDE EFFECTS?

Greater than 95% of the most common adverse reactions were mild to moderate, making ODOMZO a tolerable treatment option.^{1,8}

WERE THERE ANY SEVERE SIDE EFFECTS?

There were no severe, medically significant, or life-threatening side effects that occurred during the pivotal trial.^{1,8}

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Embryo-fetal Toxicity (continued):

Males: Advise males to use condoms, even after a vasectomy, and to not donate semen during treatment and for at least 8 months after the last dose to avoid potential drug exposure in pregnant females or females of reproductive potential.

Blood Donation: Advise patients not to donate blood or blood products while taking ODOMZO, and for at least 20 months after the last dose because their blood or blood products might be given to a female of reproductive potential.

Musculoskeletal Adverse Reactions: Musculoskeletal adverse reactions, which may be accompanied by serum creatine kinase (CK) elevations, occur with ODOMZO and other drugs which inhibit the hedgehog Hh pathway. Obtain serum CK and creatinine levels prior to initiating therapy, periodically during treatment, and as clinically indicated. Temporary dose interruption or discontinuation of ODOMZO may be required based on the severity of musculoskeletal adverse reactions.

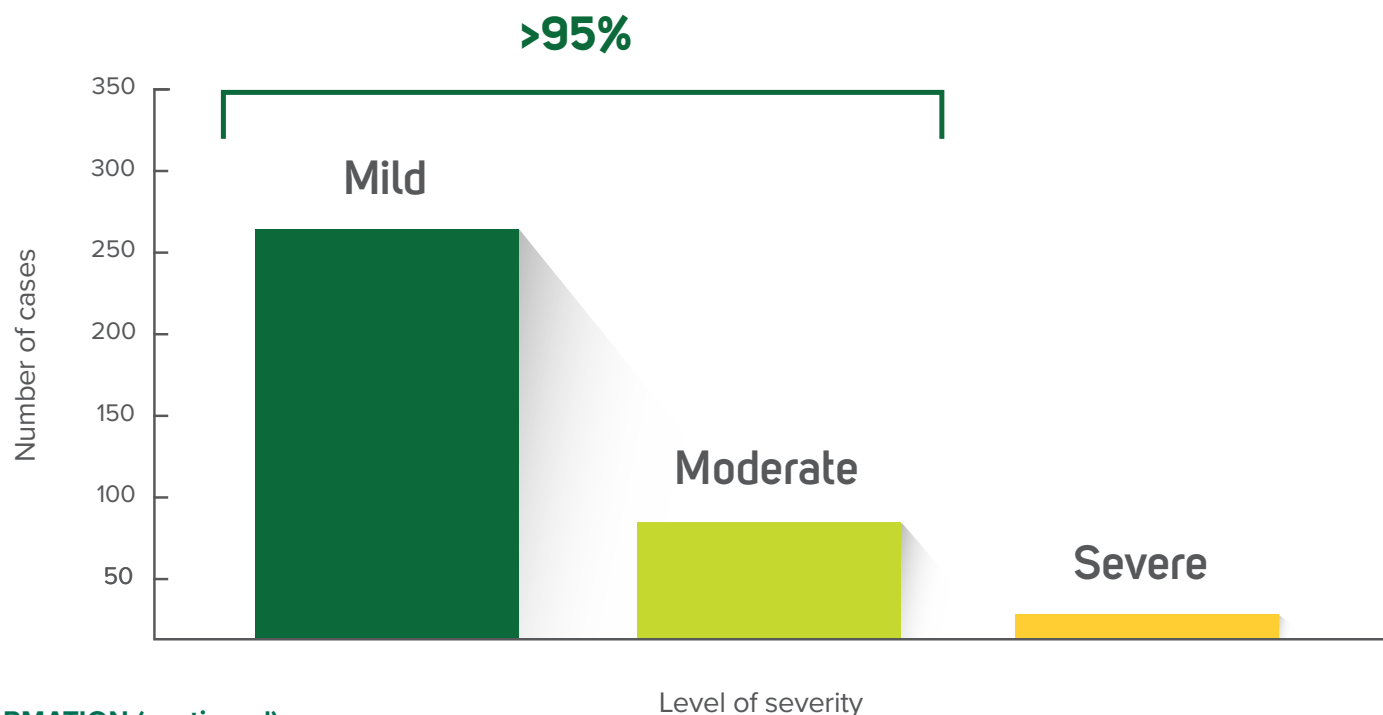
Please see additional Important Safety Information throughout, and accompanying full **Prescribing Information**, including **Boxed WARNING**.





