

OGSIVEO CAN HELP **PUT PROGRESSING DESMOID TUMORS** IN THEIR PLACE

A twice-daily oral medication that is the first and only FDA-approved treatment that can help get progressing desmoid tumors under control¹

What is OGSIVEO?

OGSIVEO is a prescription medication used to treat adults with progressing desmoid tumors who require a medicine by mouth or injection (systemic therapy). It is not known if OGSIVEO is safe and effective in children.¹

Important Safety Information

Before taking OGSIVEO tell your healthcare provider about all of your medical conditions, including if you:

- Have liver problems
- Are pregnant or plan to become pregnant. OGSIVEO can harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with OGSIVEO

Please see Important Safety Information and full Prescribing Information including Patient Information for OGSIVEO.

Visit OGSIVEO.com

Table of Contents

ABOUT DESMOID TUMORS

About Desmoid Tumors OGSIVEO Clinical Trial About OGSIVEO Desmoid Tumor Control With OGSIVEO Taking OGSIVEO	3
	5
	Starting the Conversation With Your Healthcare Provider
Important Safety Information for OGSIVEO	15
Savings and Support	17
Desmoid Tumor Advocacy Groups	18
Glossary	19
References	20





What are desmoid tumors?

Desmoid tumors are dense <u>soft-tissue tumors</u>. They can grow aggressively and affect nearby tissues and organs. They can often return, even after surgery or other treatments. A desmoid tumor is also called aggressive fibromatosis. Only 3% of soft-tissue tumors are desmoid tumors. It is a rare tumor type.²⁻⁵



In the US, **up to 1650 people** are diagnosed with desmoid tumors **every year.** 6-8



Women are more likely to be diagnosed with desmoid tumors, but men are at risk as well.^{7,9,10}



The majority of people with desmoid tumors are diagnosed in **young adulthood.**⁷



After surgery, desmoid tumors may come back—based on the tumor location and other factors. 10,11

Desmoid tumors can affect each person differently depending on where the tumor is in the body, how fast it grows, and other factors.

Learn the meanings of relevant medical words and phrases in the Glossary.

& RESULTS



What should I look for?



The risk of desmoid tumors rises for people with a family history of *familial* adenomatous polyposis (FAP).12 If a person has FAP, doctors may recommend a colectomy to help prevent colon cancer. However, for some, this surgery can increase the risk of developing desmoid tumors.⁵



Desmoid tumors can develop anywhere in the body where there is soft **connective tissue.**³ For example: tumors may form in tissues inside the *abdomen* (intra-abdominal), the chest, legs and feet, arms and hands, or the head and neck.5



Desmoid tumors do not spread to other parts of the body (metastasize).

Although they are not *malignant*, they can cause serious health problems as they grow. They can affect and damage surrounding organs, muscles, blood vessels, and nerves.^{2,3}



Desmoid tumor symptoms can vary based on where the tumor is located.

For example: A tumor inside the abdomen may cause digestive system blockages, pain, malaise, abdominal swelling, weight loss, or muscle wasting. 5,13,14 Tumors in the arms or legs may cause limited movement, deformity, pain, or muscle problems. 5,15,16

Identifying progression

It's important to know if your tumor is progressing, or getting worse. ¹⁷ Signs of *progression* may include:

- Changes in imaging tests. The tumor may appear bigger on a CT scan or MRI¹⁸
- New or changing symptoms. You may have new symptoms, or your existing symptoms -such as pain-may worsen¹⁸

Monitoring your symptoms and reporting them to your healthcare providers may help them create a more personalized treatment plan.



OGSIVEO was studied in a broad range of patients with desmoid tumors in the largest completed clinical trial of its kind

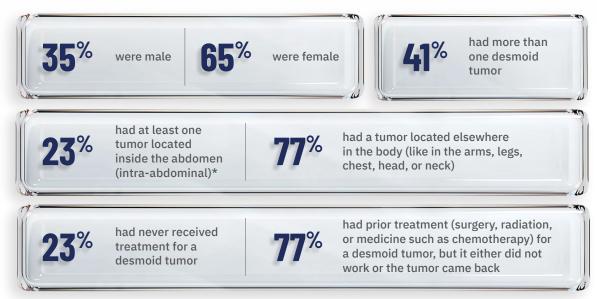
The goals of the trial were to assess the benefits, safety, and tolerability of OGSIVEO in the treatment of adult patients with growing desmoid tumors.¹

- The trial compared OGSIVEO to *placebo* (a pill with no active medicine) in 142 adults
 - 70 people were randomly assigned to receive OGSIVEO, and the remaining 72 people were randomly assigned to receive placebo
- Neither the people in the trial nor their doctors knew whether they were getting OGSIVEO or placebo
- People didn't find out whether they were taking OGSIVEO or placebo until they left the trial (due to either their desmoid tumor progressing, side effects, or other reasons)

All of the people who participated in the clinical trial:1,19

- Were 18 years of age or older
- Had desmoid tumors that grew larger (20% or more) over the past 12 months
- Fell into one of these categories:
 - Had not received any treatment and were not candidates for surgery
 - Had their tumors come back after treatment
 - Had tumors that were not responsive to treatment

Of the people in the clinical trial:1



^{*}Patients who had multiple desmoid tumors inside the abdomen and elsewhere in the body were classified as having intra-abdominal tumors.



