

Please join us for a presentation on the VOYXACT® (sibeprenlimab-szsi) Prescribing Information Overview



INDICATION

VOYXACT is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether VOYXACT slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Please see **IMPORTANT SAFETY INFORMATION** below.



Program objectives

- State the indication and approved use for VOYXACT
- Discuss key safety information including contraindications, warnings & precautions, adverse reactions, drug interactions, and use of VOYXACT in specific populations
- Summarize VOYXACT's pivotal clinical trial findings
- Explain the mechanism of action for VOYXACT
- Explain VOYXACT dosing and administration



Presented by

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This program will be held on

Thursday, April 30, at 7:30 AM

Product Theater in Ballroom A/B



This program/event is developed and offered by Otsuka America Pharmaceutical, Inc. This is not an official program/event of the Cleveland Clinic.

Speaker is a paid consultant of Otsuka America Pharmaceutical, Inc., or an employee of Otsuka Pharmaceutical Development & Commercialization, Inc. The intended audience for this program is healthcare professionals involved in the treatment of patients with IgA nephropathy.

IMPORTANT SAFETY INFORMATION for VOYXACT® (sibeprenlimab-szsi)

CONTRAINDICATION

VOYXACT is contraindicated in patients with serious hypersensitivity to sibeprenlimab-szsi or any of the excipients of VOYXACT.

WARNINGS AND PRECAUTIONS

Immunosuppression and Increased Risk of Infections: VOYXACT suppresses the immune system by reducing antibody production, which may increase the risk of infections. Patients with chronic or recurring infections may have an increased risk of serious infection. In clinical trials, infections occurred in 49% of patients treated with VOYXACT compared with 45% of patients treated with placebo.

Before initiating VOYXACT, assess patients for active infections. During treatment, monitor patients for signs and symptoms of infection. If a serious infection develops, consider interrupting VOYXACT until the infection is controlled.

Immunosuppression and Immunization Risks: Because of its mechanism of action, VOYXACT may interfere with immune responses to vaccines and increase the risk of infection from live vaccines. Live vaccines are not recommended within 30 days prior to initiation of VOYXACT or during treatment with VOYXACT as safety has not been established. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving VOYXACT or on the efficacy of immunizations administered while receiving VOYXACT.

Common Adverse Reactions: The most common adverse reactions (reported in $\geq 10\%$ of patients treated with VOYXACT and at a higher incidence than placebo) in patients treated with VOYXACT and placebo, respectively, were infections (49% versus 45%) and injection site reactions (24% versus 23%). The most common infection was upper respiratory infection (15% versus 14%), and the most common injection site reaction was injection site erythema (13% versus 12%). Most adverse reactions were reported as mild or moderate and resolved without treatment interruption or discontinuation.

Pregnancy: There are no available data on VOYXACT use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Monoclonal antibodies, such as sibeprenlimab-szsi, can be actively transported across the placenta as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy.

Lactation: There are no data on the presence of sibeprenlimab-szsi in human milk, the effects of sibeprenlimab-szsi on the breastfed infant, or the effects of sibeprenlimab-szsi on milk production.

Pediatric Use: Safety and effectiveness of VOYXACT in pediatric patients have not been established.

Geriatric Use: Clinical studies of VOYXACT did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger adult patients.

Pregnant women exposed to VOYXACT, or their healthcare providers, should report VOYXACT exposure by calling 1-833-869-9228 or visiting www.VOYXACT.com

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 or FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).

Please see **FULL PRESCRIBING INFORMATION** at this presentation.

This program is sponsored by Otsuka America Pharmaceutical, Inc.

In accordance with the PhRMA Code on Interactions with Health Care Professionals, attendance at this program is limited to only Healthcare Professionals (Physicians, Nurse Practitioners, Physician Assistants, RNs, Clinical Pharmacists, Social Workers) involved in the treatment of patients with IgA nephropathy. Accordingly, attendance by guests or spouses is not permitted.

This invitation-only program is not a Continuing Medical Education (CME) activity.

This program may include the provision of a modest meal. Otsuka does not offer such a meal to healthcare professionals (HCPs) whose institutions prohibit such hospitality, nor does Otsuka offer a meal where federal or state laws (e.g., Vermont and Minnesota) limit an HCP's ability to accept such a meal. Accordingly, please consult your legal or ethics advisor regarding any applicable limitation before attending this program. If you are licensed to practice in a state where meals are either prohibited and/or restricted and you accept a meal, you understand that you will be required to reimburse Otsuka for the cost of the meal.

Please note that Otsuka will use your personal information to report the value of a provided meal pursuant to applicable federal and/or state laws.

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