You are invited to an educational program sponsored by Recordati Rare Diseases

SYLVANT®: The first & only FDA-approved therapy for your patients with Idiopathic Multicentric Castleman Disease (iMCD)

Presented by:

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CEO, Access for Advanced Health Institute

Clinical Professor, University of Washington

Date and Time:

Monday, July 22, 2024

6:00 – 8:30pm (PDT)

Location:

Carpe Diem Restaurant

1001 2nd St. Suite #185

Napa, CA 94559

To attend, please contact

Sheila Babby at sheila.babby@recordati.com or 925-719-1002

RRD is committed to complying with all legal requirements. If you are subject to a restriction based on your practice location or institutional affiliation, RRD kindly asks that you not attend this event.
This event is conducted in accordance with the PhRMA Code on Interactions with Healthcare Professionals and is limited to Healthcare Professionals. Attendance by guests or spouses is not permitted. Federal and state laws restrict and/or require disclosure of items RRD provides to Healthcare Professionals, including meals, refreshments, and transportation.

SYLVANT® (siltuximab) for injection

INDICATIONS AND USAGE

SYLVANT® (siltuximab) is an interleukin-6 (IL-6) antagonist indicated for the treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative.

Limitations of Use
SYLVANT was not studied in patients with MCD who are HIV positive or HHV-8 positive because SYLVANT did not bind to virally produced IL-6 in a nonclinical study.

IMPORTANT SAFETY INFORMATION

SYLVANT is contraindicated in patients experiencing a severe hypersensitivity reaction to siltuximab or any of the excipients in SYLVANT.

Concurrent Active Severe Infections: Do not administer SYLVANT to patients with severe infections until the infection resolves. SYLVANT may mask signs and symptoms of acute inflammation including suppression of fever and of acute Phase reactants such as C-reactive protein (CRP). Monitor patients receiving SYLVANT closely for infections. Institute prompt anti-infective therapy and do not administer further SYLVANT until the infection resolves.

Vaccinations: Do not administer live vaccines to patients receiving SYLVANT because IL-6 inhibition may interfere with the normal immune response to new antigens.

Infusion Related Reactions and Hypersensitivity: Stop the infusion of SYLVANT if the patient develops signs of anaphylaxis. Discontinue further therapy with SYLVANT. Stop the infusion if the patient develops a mild to moderate infusion reaction. If the reaction resolves, the SYLVANT infusion may be restarted at a lower infusion rate. Consider medicating with antihistamines, acetaminophen, and corticosteroids. Discontinue SYLVANT if the patient does not tolerate the infusion following these interventions.

Administer SYLVANT in a setting that provides resuscitation equipment, medication, and personnel trained to provide resuscitation.

Gastrointestinal (GI) Perforation: Gastrointestinal (GI) perforation has been reported in clinical trials although not in MCD trials. Use with caution in patients who may be at increased risk for GI perforation. Promptly evaluate patients presenting with symptoms that may be associated or suggestive of GI perforation.

The most common adverse reactions (>10% compared to placebo) in the MCD clinical trial were rash, pruritus, upper respiratory tract infections, increased weight, and hyperuricemia.

Cytochrome P450 Substrates: Upon initiation or discontinuation of SYLVANT, in patients being treated with CYP450 substrates with a narrow therapeutic index, perform therapeutic monitoring of effect (e.g., warfarin) or drug concentration (e.g., cyclosporine or theophylline) as needed and adjust dose. The effect of SYLVANT on CYP450 enzyme activity can persist for several weeks after stopping therapy. Exercise caution when SYLVANT is co-administered with CYP3A4 substrate drugs where a decrease in effectiveness would be undesirable (e.g., oral contraceptives, lovastatin, atorvastatin).

Pregnancy and Lactation: SYLVANT may cause embryo-fetal harm when administered to pregnant women. Advise female patients of reproductive potential to use effective contraception during treatment with SYLVANT and for 3 months after the last dose. Advise females not to breastfeed during treatment with SYLVANT and for 3 months after the final dose.

Dosing and Administration: Perform hematology laboratory tests prior to each dose of SYLVANT therapy for the first 12 months and every 3 dosing cycles thereafter. If treatment criteria outlined in the Prescribing Information are not met, consider delaying treatment with SYLVANT. Do not reduce dose.

Before prescribing SYLVANT, please read the Full Prescribing Information.

sylvant® siltuximab