OGSIVEO can help control desmoid tumor progression

OGSIVEO is shown to be effective and safe—with impactful clinical trial results:1



OGSIVEO lowered the chance of tumor progression† or death



OGSIVEO **shrank tumors** for some people and, in certain cases, tumors disappeared



Patients reported reduced pain with OGSIVEO

[†]In the trial, progression could mean one of two things: **1)** The tumor was growing bigger by 20% or more, or **2)** The person felt new or worsening symptoms that caused them to stop treatment and leave the trial, and start a different type of treatment for the desmoid tumor(s).^{1,19}

What are the possible side effects of OGSIVEO?1

OGSIVEO can cause serious side effects, including:

Diarrhea Ovarian problems

Liver problems New non-melanoma skin cancers

Electrolyte (salt) problems

OGSIVEO can 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 of the possible side effects of OGSIVEO. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

It's a good idea to talk to your healthcare provider about what you may expect before starting treatment with OGSIVEO.





About **OGSIVEO** and how it works

OGSIVEO is a systemic therapy, meaning it works throughout the entire body^{1,20}—unlike surgery and radiation which are local therapies, meaning they are typically focused on a single place in the body.²¹

OGSIVEO is not a chemotherapy. It's a targeted therapy that is thought to work by interfering with gamma secretase—an enzyme that may affect how certain types of cells grow, including desmoid tumor cells.1,22

Here is how OGSIVEO is thought to work, but the precise mechanism of action is unknown.

This is an example of a desmoid tumor on a person's upper arm. 23,*



*This is a graphic representation of a desmoid tumor, not an actual patient case.

certain signals for cell growth.^{1,26}





What should I tell my doctor before taking OGSIVEO?

Tell your healthcare provider about all of your medical conditions, including if you:1

- Have liver problems
- Are pregnant or plan to become pregnant. OGSIVEO can harm your unborn baby. Tell your healthcare
 provider if you become pregnant or think you may be pregnant during treatment with OGSIVEO

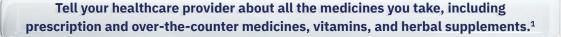


Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with OGSIVEO
- You should use effective birth control (contraception) during treatment with OGSIVEO and for 1 week after the last dose. Talk to your healthcare provider about birth control methods that may be right for you
- Stop taking OGSIVEO and tell your healthcare provider right away if you become pregnant

Males with female partners who are able to become pregnant should use effective birth control (contraception) during treatment with OGSIVEO and for 1 week after the last dose.

• Are breastfeeding or plan to breastfeed. It is not known if OGSIVEO passes into your breast milk. Do not breastfeed during treatment with OGSIVEO and for 1 week after the last dose





Did you know?

<u>Proton pump inhibitors (PPIs)</u>, <u>H2 blockers</u>, and <u>antacids</u> are different types of medicines that affect stomach acid. They may be available over-the-counter or with a prescription.²⁷⁻²⁹

You should avoid taking PPIs and H2 blockers during treatment with OGSIVEO.1

- PPIs and H2 blockers reduce the amount of stomach acid made by the cells lining the stomach^{27,28}
- PPIs and H2 blockers may be used for acid reflux or a stomach ulcer^{27,28}
 - Omeprazole (Prilosec®), lansoprazole (Prevacid®), and esomeprazole (Nexium®) are examples of PPIs
 - Cimetidine (Tagamet HB®), famotidine (Pepcid®), and nizatidine (Axid®) are examples of H2 blockers

If you take an antacid medicine, OGSIVEO should be taken 2 hours before or 2 hours after taking the antacid.¹

- Antacids work by neutralizing stomach acid to help treat heartburn and indigestion^{29,30}
 - Tums®, Rolaids®, and Mylanta® are examples of antacids

Ask your healthcare provider if you are not sure if you take one of these medicines.





OGSIVEO provided effective desmoid tumor control

OGSIVEO TRIAL

& RESULTS



In the clinical trial, OGSIVEO reduced the chance of a participant's disease getting worse during the study by 71% compared with a placebo.

