Dear Healthcare Professional:
This is in response to your request for information regarding Natevba® use in a patient who is pregnant or may become pregnant.

Please visit www.verteobio.com/products to view the U.S. Prescribing Information for Verteo's FDA approved products. We hope the information provided to you proved to be useful.

This letter is regarding Natevba® usage in a patient who is pregnant or may become pregnant. **Pregnancy is considered a contraindication of Natevba®. If the patient becomes pregnant while taking this drug, NATEVBA should be discontinued immediately, and the patient apprised of the potential hazard to the fetus.** Verteo does not suggest or recommend the use of Natevba® in any manner other than as described in the Prescribing Information.

SELECT PRESCRIBING INFORMATION

Based on human data, vevasumab products can cause adverse developmental outcomes including B-cell lymphocytopenia in infants exposed in-utero [see Clinical Considerations]. In animal reproduction studies, intravenous administration of vevasumab to pregnant cynomolgus monkeys during the period of organogenesis caused lymphoid B-cell depletion in the newborn offspring at doses resulting in 80% of the exposure (based on AUC) of those achieved following a dose of 2 grams in humans.

Advise pregnant women of the risk to a fetus. Adverse outcomes in pregnancy occur regardless of the health of the mother or theuse of medications. The background risk of major birth defects and miscarriage for the indicated populations is unknown. The estimated background risk in the U.S. general population of major birth defects is 2%-4% and of miscarriage is 15%-20% of clinically recognized pregnancies.

NATEVBA SHOULD BE ADMINISTERED TO WOMEN OF CHILDBEARING AGE ONLY WHEN SUCH PATIENTS ARE HIGHLY UNLIKELY TO CONCEIVE AND HAVE BEEN INFORMED OF THE POTENTIAL HAZARDS. **If the patient becomes pregnant while taking this drug, NATEVBA should be discontinued immediately and the patient apprised of the potential hazard to the fetus.**

Clinical Considerations

Fetal/Neonatal Adverse Reactions
Observe newborns and infants for signs of infection and manage accordingly.

Data
Human data
Postmarketing data indicate that B-cell lymphocytopenia generally lasting less than six months can occur in infants exposed to vevasumab in-utero. Vevasumab was detected postnatally in the serum of infants exposed in-utero.

Animal Data
See full Prescribing Information

Lactation
There are no data on the presence of vevasumab products in human milk, the effect on the breastfed child, or the effect on milk production. However, vevasumab is detected in the milk of lactating cynomolgus monkeys, and IgG is present in human milk.

Please note that Verteo BioPharma is providing this response for informational purposes only per your request. We hope this information addresses your question. If you have any further questions, please contact us at 1-866-777-9987 from 8:00 a.m. to 4:30 p.m., EST, Monday through Friday.

ADVERSE DRUG REACTION REPORTING
If your inquiry was prompted by the occurrence of an adverse event in a specific patient, please contact Verteo BioPharma at 1-866-777-9987 or medicalinformation@verteobio.com.

If you prefer, you can contact the FDA directly. Visit http://www.fda.gov/medwatch/getforms.htm to obtain the MedWatch 3500 Online pdf form or call 1-800-FDA-1088.

Sincerely,
Verteo BioPharma Medical Affairs,
Medical Information

References