More than 95% of the most common side effects are mild to moderate.

ODOMZO® is a treatment option that most people can handle because **more than 95% of the most common side effects are mild to moderate.**



IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Musculoskeletal Adverse Reactions: Musculoskeletal adverse reactions, which may be accompanied by serum creatine kinase (CK) elevations, occur with ODOMZO and other drugs which inhibit the hedgehog Hh pathway. Obtain serum CK and creatinine levels prior to initiating therapy, periodically during treatment, and as clinically indicated. Temporary dose interruption or discontinuation of ODOMZO may be required based on the severity of musculoskeletal adverse reactions.

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Tips to help patients manage side effects

Choosing an HHI treatment with tolerable side effects can make it easier for patients to stick to their treatment plan exactly as recommended. But, if your patients are experiencing side effects, here are some tips you can share to help manage them.⁹⁻¹⁴



For muscle cramps/spasms⁹:

- Drink plenty of water
- Gently stretch and massage the cramping muscle
- Apply heat to tight muscles by using a heating pad or by taking a warm bath
- Apply cold compress to tender muscles using an ice pack



For tiredness¹⁰:

- Stay physically active. This can help relieve tiredness
- Try mind-body activities such as yoga, massage, and music therapy
- Do important tasks earlier in the day, before you get tired



For mild diarrhea¹¹:

- Drink plenty of clear fluids, like water or broth, to avoid dehydration
- Have small, frequent meals that are easy to eat like bananas, rice, applesauce, and toast
- Avoid caffeine, alcohol, dairy, fat, spicy foods, fiber, and orange juice



For hair loss¹²:

- Choose a mild shampoo. Consider not washing your hair every day
- Pat dry hair and avoid blow drying
- Avoid curling, straightening, or coloring your hair using chemicals
- Protect your scalp from the sun by using sunscreen, a hat, or a scarf



For changes in how things taste¹³:

- Eat foods that taste and smell good even if they are unfamiliar
- Try cold or room-temperature foods, which tend to smell less
- If red meat does not taste good, try other proteins such as chicken, eggs, fish, peanut butter, beans, and dairy
- Flavor foods with spices, herbs, sugar, lemon, sauces, and marinades



For nausea and vomiting¹⁴:

- Relaxation and meditation may help distract you from feeling nauseous
- Acupuncture treatment may also help
- Medicines are available to prevent nausea or vomiting

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Premature Fusion of the Epiphyses: ODOMZO is not indicated for use in pediatric patients. Premature fusion of the epiphyses has been reported in pediatric patients exposed to ODOMZO and other Hh pathway inhibitors. In some cases, fusion progressed after discontinuation.

Please see additional Important Safety Information throughout, and accompanying full **Prescribing Information**, including **Boxed WARNING**.





Communication is key.

You may experience muscle cramps/spasms, tiredness, mild diarrhea, hair loss, changes in how things taste, and/or nausea and vomiting. Always tell your doctor if you're experiencing any side effects. Do not stop taking your medication without guidance from your doctor. They may have tips that can help.

Schedule follow-up appointments to stay in touch with your doctor about any possible side effects.

ARE YOU EXPERIENCING ANY OF THESE? COMMUNICATE WHEN AND HOW FREQUENTLY TO YOUR DOCTOR:



Muscle cramps/spasms



Tiredness



Mild diarrhea



Hair loss



Changes in how things taste



Nausea and vomiting

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Premature Fusion of the Epiphyses: ODOMZO is not indicated for use in pediatric patients. Premature fusion of the epiphyses has been reported in pediatric patients exposed to ODOMZO and other Hh pathway inhibitors. In some cases, fusion progressed after discontinuation.

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Proven results with ODOMZO®

WHAT KIND OF RESULTS DID ODOMZO® HAVE?

In the pivotal BOLT* trial:



ODOMZO resulted in
> 2 YEARS with lesion reduction in half of patients^{1,2,†}
median duration of response

BOLT=Basal cell carcinoma Outcomes with LDE225 Treatment.

*BOLT trial: a multicenter (58 centers, 12 countries), randomized, double-blind, phase II study evaluating once-daily dosing of ODOMZO in 194 patients with locally advanced basal cell carcinoma (laBCC).

Patients were randomized 1:2 to the 200 mg or 800 mg dose.

†Based on centrally reviewed data.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Drug Interactions: Avoid concomitant administration of ODOMZO with strong and moderate CYP3A inhibitors. If a moderate CYP3A inhibitor must be used, administer for less than 14 days and monitor closely for adverse reactions, particularly musculoskeletal. Avoid concomitant administration of ODOMZO with strong and moderate CYP3A inducers.