This is known as progression-free survival. 1,19

Results with OGSIVEO were generally consistent across different participant characteristics:19

- Gender
- Whether a person had prior treatment for desmoid tumors or not
- Type of prior treatment

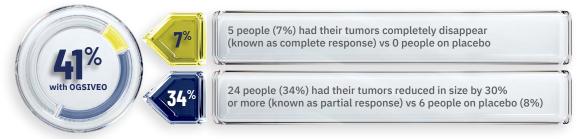
- Changes in tumor DNA
- Number and location of tumors
- Family history of familial adenomatous polyposis (FAP)

Limitations: The study was not designed to specifically compare these characteristics and detect differences.

OGSIVEO also helped shrink desmoid tumors or caused them to completely disappear in some people1

Percentage of people whose tumors responded—as confirmed by MRI or CT scans

When a tumor shrinks by 30% or more or disappears completely, this is known as an <u>objective response</u>^{1,19}



Objective Response

In patients who responded to OGSIVEO, tumors began to shrink between 2.6 and 19.4 months after starting therapy. The *median* (middle) amount of time it took for tumors to begin shrinking was 5.6 months, compared to 11.1 months (2.8 to 16.4 months) for patients taking placebo.¹⁹

Limitations: This was an *exploratory analysis*, meaning it was not specifically designed to find differences between OGSIVEO and placebo. Therefore, these results may be due to chance and should be interpreted carefully. Individual results may vary from the clinical trial experience.





In the clinical trial, 95% of side effects were mild or moderate in intensity and occurred within 1 month of starting treatment with OGSIVEO.¹⁹

OGSIVEO can cause serious side effects, including:1

Diarrhea

Diarrhea is common during treatment with OGSIVEO, and may sometimes be severe. Your healthcare provider may tell you to drink more fluids, or may tell you to take antidiarrheal medicines. Tell your healthcare provider right away if you have diarrhea that lasts longer than a few days and does not get better after taking antidiarrheal medicines.

Ovarian problems

Females who are able to become pregnant may have ovarian problems and changes in their menstrual cycle during treatment with OGSIVEO. OGSIVEO may affect fertility which may affect your ability to have a child. Tell your healthcare provider if you have any changes in your menstrual cycle or any hot flashes, night sweats, or vaginal dryness during treatment with OGSIVEO.

Liver problems

OGSIVEO can cause an increase in liver enzymes. Your healthcare provider will do blood tests to check your liver function before you start and during your treatment with OGSIVEO.

New non-melanoma skin cancers

Your healthcare provider will do skin exams before and during treatment with OGSIVEO if you are at risk for skin cancer. Tell your healthcare provider if you have any new or changing skin lesions.

Electrolyte (salt) problems

Your healthcare provider will do blood tests to check your phosphate and potassium levels during treatment with OGSIVEO and may give you medicines to treat low phosphate or low potassium if needed. Tell your healthcare provider if you develop any muscle pain or weakness.

If you think you may be experiencing any side effects, call your healthcare provider. Your healthcare provider may recommend medications or other approaches to help you manage side effects. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OGSIVEO.

These are not all of the possible side effects of OGSIVEO. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.



Patients reported reduced pain—one of the most common symptoms of desmoid tumors—with **OGSIVEO**



People filled out questionnaires at different points during the trial Patients reported that OGSIVEO reduced pain^{1,19}

- More than 50% of patients entering the clinical trial had pain. Over the course of the trial, people continued to report their pain
- People taking OGSIVEO reported reductions in **worst pain** compared with those taking placebo

Limitations: Meaningful changes in pain levels were difficult to estimate in the clinical trial because not all patients completed the pain questionnaires at each timepoint, and because the number of patients completing questionnaires differed between OGSIVEO and placebo treatment groups. Definitive conclusions cannot be made about the impact of OGSIVEO on pain.

The most common side effects of OGSIVEO are:1

- Rash
- Nausea
- Tiredness
- Mouth sores

- Headache
- Stomach (abdominal) pain
- Cough

- Hair loss
- Upper respiratory infection
- Shortness of breath

OGSIVEO can 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 of the possible side effects of OGSIVEO. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.





With OGSIVEO, I can plan my medication routine easily. OGSIVEO comes in pill form—so I can take it at home. I just set an alarm to remind me.

- Dana, Patient taking OGSIVEO





OGSIVEO is convenient to take at home

Recommended starting dose: 150 mg tablet







Take OGSIVEO exactly as your doctor tells you to take it.







Tablets shown are not actual size. See blister pack for opening and use instructions.

OGSIVEO blister packs may help you track your dose more easily with clear AM/PM dosing by day of the week

- Each blister pack contains a 7-day supply
- Four blister packs provide a 28-day supply

How should I take OGSIVEO?1

OGSIVEO is an oral medicine you can take with or without food.

