You are cordially invited to attend this educational program

A New Treatment Strategy in cGVHD

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Sidney Kimmel Cancer Center I Philadelphia, PA

Wednesday, February 19, 2025
6:00 PM
Eastern Standard Time

Selden Standard
3921 Second Ave
Detroit, MI 48201

The program will begin at 6:00 PM. Please plan to arrive 15 minutes early.
Due to a change in policy, Incyte will no longer provide or pay for alcohol at Speaker Programs.
Appropriate attendees include licensed healthcare professionals (HCPs) with a direct role in patient care.

REGISTRATION

Online https://sphase.info/inc11960

You may also register by contacting your Incyte Representative Joann Fawaz at (302) 438-9314 or jfawaz@incyte.com with the following information: name, title/degree, state(s) and state license number(s), affiliation, address, phone, and email.

Prior to registering, please review the program title and speaker to ensure you have not attended this program before.

Please see accompanying Full Prescribing Information for Niktimvo.

Please note this program is intended for US healthcare professionals (HCPs) who practice in a specialty relevant to the program's FDA-approved indication or disease state. This program is sponsored by Incyte Corporation and is not eligible for CE credits.

This is an educational event intended only for appropriate healthcare professionals. Spouses, guests, and other individuals who are not the intended audience of this educational program are not permitted to attend. Healthcare professionals who are subject to federal, state, or local laws or government ethics restrictions may not attend this event. Incyte will report the cost of any meals provided at this event as required by federal, state, or local laws.

Incyte and its representatives will process your personal information that you provide when you register in order to attend an educational event presented by Incyte. You can learn more about Incyte's privacy practices at the following site: https://www.incyte.com/privacy-policy.
Please contact privacy@incyte.com if you have any questions or concerns.

Niktimvo™
(axatilimab-csfr)
50 mg/mL for injection, for intravenous use

IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

Niktimvo™ (axatilimab-csfr) is a colony stimulating factor-1 receptor (CSF-1R)-blocking antibody indicated for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg.

WARNINGS AND PRECAUTIONS

Infusion-Related Reactions

Niktimvo™ (axatilimab-csfr) can cause infusion-related reactions. Infusion-related reactions, including hypersensitivity reactions, occurred in 18% of patients who received Niktimvo in the clinical trial (AGAVE-201), with Grade 3 or 4 reactions in 1.3%.

Premedicate with an antihistamine and an antipyretic for patients who have previously experienced an infusion-related reaction to Niktimvo. Monitor patients for signs and symptoms of infusion-related reactions, including fever, chills, rash, flushing, dyspnea, and hypertension. Interrupt or slow the rate of infusion or permanently discontinue Niktimvo based on severity of the reaction.

Embryo-Fetal Toxicity

Based on its mechanism of action, Niktimvo may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with Niktimvo and for 30 days after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 44% of patients who received Niktimvo (N=79). Serious adverse reactions in > 2 patients included infection (pathogen unspecified) (14%), viral infection (14%), and respiratory failure (5.1%). Permanent discontinuation of Niktimvo due to an adverse reaction occurred in 10% of patients and dose reduction due to adverse reaction occurred in 8% of patients. Dose interruptions due to an adverse reaction occurred in 44% of patients. The adverse reactions leading to dose interruption in > 2 patients were viral infection, infection (pathogen unspecified), bacterial infection, musculoskeletal pain, and pyrexia.

The most common (≥ 15%) adverse reactions, including laboratory abnormalities, were increased aspartate aminotransferase (AST), infection (pathogen unspecified), increased alanine aminotransferase (ALT), decreased phosphate, decreased hemoglobin, viral infection, increased gamma glutamyl transferase (GGT), musculoskeletal pain, increased lipase, fatigue, increased amylase, increased calcium, increased creatine phosphokinase (CPK), increased alkaline phosphatase (ALP), nausea, headache, diarrhea, cough, bacterial infection, pyrexia, and dyspnea.

Clinically relevant adverse reactions in < 10% of patients who received Niktimvo included:

- *Eye disorders*: periorbital edema
- *Skin and subcutaneous skin disorders:* pruritus
- *Vascular disorders:* hypertension

Immunogenicity: Anti-Drug Antibody–Associated Adverse Reactions

Across treatment arms in patients with cGVHD who received Niktimvo in clinical trials, among the patients who developed anti-drug antibodies (ADAs), hypersensitivity reactions occurred in 26% (13/50) of patients with neutralizing antibodies (NAb) and in 4% (2/45) of those without NAb.

USE IN SPECIFIC POPULATIONS

Lactation

Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment and for 30 days after the last dose of Niktimvo.

Females and Males of Reproductive Potential

Pregnancy Testing

Verify pregnancy status in females of reproductive potential prior to initiating Niktimvo.

Contraception

Females

Advise females of reproductive potential to use effective contraception during treatment with Niktimvo and for 30 days after the last dose of Niktimvo.

DOSAGE AND ADMINISTRATION

Dosage Modifications for Adverse Reactions

Monitor aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), creatine phosphokinase (CPK), amylase, and lipase prior to the start of Niktimvo therapy, every 2 weeks for the first month, and every 1 to 2 months thereafter until abnormalities are resolved. See Table 1 in the Prescribing Information for more recommendations.

Please see accompanying Full Prescribing Information for Niktimvo.

10% Total Recycled Fiber

Niktimvo™ (axatilimab-csfr) 50 mg/mL for injection, for intravenous use