Please see additional Important Safety Information throughout, and accompanying full **Prescribing Information**, including **Boxed WARNING**.



ABOUT ODOMZO®

SAFETY

SIDE EFFECTS

RESULTS

THE ODOMZO EFFECT



How well does ODOMZO[®] work?

In studies, about 6 out of 10 patients saw their laBCC get smaller by half or even more. This means that ODOMZO can help shrink the tumors and treat the skin cancer.



ODOMZO resulted in
> 2 YEARS with lesion reduction
in half of patients
median duration of response

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Drug Interactions: Avoid concomitant administration of ODOMZO with strong and moderate CYP3A inhibitors. If a moderate CYP3A inhibitor must be used, administer for less than 14 days and monitor closely for adverse reactions, particularly musculoskeletal. Avoid concomitant administration of ODOMZO with strong and moderate CYP3A inducers.

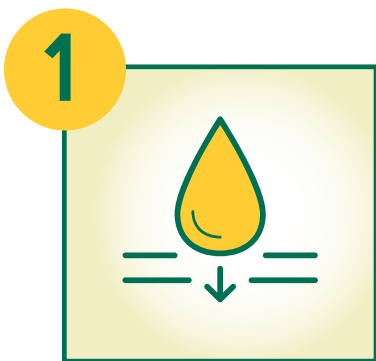
Geriatric Use: There was a higher incidence of serious adverse events, Grade 3 and 4, and events requiring dose interruption or discontinuation in patients ≥ 65 years compared with younger patients; this was not attributable to an increase in any specific adverse event.

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



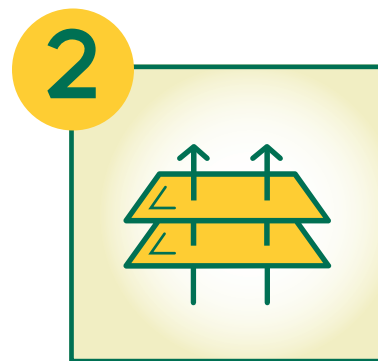


The ODOMZO® Effect



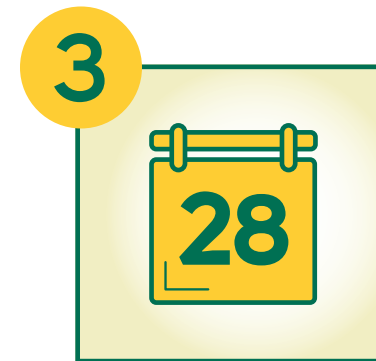
Quickly absorbed into the lesion¹

- ODOMZO reaches its highest concentration in the body within 2-4 hours after it's taken
- It is efficiently delivered and rapidly distributed throughout the body



Works right where you need it^{1,4,15}

- ODOMZO is highly lipophilic, which results in enhanced absorption into the skin—where laBCC resides
- It also has a high volume of distribution (9166 L), resulting in high tissue penetration



Stays in the body for a long time¹

- ODOMZO has a 28-day elimination half-life, which means it stays in the body for a long time
- It works to block activity within the hedgehog pathway, even during dose-modification periods

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Geriatric Use: There was a higher incidence of serious adverse events, Grade 3 and 4, and events requiring dose interruption or discontinuation in patients ≥ 65 years compared with younger patients; this was not attributable to an increase in any specific adverse event.

Most Common Adverse Reactions: The most common adverse reactions occurring in $\geq 10\%$ of patients were muscle spasms (54%), alopecia (53%), dysgeusia (46%), fatigue (41%), nausea (39%), musculoskeletal pain (32%), diarrhea (32%), decreased weight (30%), decreased appetite (23%), myalgia (19%), abdominal pain (18%), headache (15%), pain (14%), vomiting (11%), and pruritus (10%).

Please see additional Important Safety Information throughout, and accompanying full **Prescribing Information**, including **Boxed WARNING**.





Feel good about choosing ODOMZO®.

ODOMZO is proven to work for laBCC

Nearly 6 out of 10 patients
saw their tumors shrink
by half or more.

ODOMZO is not chemotherapy

It blocks a pathway in the
body that helps stop the
growth of cancer cells.

ODOMZO has tolerable side effects

More than 95% of side effects
were mild to moderate in the
clinical study.

You may experience muscle cramps/spasms, tiredness, mild diarrhea, hair loss, changes in how things taste, or nausea and vomiting. Call your doctor if you experience any of these side effects. They may have tips that can help.

What is ODOMZO?