- OGSIVEO comes in 50 mg, 100 mg, and 150 mg tablets
- The recommended dosage of OGSIVEO is 150 mg taken 2 times a day
- Take OGSIVEO exactly as your healthcare provider tells you to take it
- Swallow OGSIVEO tablets whole. Do not break, crush, or chew
- If you take an antacid medicine, take OGSIVEO 2 hours before or 2 hours after taking the antacid
- Tell your doctor about all the medicines you take—including prescription and over-the-counter medicines, vitamins, and herbal supplements

Learn more about taking OGSIVEO on the next page.



Taking OGSIVEO (continued)



What if I vomit or miss a dose?

If you vomit after taking a dose or miss a dose of OGSIVEO, take your next dose at the regular time. Do not take 2 doses of OGSIVEO to make up the dose.¹



What should I avoid when taking OGSIVEO?

Certain foods or medicines may cause a change in the way OGSIVEO acts in the body. Avoid eating or drinking grapefruit products, Seville oranges, and starfruit during treatment with OGSIVEO.

You should avoid taking proton pump inhibitors (PPIs) or H2 blockers during treatment with OGSIVEO. Ask your healthcare provider if you are not sure if you take one of these medicines.¹



How long will I take OGSIVEO?

Take OGSIVEO as long as your doctor tells you to stay on treatment. In general, you will keep taking OGSIVEO unless your tumor grows (progresses), your symptoms worsen, or you have troublesome side effects that cannot be managed, as determined with your doctor.

During the clinical trial, people took OGSIVEO for a time period ranging from less than 1 month to over 2.5 years. Some people even continued taking OGSIVEO during the study extension period.¹



How do I store OGSIVEO?

- Store OGSIVEO tablets at room temperature between 68°F to 77°F (20°C to 25°C)
- Keep OGSIVEO and all medicines out of reach of children¹



Tips for taking medication

- Make it part of your daily routine. For example, take your medication before or after brushing your teeth³¹
- Set daily reminders on your phone. It might help make remembering to take your medication easier
- When traveling, bring enough of your medication plus a few days' extra³¹



Starting the conversation with your healthcare provider



Understanding what you may expect on OGSIVEO

Ask your healthcare provider any questions you may have about taking OGSIVEO.

Here are 3 questions that can help get the conversation started:

- What might I expect if I start taking OGSIVEO?
- How will you and the care team monitor my treatment with OGSIVEO?
- What should I do if I experience side effects?

Tell your care team about any side effects you experience while taking OGSIVEO1

Side effects can start within the first month of taking OGSIVEO.¹⁹ There might be supportive medicines, therapies, or dietary adjustments that your doctor or care team can recommend for certain side effects to help during treatment. Let them know what you experience. Your doctor may recommend pausing treatment until side effects subside. Your doctor may also determine if a lower dose or stopping treatment is right for you. Always follow your doctor's recommendations.

Diarrhea is a common side effect of OGSIVEO and may sometimes be severe

- Your doctor may recommend an over-the-counter anti-diarrheal medication or other strategies to manage it. Loperamide is an example of an anti-diarrheal medication. Let your doctor know right away if you have diarrhea that lasts longer than a few days and does not get better after taking antidiarrheal medicines¹
- Staying hydrated can help. Drink plenty of fluids throughout the day. You may also find it easier to eat smaller meals more often instead of large ones. Consider choosing bland foods and avoiding foods and beverages that may cause stomach upset, such as caffeine, alcohol, dairy, and spicy, fatty, or greasy foods^{32,33}
- Keeping track of your bowel movements can be helpful for your doctor. This includes how often you go, the consistency of your stools, and any discomfort you experience^{32,33}

Your healthcare provider may recommend medications or other approaches to help you manage possible side effects.





Important Safety Information for OGSIVEO

What is OGSIVEO?

OGSIVEO is a prescription medication used to treat adults with progressing desmoid tumors who require a medicine by mouth or injection (systemic therapy). It is not known if OGSIVEO is safe and effective in children.

Important Safety Information

Before taking OGSIVEO tell your healthcare provider about all of your medical conditions, including if you:

- Have liver problems.
- Are pregnant or plan to become pregnant. OGSIVEO can harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment.

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment with OGSIVEO.
- You should use effective birth control during treatment and for 1 week after the last dose. Talk to your healthcare provider about methods that may be right for you.
- Stop taking OGSIVEO and tell your healthcare provider right away if you become pregnant.

Males with female partners who are able to become pregnant should use effective birth control during treatment with OGSIVEO and for 1 week after the last dose.

 Are breastfeeding or plan to breastfeed. It is not known if OGSIVEO passes into your breast milk. Do not breastfeed during treatment with OGSIVEO and for 1 week after the last dose.

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

You should avoid taking proton pump inhibitors (PPIs) and H2 blockers during treatment with OGSIVEO. Ask your healthcare provider if you are not sure if you take one of these medicines.

How should I take OGSIVEO?

- Take OGSIVEO exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OGSIVEO if you develop side effects.
- Take OGSIVEO 2 times a day with or without food.
- Swallow OGSIVEO tablets whole. Do not break, crush, or chew.
- If you take an antacid medicine, take OGSIVEO 2 hours before or 2 hours after the antacid.
- If you vomit after taking a dose or miss a dose of OGSIVEO, take your next dose at your regular time. Do not take 2 doses of OGSIVEO to make up the dose.

What should I avoid while taking OGSIVEO?

Avoid eating or drinking grapefruit products, Seville oranges, and starfruit during treatment with OGSIVEO.

Please see full Prescribing Information and Patient Information for OGSIVEO.





Important Safety Information for OGSIVEO (continued)

What are the possible side effects of OGSIVEO?

OGSIVEO can cause serious side effects, including:

- Diarrhea. Diarrhea is common with OGSIVEO and may sometimes be severe. Your healthcare provider may tell you to drink more fluids or to take antidiarrheal medicines. Tell your healthcare provider right away if you have diarrhea that lasts longer than a few days and does not get better after taking antidiarrheal medicines.
- Ovarian problems. Females who are able to become pregnant may have ovarian problems and changes in their menstrual cycle during treatment. OGSIVEO may affect fertility which may affect your ability to have a child. Tell your healthcare provider if you have any changes in your menstrual cycle or hot flashes, night sweats, or vaginal dryness during treatment.
- Liver problems. OGSIVEO can increase liver enzymes. Your healthcare provider will do blood tests to check your liver function before you start and during treatment with OGSIVEO.
- New non-melanoma skin cancers. Your healthcare provider will do skin exams before and during treatment with OGSIVEO if you are at risk for skin cancer. Tell your healthcare provider if you have any new or changing skin lesions.
- Electrolyte (salt) problems. Your healthcare provider will do blood tests to check your phosphate and potassium levels during treatment and may give you medicines to treat low phosphate or low potassium if needed. Tell your healthcare provider if you develop any muscle pain or weakness.

Tell your healthcare provider right away if you have any side effect that bothers you or that does not go away. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with OGSIVEO.

The most common side effects of OGSIVEO are:

- rash
- nausea
- tiredness
- mouth sores
- headache

- stomach (abdominal) pain
- cough
- hair loss
- upper respiratory infection
- shortness of breath

OGSIVEO can 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 of the possible side effects of OGSIVEO. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please see full Prescribing Information and Patient Information for OGSIVEO.



Connecting you to support on your treatment journey

Need help getting started on or staying on track with OGSIVEO?

SpringWorks CareConnections[™] is a free, personalized patient support program to help you navigate your insurance coverage and answer questions about your treatment.





Insurance Navigation and Financial Help

- The SpringWorks CareConnections Nurse Advocates can offer information about financial assistance options, as well as information that explains your insurance coverage
- Commercially insured patients may pay as little as a \$0 copay for each OGSIVEO prescription through the Commercial Copay Program*



Personalized Educational and Emotional Support for Patients

- The SpringWorks CareConnections team of dedicated Nurse Advocates can provide you with ongoing, personalized support no matter where you are in your treatment journey with OGSIVEO†
- If you have started taking OGSIVEO, you can count on support from your Nurse Advocate to help keep you on track with your treatment

Visit www.springworkstxcares.com to enroll in the Commercial Copay Program

For questions and further information on the support available through SpringWorks CareConnections, please call 844-CARES-55 (844-227-3755), Monday – Friday 8 AM – 10 PM ET or visit www.springworkstxcares.com



^{*}Terms and conditions apply. Copay program is subject to an annual benefit maximum. Full terms and conditions provided during enrollment process and are available upon request by contacting SpringWorks CareConnections at 844-CARES-55 (844-227-3755).

[†]The SpringWorks CareConnections Patient Support Program is not intended to take the place of your healthcare provider, and the team of Nurse Advocates cannot provide medical or clinical advice.

Advocacy groups and additional desmoid tumor resources*

You may find it helpful to reach out to the organizations listed below for information, support, or to connect with others who are living with desmoid tumors.



Desmoid Tumor Research Foundation (DTRF)

dtrf.org



Rein in Sarcoma

reininsarcoma.org



National Organization for Rare Disorders (NORD)

rarediseases.org



Sarcoma Alliance for Research through Collaboration (SARC)

sarctrials.org



Northwest Sarcoma Foundation

www.nwsarcoma.org



NCCN Guidelines for Patients® Soft Tissue Sarcoma

nccn.org



Global Genes

globalgenes.org



Sarcoma Foundation of America

curesarcoma.org

^{*}SpringWorks Therapeutics, Inc. is providing these links to help patients find more information about desmoid tumors, but inclusion on this list does not represent an endorsement or a recommendation from SpringWorks for any group or organization. The organizations listed are independent of SpringWorks.



