IMPORTANT SAFETY INFORMATION

WHAT IS NATEVBA® (vevasumab)?

Natevba is a prescription medicine used for the treatment of adult patients with X-antigen positive Non-Hodgkin's Lymphoma (XA+ NHL), including:

- Relapsed or refractory XA+ NHL.
- Previously untreated XA+ NHL in combination with chemotherapy and as maintenance therapy in patients who achieve a partial or complete response.

Natevba is indicated for reducing signs and symptoms, including major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA).

WARNINGS AND PRECAUTIONS

Natevba is not for everyone, including anyone who has previously had an allergic reaction to it. It is not for patients with a known hypersensitivity, those with liver problems, or individuals who are currently taking pimozide. Additionally, Natevba should not be used by women who are pregnant, planning to become pregnant, or nursing.

Before starting Natevba, it is important to evaluate patients thoroughly and prepare for the management of potential adverse events. During treatment, monitor patients closely for any signs or symptoms of severe reactions to ensure appropriate intervention. The following precautions highlight critical areas of concern:

- Infusion-Related Reactions: Severe reactions, including urticaria, hypotension, angioedema, and anaphylaxis, can occur. Premedicate with antihistamines and acetaminophen. For serious reactions, discontinue and manage symptoms.
- Severe Mucocutaneous Reactions: Includes Stevens-Johnson syndrome and toxic epidermal necrolysis, which may be fatal. Discontinue Natevba if such reactions occur.
- Hepatitis B Reactivation: Reactivation can lead to serious outcomes, including death. Screen all patients and consult with experts for managing HBV.
- Progressive Multifocal Leukoencephalopathy (PML): Monitor for new or worsening neurologic symptoms.
- Tumor Lysis Syndrome (TLS): Can occur within 12-24 hours of infusion, potentially leading to renal failure or cardiac issues. Administer prophylaxis and monitor renal function.
- Infections: Serious infections, including bacterial, fungal, and viral, may occur. Monitor closely and treat appropriately.
- Cardiovascular Reactions: Discontinue Natevba for serious cardiac events, including myocardial infarction and arrhythmias.
- Renal Toxicity: Monitor renal function, especially in patients with concomitant cisplatin therapy.

- Bowel Obstruction and Perforation: Discontinue if symptoms such as severe abdominal pain or vomiting occur.
- Embryo-Fetal Toxicity: Can cause fetal harm. Advise females of reproductive potential to use effective contraception during treatment and for 12 months after the final dose.

ADVERSE REACTIONS

The most common adverse reactions (≥25%) include:

- Infusion-related reactions
- Fever
- Lymphopenia
- Chills
- Infection
- Asthenia
- Diarrhea
- Nausea
- Muscle and joint pain

DRUG INTERACTIONS

Before initiating treatment with Natevba, a patient's complete medical history and current medications should be confirmed to identify potential drug interactions and ensure safe administration. Conduct baseline blood tests to evaluate liver function and cholesterol levels in patients with symptoms of liver abnormalities or hyperlipidemia, and monitor these parameters as clinically indicated during treatment. Concomitant use with cisplatin increases the risk of renal toxicity. Monitor renal function closely.

USE IN SPECIFIC POPULATIONS

Special consideration is needed for patients in certain populations, as their responses to Natevba treatment may differ. Ensure that treatment decisions are tailored to the unique needs and potential risks in these groups:

- Pregnancy: May cause fetal harm. Advise females to use effective contraception.
- Lactation: Advise women not to breastfeed during treatment and for at least 6 months after the last dose.
- Geriatric Use: Patients ≥70 years of age may not derive benefit from Natevba.

REPORTING ADVERSE REACTIONS

Report suspected adverse reactions to Verteo Biopharma at 1-888-483-5555 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch