PLEASE REVIEW

Drug Information
PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 219.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Ogsiveo™: The First & Only Treatment for Desmoid Tumors

The U.S. Food and Drug Administration (FDA) has approved Ogsiveo™ (nirogacestat), the first and only treatment for adults with desmoid tumors.

Background

Desmoid tumors are locally aggressive and invasive soft-tissue tumors that can lead to substantial morbidity. They can be life-threatening if vital structures are impacted. Although they do not metastasize, these tumors are often refractory to existing off-label therapies and often have recurrence following surgical resection.

Up until the approval of Ogsiveo™, there were no evidence-based guidelines as to the appropriate choice of agent for systemic therapy. Systemic therapy may be classified into cytotoxic chemotherapy and less toxic therapies, such as tyrosine kinase inhibitors, nonsteroidal anti-inflammatory drugs (NSAIDs), and hormonal therapy.

The National Comprehensive Cancer Network (NCCN) suggest systemic therapy as a treatment choice for unresectable desmoid tumors and those for which surgery would not be an option but provide limited guidance as to the choice of an agent.

A New Treatment Choice

Ogsiveo™ (nirogacestat) is an oral gamma secretase inhibitor that is indicated for the treatment of adult patients with progressing desmoid tumors who require systemic treatment. It is an oral tablet that comes in a 50 mg strength. The recommended dosage is 150 mg orally twice daily. Warnings and precautions include diarrhea, ovarian toxicity, hepatotoxicity, non-melanoma skin cancers, electrolyte abnormalities and fetal toxicity.

Ogsiveo™ received approval from the US Food and Drug Administration (FDA) for the treatment of desmoid tumors in November 2023. The FDA's approval of Ogsiveo™ was based on data from the pivotal Phase III DeFi clinical trial.

CLINICAL PEARLS BY PHARMPIX

In the clinical trial, the patients treated with Ogsiveo™ showed a 71% reduction in the risk of disease progression compared to the placebo group. Additionally, Ogsiveo™ shrank tumors in 41% of patients with desmoid tumors, compared to 8% in patients treated with a placebo. The complete response rate was 7% in the Ogsiveo™ group and 0% in the placebo group.

Additional information can be found at: https://www.ogsiveo.com/

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-ext 219. Our pharmacists will help you. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

PharmPix Drug Information Communication Number COM-2023-078 December 2023

REFERENCES:
1.   Springworks Therapeutics, Inc. (2023). Ogsiveo™ (nirogacestat). [Full Prescribing Information]. U.S. Food & Drug Administration Drugs@FDA Website: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217677s000lbl.pdf
2.   Ogsiveo for the treatment of desmoid tumours, US. Clinical Trials Arena. (2023). https://www.clinicaltrialsarena.com/projects/ogsiveo-treatment-desmoid-tumours-us/