December 13, 2013

# Alexion Provides Update on Previously Communicated November 2013 Voluntary Nationwide Recall of Two Lots of Soliris® (eculizumab) Concentrated Solution for Intravenous Infusion

CHESHIRE, Conn.--(BUSINESS WIRE)-- Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today is providing further information regarding a previously communicated voluntary recall of two lots of Soliris® (eculizumab) Concentrated Solution for Intravenous Infusion. As stated on Nov. 12, 2013, the two lots were found to contain visible particles. At that time, Alexion provided instructions to return any unused vials of Soliris from these two lots at the distributor level. Alexion is now providing the same instructions at the hospital/user level.

The administration of particulate, if present in a parenteral drug, poses a potential safety risk to patients in two general areas: immunogenicity and thromboembolic events. Particulates could cause blockage of flow of blood in vessels, which could be life-threatening. To date, there have been no product complaints of particulates, or identifiable safety concerns attributed to the product consumed from the affected lots. As previously stated, Alexion does not anticipate any interruption to patient supply of Soliris.

The product is approved as a treatment for patients with paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome, two ultra-rare disorders. Alexion and its distributors typically ship Soliris to healthcare providers in small quantities, which are timed to individual patient infusions, with the product being consumed before more is shipped. As product was last shipped on Nov. 1, 2013, Alexion believes there is little, if any, inventory currently being held at the hospital or user level.

The following table lists the two affected lots, which were distributed nationwide.

| Product | Lot | Expiration Date | First Ship Date | Last Ship Date |
|---|---|---|---|---|
| Soliris® (eculizumab)<br>300 mg/30 mL<br>Concentrated solution for intravenous infusion only<br>NDC 25682-001-01 | 10010A | Oct. 31, 2015 | Oct. 11, 2013 | Nov. 1, 2013 |
| | 10001-1 | July 31, 2014 | June 4, 2012 | May 8, 2013 |

As previously disclosed, Alexion believes that it has identified the filling process step that resulted in the presence of the visible particles and implemented the change necessary to correct the issue. To date, visible particles have not been observed in other lots of Soliris distributed in the U.S.

**Any person in possession of vials of Soliris from these lots should stop use and arrange for return of the product to Alexion immediately by calling 1-888-SOLIRIS (888-765-4747).**

**Alexion will replace any recalled vials of Soliris. Unaffected lot numbers can continue to be used according to the instructions for use.**

Healthcare professionals and pharmacists with questions regarding this recall can contact Alexion at 1-888-765-4747. Patients should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail**: Use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

**About Alexion**

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company focused on serving patients with severe and ultra-rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Alexion is the global leader in complement inhibition and has developed and markets Soliris® (eculizumab) as a treatment for patients with PNH and aHUS, two debilitating, ultra-rare and life-threatening disorders caused by chronic uncontrolled complement activation. Soliris is currently approved in nearly 50 countries for the treatment of PNH, and in the United States, European Union, Japan and other countries for the treatment of aHUS. Alexion is evaluating other potential indications for Soliris in additional severe and ultra-rare disorders beyond PNH and aHUS, and is developing other highly innovative biotechnology product candidates across multiple therapeutic areas. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at: www.alexionpharma.com.

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**Safe Harbor Statement**

This news release includes forward-looking statements relating to continued adequacy of supply of Soliris, and identification and correction of the cause of the visible particles. These statements are subject to risks, uncertainties and other factors, including risks related to continuous product inventory and supply, the uncertainties involved in manufacturing of biologic products, and whether the FDA, EMA or other international regulatory authorities decide to take corrective or disciplinary actions against Alexion, as well as the risks that are described in detail in Alexion's Quarterly Report on Form 10-Q for the quarter ended Sept. 30, 2013, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Alexion, and Alexion assumes no duty or obligation to update or revise any such forward-looking statements or any other statement in this report.

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