

## **OGSIVEO® (nirogacestat) Now Available in 150 mg and 100 mg Tablets**

In May 2024, SpringWorks Therapeutics introduced OGSIVEO® (nirogacestat) in new blister packaging. This new product format had been in development for several years in anticipation of OGSIVEO coming to market and is available in the FDA-approved doses of 150 mg and 100 mg. Designed to improve the patient experience with OGSIVEO, the introduction of the 150 and 100 mg tablets reduces the number of pills a patient needs to take each day to only one pill twice a day, and the new blister packaging also makes tracking daily AM/PM dosing simpler for patients, which will further support compliance to therapy.

Starting January 1, the OGSIVEO bottles with 50 mg pills will no longer be available. The 150 and 100 mg tablets achieve the FDA-approved therapeutic doses of OGSIVEO with the least number of pills, therefore these are the strengths that will remain available in the new blister packaging.

For questions related to the 50 mg OGSIVEO tablets, which is not an approved dose of OGSIVEO, please have your physician reach out to SpringWorks Medical Information at 1-888-400-SWTX (1-888-400-7989) or [medinfo@springworkstx.com](mailto:medinfo@springworkstx.com).



### **About OGSIVEO® (nirogacestat)**

OGSIVEO (nirogacestat) is an oral, selective, small molecule gamma secretase inhibitor approved in the United States for the treatment of adult patients with progressing desmoid tumors who require systemic treatment.

OGSIVEO is not approved for the treatment of any other indication in the United States, or for any indication in any other jurisdiction by any other health authority.

## IMPORTANT SAFETY INFORMATION

### WARNINGS AND PRECAUTIONS

- **Diarrhea:** Diarrhea, sometimes severe, can occur in patients treated with OGSIVEO. Diarrhea occurred in 84% of patients treated with OGSIVEO, and included Grade 3 events in 16% of patients. Median time to first diarrhea event was 9 days (range: 2 to 434 days). Monitor patients and manage using antidiarrheal medications. Modify dose as recommended.
- **Ovarian Toxicity:** Female reproductive function and fertility may be impaired in patients treated with OGSIVEO. Impact on fertility may depend on factors like duration of therapy and state of gonadal function at time of treatment. Long-term effects of OGSIVEO on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.
- **Hepatotoxicity:** ALT or AST elevations occurred in 30% and 33% of patients, respectively. Grade 3 ALT or AST elevations ( $>5 \times$  ULN) occurred in 6% and 2.9% of patients. Monitor liver function tests regularly and modify dose as recommended.
- **Non-Melanoma Skin Cancers:** New cutaneous squamous cell carcinoma and basal cell carcinoma occurred in 2.9% and 1.4% of patients, respectively. Perform dermatologic evaluations prior to initiation of OGSIVEO and routinely during treatment.
- **Electrolyte Abnormalities:** Decreased phosphate (65%) and potassium (22%) occurred in OGSIVEO-treated patients. Phosphate  $<2$  mg/dL occurred in 20% of patients. Grade 3 decreased potassium occurred in 1.4% of patients. Monitor phosphate and potassium levels regularly and supplement as necessary. Modify dose as recommended.
- **Embryo-Fetal Toxicity:** OGSIVEO can cause fetal harm when administered to pregnant women. Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity and death at maternal exposures below human exposure at the recommended dose of 150 mg twice daily. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use effective contraception during treatment with OGSIVEO and for 1 week after the last dose.

### ADVERSE REACTIONS

- The most common ( $\geq 15\%$ ) adverse reactions were diarrhea (84%), ovarian toxicity (75% in the 36 females of reproductive potential), rash (68%), nausea (54%), fatigue (54%), stomatitis (39%), headache (30%), abdominal pain (22%), cough (20%), alopecia (19%), upper respiratory tract infection (17%), and dyspnea (16%).
- Serious adverse reactions occurred in 20% of patients who received OGSIVEO. Serious adverse reactions occurring in  $\geq 2\%$  of patients were ovarian toxicity (4%).
- The most common laboratory abnormalities ( $\geq 15\%$ ) were decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium.

## DRUG INTERACTIONS

- **CYP3A Inhibitors and Inducers:** Avoid concomitant use with strong or moderate CYP3A inhibitors (including grapefruit products, Seville oranges, and starfruit) and strong or moderate CYP3A inducers.
- **Gastric Acid Reducing Agents:** Avoid concomitant use with proton pump inhibitors and H2 blockers. If concomitant use cannot be avoided, OGSIVEO can be staggered with antacids (e.g., administer OGSIVEO 2 hours before or 2 hours after antacid use).
- Consult the full Prescribing Information prior to and during treatment for important drug interactions.

## USE IN SPECIFIC POPULATIONS

- Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with OGSIVEO and for 1 week after the last dose.

To report suspected adverse reactions, contact SpringWorks Therapeutics at 1-888-400-SWTX (1-888-400-7989) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Please see full U.S. [Prescribing Information](#) for OGSIVEO for more information.