Alexion Reports Progress on Commissioning of Rhode Island Manufacturing Facility as Second Source of Supply

CHMP Issues Positive Opinion for European Union; FDA Review Ongoing

CHESHIRE, Conn., Dec 02, 2009 (BUSINESS WIRE) -- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today provided updates on the regulatory review and approval, or commissioning, of Alexion's Rhode Island manufacturing facility (ARIMF) in Smithfield, Rhode Island as a second source of supply for Soliris(R) (eculizumab). The Company reported that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has issued a "positive opinion" recommending final approval of the facility by the European Commission, which is expected in early 2010. Separately, the Company expects to meet with the U.S. Food and Drug Administration (FDA) to provide additional available information, and to discuss their request for a limited number of production runs in connection with their pre-approval inspection process.

Second Source of Supply

Since 2006, Alexion has been developing ARIMF to become a second source of supply of Soliris and to manufacture other antibody products. The facility does not yet provide Soliris for commercial use in any market. As a result of the Company's previously described multi-source strategy, Alexion has existing supplies of Soliris sufficient to serve all anticipated clinical and commercial needs, while continuing to source product from its primary provider.

"We are pleased to receive the positive opinion from the CHMP, which would give us the option to use ARIMF as a second source to supply Soliris to European countries following final EU approval," said Stephen P. Squinto, Executive Vice President and Head of Research and Development at Alexion. "We now look forward to progressing our discussions and satisfying the requirements of the FDA, which would give us the additional option of using our Rhode Island facility as a second source to serve the U.S. market as well."

Separately, the Company provided an update on a previously described regulatory review of an external vialer previously used by Alexion. Alexion reported today that regulatory authorities have now permitted release to the marketplace of all batches of Soliris that were filled by this external vialer. The previously described contingent liability associated with these batches has now been completely resolved at no loss to the Company.

About Alexion

Alexion Pharmaceuticals, Inc. is a biopharmaceutical company working to develop and deliver life-changing drug therapies for patients with serious and life-threatening medical conditions. Alexion is engaged in the discovery, development and commercialization of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic and kidney diseases, transplant, cancer, and autoimmune disorders. Soliris(R) (eculizumab), Alexion's first marketed product, is approved in the U.S., European Union, Australia and Canada as a treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH), a rare, debilitating and life-threatening blood disorder. Alexion is evaluating other potential indications for Soliris as well as other formulations of eculizumab for additional clinical indications, and is pursuing development of other antibody product candidates in early stages of development. 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 contains forward-looking statements, including statements related to the commissioning of Alexion's Rhode Island Manufacturing Facility and supplies of Soliris.Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including, for example, decisions of U.S. and European regulatory authorities regarding final approval for ARIMF as an alternate source of Soliris and other antibodies, regulatory compliance and production capabilities of third party suppliers the accuracy of inventory forecasts, market conditions or clinical studies that could accelerate the use of Soliris, and a variety of other risks set forth from time to time in Alexion's filings with the Securities and Exchange Commission, including but not limited to the risks discussed in Alexion's Quarterly Report on Form 10-Q for the period ended September 30, 2009 and in our other filings with the Securities and Exchange Commission. Alexion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof, except when a duty arises under law.

SOURCE: Alexion Pharmaceuticals, Inc.

Alexion Pharmaceuticals, Inc.
Irving Adler, Sr. Director Corporate Communications
203-271-8210
or
Makovsky & Company
Kristie Kuhl, 212-508-9642 (Media)
or
Rx Communications
Rhonda Chiger, 917-322-2569 (Investors)