Abdomen (intra-abdominal): The area inside the body that includes the stomach, the small and large intestines, liver, spleen, gallbladder, and pancreas, the uterus, fallopian tubes, and ovaries, the kidneys, ureters, bladder, and blood vessels.³⁴

Antacids: Treatment for heartburn (indigestion). Antacids work by neutralizing the stomach acid that causes heartburn.²⁹

Colectomy: Surgery to remove all or part of the colon.³⁵

Connective tissue: Tissue that supports, protects, and gives structure to other tissues and organs in the body. Bone, cartilage, fat, blood, and lymphatic tissue are all types of connective tissue.³⁶

CT: A CT (or computerized tomography) scan is a procedure that may help diagnose a medical condition, plan treatment, or find out how well treatment is working. A computer is linked to an x-ray machine to record detailed pictures of different areas inside the body.³⁷

Electrolytes: Minerals with an electrical charge (also known as ions) like sodium, potassium, and phosphate. The body needs electrolytes to help keep the muscles, nerves, heart, and brain working. High or low levels of electrolytes can disrupt normal bodily function.^{38,39}

Exploratory analysis: Research that was not specifically designed to find an answer, but rather to uncover trends and patterns within data. For example, in the clinical trial, the amount of time it took for tumors to shrink in people taking OGSIVEO versus in people taking placebo was an exploratory analysis. 19,40

Familial adenomatous polyposis (FAP): FAP is caused by a gene mutation that runs in families.

In this inherited condition, abnormal growths called polyps form on the inner walls of the colon and rectum. Polyps may become cancer if they are not removed. People with FAP are at higher risk of developing desmoid tumors, often in the abdominal area.⁴¹

H2 blockers: Medicines that work by reducing the amount of stomach acid secreted by glands in the lining of your stomach.²⁸

Malignant: Cells are described as malignant when their growth is uncontrolled, with the potential to spread to other parts of the body (metastasize).⁴²

Median: The middle value in a set of measurements.⁴³

Metastasize: To spread from one area of the body to another—as when cancer cells form other tumors elsewhere in the body. For example, when cancer starts in the breast but spreads to the bones.⁴⁴

MRI: An MRI (magnetic resonance imaging) is a type of scan that takes a series of detailed images of areas inside the body. MRI uses radio waves, a powerful magnet, and a computer to record the images that can help in diagnosing a medical condition; or in planning treatment or seeing how well a treatment may be working.⁴⁵

Objective response: When a person's tumors shrink by at least 30% or disappear completely at some point during the trial. Confirmed objective response in the trial only includes participants who had a response to treatment for at least 4 weeks.^{1,19}

Placebo: An inactive substance that looks the same as, and is given the same way as, an active drug or treatment being tested. The effects of the active drug or other intervention are compared to the effects of the placebo.⁴⁶

Progression: When a desmoid tumor is getting worse.¹⁷

Progression-free survival: How long a person lives without: 1) their tumor progressing (growth) on imaging, 2) their disease symptoms or health status getting worse, or 3) dying from any cause^{1,19}

Proton pump inhibitor (PPI): Medicines that work by reducing the amount of stomach acid made by glands in the lining of your stomach.²⁷

Soft-tissue tumors: Tumors that form in areas such as muscle, fat, tendons, ligaments, lymph and blood vessels, nerves, or other connective tissues in the body.³

Systemic therapy: Treatment with medicine that travels through the bloodstream to affect cells all over the body.²⁰



References

- 1. OGSIVEO. Prescribing information. SpringWorks Therapeutics, Inc.
- 2. Cancer.Net. Desmoid tumor: introduction. Accessed February 22, 2024. https://www.cancer.net/cancer-types/desmoid-tumor/introduction

