Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: June 2, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Alexion Pharmaceuticals, Inc. - [Drug]

AFFECTED PRODUCT: **Soliris® (eculizumab) 300 mg/30 mL concentrated solution for intravenous infusion.**

SUMMARY: **Unclassified Recall; This recall has been initiated due to the presence of visible proteinaceous particles detected in a single lot during periodic stability testing for Soliris.**

The single affected Soliris lot is #10007A. Although these lots currently remain in specification, Alexion is including the following remaining lots, which were produced with the same process component during vial filling, within the scope of the U.S. recall: 10002-1, 00006-1, 10003A, 10004A, 10005A, 10005AR, 10006A and 10008A.

The following table lists the lots that are being recalled:

Product	Lot	Expiration Date	First Ship Date	Last Ship Date
Soliris®(eculizumab) 300 mg/30 mL Concentrated solution for intravenous infusion only NDC 25682-001-01	10007A	July 2015	June 17, 2013	Oct. 29, 2013
	10002-1	Aug 2014	Sept 6, 2012	Sept 9, 2013
	00006-1	Aug 2014	Oct 12, 2012	May 15, 2013
	10003A	Nov 2014	Mar 28, 2013	Oct 3, 2013
	10004A	Feb 2015	Feb 4, 2013	Sept 24, 2013
	10005A	July 2015	May 15, 2013	Oct 28, 2013
	10005AR	July 2015	Sept 23, 2013	Sept 26, 2013
	10006A	July 2015	July 8, 2013	Oct 24, 2013
	10008A	Aug 2015	Aug 16, 2013	Oct 30, 2013

The products were distributed in the U.S. to wholesalers, hospitals, and pharmacies.

SUGGESTED ACTION: **For consumer inquiry only. Healthcare professionals and pharmacists with questions regarding this recall can contact Alexion at 1-888-765-4747, Monday-Friday from 8:30am to 5:00pm ET. 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.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Alexion Initiates Voluntary Nationwide Recall of Certain Lots of Soliris® (eculizumab) Concentrated Solution for Intravenous Infusion Due to the Presence of Visible Particulate Matter in a Single Lot

-- Alexion's global supply chain continues to provide Soliris to commercial and clinical patients without interruption --

Contact
Consumer:
1-888-765-4747

Media:
Irving Adler, 203-271-8210
Executive Director, Corporate Communications

Kim Diamond, 203-439-9600
Senior Director, Corporate Communications

FOR IMMEDIATE RELEASE - June 2, 2014 - Alexion Pharmaceuticals, Inc. (NASDAQ: ALXN) today announced that it is initiating a voluntary recall of certain lots of Soliris® (eculizumab) 300 mg/30 mL concentrated solution for intravenous infusion that were manufactured using a process component during vial filling identified in the November 2013 recall to the hospital/user level. As previously stated, Alexion believes that it has identified the process component that resulted in the presence of the visible particles and implemented a change to the process. Alexion does not anticipate any interruption to patient supply. This recall has been initiated due to the presence of visible proteinaceous particles detected in a single lot during periodic stability testing for Soliris. This lot was distributed only in the U.S. No safety risks to patients who have received Soliris have been identified. There is no financial impact from the voluntary recall announced today..

The single affected Soliris lot is #10007A. Although these lots currently remain in specification, Alexion is including the following remaining lots, which were produced with the same process

component during vial filling, within the scope of the U.S. recall: 10002-1, 00006-1, 10003A, 10004A, 10005A, 10005AR, 10006A and 10008A. Following this voluntary recall, there will no longer be Soliris in the U.S. manufactured using the previously identified process component that Alexion believes resulted in the stability failure.

The administration of particulate, if present in a parenteral drug, poses a potential safety risk to patients in two general areas: immune reaction and blood clots. 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 product from the affected lot was last shipped on Oct. 29, 2013, Alexion believes there is little, if any, inventory currently being held at the hospital or user level.

