Shire's Bleeding Disorders Educational Program

OBIZUR® [Antihemophilic Factor (Recombinant), Porcine Sequence]: A Treatment for Adults With Acquired Hemophilia A[1]

Tuesday, August 27, 2019 6:00PM
Hunters Pub and Steakhouse
11269 GA-219
Hamilton, GA 31811
(706) 628-5992

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If you would like to attend this program, please contact your Shire representative, Leah Lanaman at 423-260-7803 or leah.lanaman@shire.com to RSVP by 08/25/2019 or register online at http://www.programrsvp.com/HEM-891

Program Objective

- Provide key results from the pivotal phase 2/3 clinical study assessing the safety and efficacy of OBIZUR in the treatment of bleeding episodes in adults with acquired hemophilia A (AHA).

Program Description

AHA is a potentially life-threatening bleeding disorder caused by the production of autoantibodies that inhibit the clotting function of FVIII.[2] In this program, we will review the safety and efficacy data from the pivotal phase 2/3 clinical study that led to the approval of OBIZUR, a recombinant porcine sequence FVIII, for the treatment of bleeding episodes in adults with AHA. Information and data from the clinical study will be presented to describe how OBIZUR represents a treatment option for bleeding episodes in patients with AHA.

This is a non-CME program sponsored by Shire US Inc. Shire is prohibited from providing meals to prescribers that are licensed by the State of Minnesota and healthcare professionals that are licensed by the State of Vermont. Prescribers licensed by the State of NJ may not consume a Shire-offered meal in excess of $15. Invitees cannot bring guests. Shire will collect and report healthcare professional information concerning meals and other transfers of value pursuant to the Federal Sunshine Act and state laws.

OBIZUR [Antihemophilic Factor (Recombinant) Porcine Sequence] Important Information

Indication

OBIZUR, Antihemophilic Factor (Recombinant), Porcine Sequence, is a recombinant DNA derived, antihemophilic factor indicated for the treatment of bleeding episodes in adults with acquired hemophilia A.

Limitations of Use:

- Safety and efficacy of OBIZUR has not been established in patients with a baseline anti-porcine factor VIII inhibitor titer of greater than 20 BU.
- OBIZUR is not indicated for the treatment of congenital hemophilia A or von Willebrand disease.

Detailed Important Risk Information

CONTRAINDICATIONS

OBIZUR is contraindicated in patients who have had life-threatening hypersensitivity reactions to OBIZUR or its components (including traces of hamster proteins).

Please see page 2 for additional Detailed Important Risk Information.
Please click here for OBIZUR Full Prescribing Information.

GLOBAL: https://www.shirecontent.com/PI/PDFs/OBIZUR_USA_ENG.pdf

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[Antihemophilic Factor (Recombinant), Porcine Sequence]

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Detailed Important Risk Information (Continued)

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions can occur with OBIZUR. OBIZUR contains trace amounts of hamster proteins. Early signs of allergic reactions, which can progress to anaphylaxis, include angioedema, chest-tightness, dyspnea, hypotension, wheezing, urticaria, and pruritus. Immediately discontinue administration and initiate appropriate treatment if allergic or anaphylactic-type reactions occur.

Inhibitory Antibodies

Inhibitory antibodies to OBIZUR have occurred. Monitor patients for the development of antibodies to OBIZUR by appropriate assays. If the plasma factor VIII level fails to increase as expected, or if bleeding is not controlled after OBIZUR administration, suspect the presence of an anti-porcine factor VIII antibody. If such inhibitory antibodies to anti-porcine factor VIII are suspected and there is a lack of clinical response, consider other therapeutic options.

Monitoring Laboratory Tests

- Perform one-stage clotting assay to confirm that adequate factor VIII levels have been achieved and maintained.
  - Monitor factor VIII activity 30 minutes and 3 hours after initial dose.
  - Monitor factor VIII activity 30 minutes after subsequent doses.
- Monitor the development of inhibitory antibodies to OBIZUR. Perform a Nijmegen Bethesda inhibitor assay if expected plasma factor VIII activity levels are not attained or if bleeding is not controlled with the expected dose of OBIZUR. Use Bethesda Units (BU) to report inhibitor levels

ADVERSE REACTIONS

Common adverse reactions observed in greater than 5% of subjects in the clinical trial were development of inhibitors to porcine factor VIII.

Please click here for OBIZUR Full Prescribing Information.

REFERENCES

1. Obizur [Prescribing Information].
2. Sborov DW, Rodgers GM. Acquired hemophilia a: a current review of autoantibody disease. *Clin Adv Hematol Oncol*. 2012;10(1):19-27.

Obizur
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