ODOMZO® (sonidegib) is a prescription medicine used to treat adults with a type of skin cancer, called basal cell carcinoma, that has come back following surgery or radiation or that cannot be treated with surgery or radiation.

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

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ODOMZO?

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

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



To learn more about
ODOMZO, please
visit our website by
scanning the QR code



ABOUT ODOMZO®

SAFETY

SIDE EFFECTS

RESULTS

THE ODOMZO EFFECT



IMPORTANT SAFETY INFORMATION (continued)

For females who can become pregnant:

- You should talk to your healthcare provider about the risks of ODOMZO to your unborn child.
- Your healthcare provider will do a pregnancy test before you start taking ODOMZO.
- In order to avoid pregnancy, you should use birth control during treatment, and for at least 20 months after your final dose of ODOMZO. Talk to 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 your birth control has failed.
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant.

For males:

- It is not known if ODOMZO is present in semen. Do not donate semen while you are taking ODOMZO and for at least 8 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 ODOMZO and for at least 8 months after your final dose to protect your female partner from being exposed to ODOMZO.
- Tell your healthcare provider right away if your partner becomes pregnant or thinks she is pregnant while you are taking ODOMZO.

Exposure to ODOMZO during pregnancy:

If you think that you or your female partner may have been exposed to ODOMZO during pregnancy, talk to your healthcare provider right away. If you become pregnant during treatment with ODOMZO, you or your healthcare provider should report your pregnancy to Sun Pharmaceutical Industries, Inc. at 1-800-406-7984.

What are possible side effects of ODOMZO?

ODOMZO can cause serious side effects, including:

- See “**What is the most important information I should know about ODOMZO?**”
- **Muscle Problems.** Muscle spasms and muscle pain are common with ODOMZO, but can also sometimes be symptoms of serious muscle problems. ODOMZO can increase your risk of muscle pain and, rarely a serious condition caused by injury to the muscles (rhabdomyolysis) that can lead to kidney damage. Tell your healthcare provider right away if you develop any new or worsening muscle spasms, pain or tenderness, dark urine, or decreased amount of urine during treatment with ODOMZO.

Your healthcare provider should do a blood test to check for muscle problems and to check your kidney function before you start taking ODOMZO, during treatment, and if you develop muscle problems.

The most common side effects of ODOMZO include:

- hair loss
- change in taste
- tiredness
- nausea
- diarrhea
- weight loss
- decreased appetite
- vomiting
- stomach area (abdominal) pain
- itching
- headache

What should I tell my healthcare provider before taking ODOMZO?

Before you take ODOMZO, tell your healthcare provider if you:

- have muscle pain or spasms, or have a history of a muscle disorder called rhabdomyolysis or myopathy
- have any other medical conditions
- **are pregnant or plan to become pregnant.** See “**What is the most important information I should know about ODOMZO?**”
- **are breastfeeding or plan to breastfeed.** It is not known if ODOMZO passes into your breast milk. Do not breastfeed during treatment and for 20 months after your final dose of ODOMZO. 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. ODOMZO may affect the way other medicines work, and other medicines can affect how ODOMZO works. Taking ODOMZO with other medicines can cause serious side effects.

What should I avoid while taking ODOMZO?

Do not donate blood or blood products while you are taking ODOMZO and for 20 months after your final dose. Do not donate semen while taking ODOMZO and for at least 8 months after your final dose.

ODOMZO 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.

General information about the safe and effective use of ODOMZO

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ODOMZO for a condition for which it was not prescribed. Do not give ODOMZO 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 ODOMZO that is written for health professionals.

This is a summary of the most important safety information about ODOMZO. These are not all of the possible side effects of ODOMZO. Talk with your healthcare provider or pharmacist about side effects. If you would like more information, the FDA-approved product labeling for ODOMZO can be found at www.ODOMZO.com or call 1-800-818-4555.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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



Odomzo[®]
(sonidegib) capsules
200mg

Feel good about choosing ODOMZO®.

Achieved a response in nearly

6 out of 10

patients (n=37/66; 95% CI: 43-68)²

Showed

>95%

of the most common ARs were mild or moderate^{1,8}

In a 12-month interim analysis of the BOLT* trial

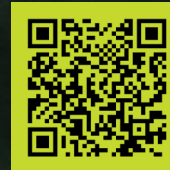
82%

(n=31/38) had an ongoing response to ODOMZO as of last follow-up (1.9 to 18.6 months)¹⁶

mRECIST criteria^{1,†}

Evaluated lesions under stringent criteria¹⁶

>2 YEARS with lesion reduction in half of patients^{1,2,‡,§}
MEDIAN DURATION OF RESPONSE



Experience the ODOMZO Effect at www.ODOMZO.com/hcp

AR=adverse reaction; CI=confidence interval; HHI=hedgehog pathway inhibitor; laBCC=locally advanced basal cell carcinoma; NR=not reached.