Soliris is approved as a treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), two ultra-rare and life-threatening 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 from the identified lots was last shipped on October 30, 2013, there is anticipated to be little, if any, material from these lots still remaining in commercial distribution.

The following table lists the lots that are being recalled, which were distributed in the U.S. to wholesalers, hospitals, and pharmacies:

Product	Lot	Expiration Date	First Ship Date	Last Ship Date
Soliris®(eculizumab) 300 mg/30 mL Concentrated solution for intravenous infusion only NDC 25682-001-01	10007A	July 2015	June 17, 2013	Oct. 29, 2013
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	10008A	Aug 2015	Aug 16, 2013	Oct 30, 2013

Alexion is notifying its distributors and customers by letter being sent via Federal Express and is arranging for replacement of all recalled products. 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), Monday-Friday from 8:30am to 5:00pm Eastern Time (ET). 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, Monday-Friday from 8:30am to 5:00pm ET. 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.

- **Complete and submit the report Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Soliris® (eculizumab)

Soliris® (eculizumab) is a first-in-class terminal complement inhibitor developed from the laboratory through regulatory approval and commercialization by Alexion. Soliris is approved in the U.S. (2007), European Union (2007), Japan (2010) and other countries as the first and only treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH), a debilitating, ultra-rare and life-threatening blood disorder, characterized by complement-mediated hemolysis (destruction of red blood cells). Soliris is indicated to reduce hemolysis in PNH patients. Soliris is also approved in the U.S. (2011), the European Union (2011), Japan (2013) and other countries as the first and only treatment for patients with atypical hemolytic uremic syndrome (aHUS), a debilitating, ultra-rare and life-threatening genetic disorder characterized by complement-mediated thrombotic microangiopathy, or TMA (blood clots in small vessels). The effectiveness of Soliris in aHUS is based on the effects on TMA and renal function. Soliris is not indicated for the treatment of patients with Shiga toxin *E. coli*-related hemolytic uremic syndrome (STEC-HUS). More information, including the full prescribing information on Soliris, is available at www.soliris.net.

Important Safety Information

The U.S. product label for Soliris includes a boxed warning: "Life-threatening and fatal meningococcal infections have occurred in patients treated with Soliris. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early [see Warnings and Precautions (5.1)]. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients with complement deficiencies. Immunize patients with a meningococcal vaccine at least 2 weeks prior to administering the first dose of Soliris, unless the risks of delaying Soliris therapy outweigh the risk of developing a meningococcal infection [See Warnings and Precautions (5.1) for additional guidance on the management of the risk of meningococcal infection]. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected. Soliris is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Under the Soliris REMS, prescribers must enroll in the program [see Warnings and Precautions (5.2)]. Enrollment in the Soliris REMS program and additional information are available by telephone: 1-888-SOLIRIS (1-888-765-4747)."

In patients with PNH, the most frequently reported adverse events observed with Soliris treatment in clinical studies were headache, nasopharyngitis (runny nose), back pain and nausea. Soliris treatment of patients with PNH should not alter anticoagulant management because the effect of withdrawal of anticoagulant therapy during Soliris treatment has not been established. In patients with aHUS, the most frequently reported adverse events observed with Soliris treatment in clinical studies were headache, diarrhea, hypertension, upper respiratory infection, abdominal pain, vomiting, nasopharyngitis, anemia, cough, peripheral edema, nausea, urinary tract infections, pyrexia. Soliris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). Please see full prescribing information for Soliris, including boxed WARNING regarding risk of serious meningococcal infection.
http://soliris.net/sites/default/files/assets/soliris_pi.pdf

About Alexion

Alexion is a biopharmaceutical company focused on serving patients with severe and 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 paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (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 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, including asfotase alfa, across multiple therapeutic areas. This press release and further information about Alexion can be found at: www.alexionpharma.com.

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 March 31, 2014, 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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