OGSIVEO TRIAL

& RESULTS

- 3. NIH. National Cancer Institute Center for Cancer Research. Desmoid tumor. Accessed February 22, 2024. https://www.cancer.gov/pediatricadult-rare-tumor/rare-tumors/rare-soft-tissue-tumors/desmoid-tumor
- 4. Kasper B, Baumgarten C, Garcia J, et al. Desmoid Working Group. An update on the management of sporadic desmoid-type fibromatosis: European Consensus Initiative between Sarcoma PAtients EuroNet (SPAEN) and European Organization for Research and Treatment of Cancer (EORTC)/Soft Tissue and Bone Sarcoma Group (STBSG). Ann Oncol. 2017;28(10):2399-2408.
- 5. Constantinidou A, Scurr M, Judson I, Litchman C. Clinical presentation of desmoid tumors. In: Litchman C, ed. Desmoid Tumors. Springer; 2012:chap 2. Accessed February 22, 2024. https://www.researchgate. net/publication/226455135
- 6. Orphanet Report Series: Rare Diseases Collection. Prevalence and incidence of rare diseases: bibliographic data. Number 1, January 2022. Accessed February 22, 2024. https://www.orpha.net/orphacom/cahiers/ ${\tt docs/GB/Prevalence_of_rare_diseases_by_alphabetical_list.pdf}$
- 7. van Broekhoven DLM, Grünhagen DJ, den Bakker MA, van Dalen T, Verhoef C. Time trends in the incidence and treatment of extra-abdominal and abdominal aggressive fibromatosis: population-based study. \emph{Ann} Surg Oncol. 2015;22(9):2817-2823.
- 8. U.S. Department of Commerce. News Blog. U.S. population estimated at 332,403,650 on Jan. 1, 2022. Accessed February 22, 2024. https:// www.commerce.gov/news/blog/2022/01/us-population-estimated-332403650-jan-1-2022
- Penel N, Coindre JM, Bonvalot S, et al. Management of desmoid tumours: a nationwide survey of labelled reference centre networks in France. Eur J Cancer. 2016;58:90-96.
- 10. Skubitz KM. Biology and treatment of aggressive fibromatosis or desmoid tumor. Mayo Clin Proc. 2017;92(6):947-964.
- 11. Easter DW, Halasz NA. Recent trends in the management of desmoid tumors. Summary of 19 cases and review of the literature. Ann Surg. 1989;210(6):765-769.
- 12. Gurbuz AK, Giardiello FM, Petersen GM, et al. Desmoid tumours in familial adenomatous polyposis. Gut. 1994;35(3):377-381.
- 13. Shinagare AB, Ramaiya NH, Jagannathan JP, et al. A to Z of desmoid tumors. AJR Am J Roentgenol. 2011;197(6):W1008-W1014.
- 14. Tchangai BK, Tchaou M, Alassani F, et al. Giant abdominopelvic desmoid tumour herniated trough perineum: case report. J Surg Case Rep. 2021;2021(8):rjab295. doi:10.1093/jscr/rjab295.
- 15. McDonald ES, Yi ES, Wenger DE. Best cases from the AFIP: extraabdominal desmoid-type fibromatosis. Radiographics. 2008;28(3):901-906.
- 16. Scaramussa FS, Castro UB. Desmoid tumor in hand: a case report. SM J Orthop. 2016;2(3):1036.
- **17.** NCI (National Cancer Institute). Dictionary of cancer terms: progression. Accessed February 22, 2024. https://www.cancer.gov/publications/ dictionaries/cancer-terms/def/progression
- 18. Gronchi A, et al. Desmoid Tumor Working Group. The management of desmoid tumours: joint global consensus-based guideline approach for adult and paediatric patients [supplementary appendix]. Eur J Cancer. 2020:127:96-107.
- 19. Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a gamma-secretase inhibitor for desmoid tumors. N Engl J Med. 2023;388(10):898-912.
- 20. NIH. National Cancer Institute. NCI dictionary of cancer terms: systemic therapy. Accessed February 22, 2024. https://www.cancer.gov/ publications/dictionaries/cancer-terms/def/systemic-therapy
- 21. NIH. National Cancer Institute. NCI Dictionary of Cancer Terms. Local therapy. Accessed February 22, 2024. https://www.cancer.gov/search/ results?swKeyword=local+therapy
- 22. NIH. National Cancer Institute. Targeted Therapy to Treat Cancer. Accessed February 22, 2024. https://www.cancer.gov/about-cancer/ treatment/types/targeted-therapies.
- 23. Penel N, Chibon F, Salas S. Adult desmoid tumors: biology, management and ongoing trials. Curr Opin Oncol. 2017;29(4):268-274.