*About the BOLT trial: a multicenter (58 centers, 12 countries), randomized, double-blind, phase II trial evaluating once-daily dosing of ODOMZO in 194 patients with laBCC. Patients were randomized 1:2 to the 200 mg or 800 mg dose.^{1,16}

†mRECIST=modified Response Evaluation Criteria In Solid Tumors. It measures complete response based on histology, photography, and magnetic resonance imaging.

‡At 30 months, the median duration of response was 26.1 months (95% CI: 10.1 months, NR).

§Based on centrally reviewed data.

References: 1. ODOMZO [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; 08/2023. 2. Lear JT, Migden MR, Lewis KD, et al. Long-term efficacy and safety of sonidegib in patients with locally advanced and metastatic basal cell carcinoma: 30-month analysis of the randomized phase 2 BOLT study. *J Eur Acad Dermatol Venereol.* 2018;32(3):372-381. 3. Skin Cancer Foundation. Basal Cell Carcinoma Overview. Accessed December 12, 2023. <https://www.skincancer.org/skin-cancer-information/basal-cell-carcinoma/> 4. Mayo Clinic. Basal cell carcinoma. Accessed December 12, 2023. <https://www.mayoclinic.org/diseases-conditions/basal-cell-carcinoma/symptoms-causes/syc-20354187> 5. Fuchs A, Marmur E. The kinetics of skin cancer: progression of actinic keratosis to squamous cell carcinoma. *Dermatol Surg.* 2007;33(9):1099-1101. 6. American Cancer Society. What are basal and squamous cell skin cancers? Accessed December 12, 2023. <https://www.cancer.org/cancer/types/basal-and-squamous-cell-skin-cancer/about/what-is-basal-and-squamous-cell.html> 7. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Basal Cell Skin Cancer V.2.2024. © National Comprehensive Cancer Network, Inc. 2023. All rights reserved. Accessed December 12, 2023. To view the most recent and complete version of the guideline, go online to NCCN.org 8. Dummer R, Guminski A, Gutzmer R, et al. Long-term efficacy and safety of sonidegib in patients with advanced basal cell carcinoma: 42-month analysis of the phase II randomized, double-blind BOLT study. *Br J Dermatol.* 2020;182(6):1369-1378. 9. American Academy of Orthopedic Surgeons. Muscle cramp. Accessed December 12, 2023. <https://orthoinfo.aaos.org/en/diseases-conditions/muscle-cramp/> 10. Mayo Clinic. Cancer fatigue: why it occurs and how to cope. Accessed December 12, 2023. <https://www.mayoclinic.org/diseases-conditions/cancer/in-depth/cancer-fatigue/art-20047709> 11. Mayo Clinic. Diarrhea. Accessed December 12, 2023. <https://www.mayoclinic.org/diseases-conditions/diarrhea/symptoms-causes/syc-20352241> 12. Mayo Clinic. Chemotherapy and hair loss: what to expect during treatment. Accessed December 12, 2023. <https://www.mayoclinic.org/tests-procedures/chemotherapy/in-depth/hair-loss/art-20046920> 13. Mayo Clinic. Eating during cancer treatment: tips to make food tastier. Accessed December 12, 2023. <https://www.mayoclinic.org/diseases-conditions/cancer/in-depth/cancer/art-20047536> 14. Mayo Clinic. Chemotherapy nausea and vomiting: prevention is best defense. Accessed December 12, 2023. <https://www.mayoclinic.org/tests-procedures/chemotherapy/in-depth/cancer/art-20047517> 15. Gutzmer R, Loquai C, Robert C, et al. Key clinical adverse events in patients with advanced basal cell carcinoma treated with sonidegib or vismodegib: a post hoc analysis. *Dermatol Ther (Heidelb).* 2021;11(5):1839-1849. 16. Dummer R, Guminski A, Gutzmer R, et al. The 12-month analysis from Basal Cell Carcinoma Outcomes with LDE225 Treatment (BOLT): a phase II, randomized, double-blind study of sonidegib in patients with advanced basal cell carcinoma. *J Am Acad Dermatol.* 2016;75(1):113-125; 125.e1-125.e5.

INDICATION

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Odomzo®
(sonidegib) capsules
200mg