- 24. Carothers AM, Rizvi H, Hasson RM, et al. Mesenchymal stromal cell mutations and wound healing contribute to the etiology of desmoid tumors. Cancer Res. 2012;72(1):346-355.
- 25. Villalobos VM, Hall F, Jimeno A, et al. Long-term follow-up of desmoid fibromatosis treated with PF-03084014, an oral gamma secretase inhibitor. Ann Surg Oncol. 2018;25(3):768-775.
- 26. Shang H, Braggio D, Lee YJ, et al. Targeting the Notch pathway: a potential therapeutic approach for desmoid tumors. Cancer. 2015;121(22):4088-4096.
- 27. NIH. National Library of Medicine. Medline plus: Proton pump inhibitors. Accessed February 22, 2024. https://medlineplus.gov/ency/ patientinstructions/000381.htm
- 28. NIH. National Library of Medicine. Medline plus: H2 blockers. Accessed February 22, 2024. https://medlineplus.gov/ency/ patientinstructions/000382.htm
- 29. NIH. National Library of Medicine. Medline plus: Taking Antacids. Accessed February 22, 2024. https://medlineplus.gov/ency/ patientinstructions/000198.htm
- 30. NIH. National Library of Medicine. Medline plus: Calcium Carbonate. Accessed February 22, 2024. https://medlineplus.gov/druginfo/meds/a601032.html
- 31. U.S. Food & Drug Administration. Why you need to take your medications as prescribed or instructed. Accessed February 22, 2024. https://www. fda.gov/drugs/special-features/why-you-need-take-your-medicationsprescribed-or-instructed
- 32. Cancer.org. American Cancer Society: diarrhea. Accessed March 29, 2024. https://www.cancer.org/content/dam/CRC/PDF/Public/8919.00.pdf
- 33. Cancer.net. ASCO answers: diarrhea. Accessed March 29, 2024. https:// www.cancer.net/sites/cancer.net/files/asco_answers_tipsheet_diarrhea.pdf
- 34. NIH. National Library of Medicine. Medline plus: Abdominal exploration-series-normal anatomy. Accessed February 22, 2024. https:// medlineplus.gov/ency/presentations/100049_1.htm
- 35. NIH. National Cancer Institute. NCI dictionary of cancer terms: colectomy. Accessed February 22, 2024. https://www.cancer.gov/search/ results?swKeyword=colectomy
- 36. NIH. National Cancer Institute. NCI dictionary of cancer terms: connective tissue. Accessed February 22, 2024. https://www.cancer.gov/ search/results?swKeyword=connective+tissue
- 37. NIH. National Cancer Institute. NCI dictionary of cancer terms: CT scan. Accessed February 22, 2024. https://www.cancer.gov/publications/ dictionaries/cancer-terms/def/ct-scan
- 38. NIH. National Library of Medicine. Medline plus: Electrolytes. Accessed February 22, 2024. https://medlineplus.gov/ency/article/002350. htm#:~:text=Electrolytes%20are%20minerals%20in%20your,Your%20 muscle%20function
- 39. Shrimanker I, Bhattarai S. Electrolytes. [Updated 2022 Jul 25]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Accessed February 22, 2024. https://www.ncbi.nlm.nih.gov/ books/NBK541123
- **40.** NIH. Toolkit For Patient-Focused Therapy Development. Glossary: Endpoint. Accessed April 1, 2024. https://toolkit.ncats.nih.gov/glossary/endpoint/
- 41. NIH. National Cancer Institute. NCI dictionary of cancer terms: FAP. Accessed February 22, 2024. https://www.cancer.gov/publications/ dictionaries/cancer-terms/def/fap
- 42. NIH. National Cancer Institute. NCI dictionary of cancer terms: malignant. Accessed February 22, 2024. https://www.cancer.gov/publications/ dictionaries/cancer-terms/def/malignant
- **43.** NIH. National Cancer Institute. NCI dictionary of cancer terms: median. Accessed March 29, 2024. https://www.cancer.gov/publications/ dictionaries/cancer-terms/def/median
- 44. NIH. National Cancer Institute. NCI dictionary of cancer terms: metastasize. Accessed February 22, 2024. https://www.cancer.gov/ publications/dictionaries/cancer-terms/def/metastasize
- 45. NIH. National Cancer Institute. NCI dictionary of cancer terms: MRI. Accessed February 22, 2024. https://www.cancer.gov/ publications/dictionaries/cancer-terms/def/mri
- 46. NIH. National Cancer Institute. NCI dictionary of cancer terms: placebo. Accessed February 22, 2024. https://www.cancer.gov/publications/ dictionaries/cancer-terms/def/placebo







Actor portrayal. Individual results may vary.

OGSIVEO CAN HELP FREE YOU FROM THE GRIP OF DESMOID TUMORS

Help keep desmoid tumors under control—with the **first and only** FDA-approved treatment that can help shrink progressing **desmoid tumors**.¹

Talk to your doctor to find out if OGSIVEO may be right for you.

Access helpful resources during your treatment journey with the OGSIVEO <u>Digital Resource Kit</u>, and download the OGSIVEO treatment tracker—a tool to help monitor symptoms and side effects.

What is OGSIVEO?

OGSIVEO is a prescription medication used to treat adults with progressing desmoid tumors who require a medicine by mouth or injection (systemic therapy). It is not known if OGSIVEO is safe and effective in children.

Important Safety Information

Before taking OGSIVEO tell your healthcare provider about all of your medical conditions, including if you:

- Have liver problems
- Are pregnant or plan to become pregnant. OGSIVEO can harm your unborn baby. Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with OGSIVEO



