Alexion Receives FDA Approval of Rhode Island Manufacturing Facility for Soliris(R) Supply

-- Follows Earlier EMA Approval for Facility --
-- Provides Second Source for Commercial and Clinical Needs --

CHESHIRE, Conn., Aug 23, 2010 (BUSINESS WIRE) -- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today announced that the US Food and Drug Administration (FDA) has approved Alexion's Rhode Island manufacturing facility (ARIMF) in Smithfield, Rhode Island as a second source of commercial supply for Soliris(R) (eculizumab). Earlier this year, Alexion reported that the European Medicines Agency had approved ARIMF as a second source of supply for Soliris in the European Union (EU). In addition to sourcing Soliris from ARIMF, the Company will maintain its agreement with its long-time contract manufacturer; either source can now meet all of the Company's forecasted commercial and clinical needs for Soliris in the US and EU, which territories accounted for more than 90% of the Company's 2009 revenues. Additionally, Alexion has applied for regulatory approvals for ARIMF in other countries where it has, or is establishing, commercial operations.

Soliris is the only drug specifically indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH), an ultra-rare, debilitating and life-threatening blood disorder. Soliris was approved by the FDA and the European Commission in 2007, as well as by the regulatory authorities of other countries, including Japan's Ministry of Health, Labour and Welfare (MHLW) in 2010. In addition, more than a dozen clinical studies of Soliris as a treatment for patients with other severe and ultra-rare disorders are currently underway in areas that include nephrology and transplant. Among these are clinical studies with Soliris treatment of two cohorts of patients with atypical hemolytic uremic syndrome (aHUS) as well as transplant patients at elevated risk of antibody-mediated graft rejection.

"Since before the launch of Soliris in 2007, we recognized the critical importance of ensuring the continuity of treatment for patients with ultra-rare and life-threatening diseases," said Stephen P. Squinto, Executive Vice President and Head of Research and Development at Alexion. "Uninterrupted world-wide supply of Soliris provides patients with continued access to stable treatment regimens, and also supports our growing clinical development programs."

About Soliris

Soliris (eculizumab) is a first-in-class terminal complement inhibitor developed from the laboratory through regulatory approval by Alexion. Soliris has been approved by the healthcare authorities in the U.S., European Union, Japan and other countries as the first treatment for patients with PNH, an ultra-rare, debilitating and life-threatening blood disorder defined by hemolysis, or the destruction of red blood cells. Prior to these approvals, there was no therapy specifically available for the treatment of PNH.

Patients with PNH in more than 20 countries now have access to Soliris therapy through national or private healthcare providers. As the first terminal complement inhibitor to be approved in countries around the world, Soliris represents a long-sought breakthrough in medical innovation. Alexion's innovative approach to complement inhibition has received some of the pharmaceutical industry's highest honors: the 2008 Prix Galien USA Award for Best Biotechnology Product with broad implications for future biomedical research, and the 2009 Prix Galien France Award in the category of Drugs for Rare Diseases. More information on Soliris is available at www.soliris.net.

Important Safety Information

Soliris is generally well tolerated in patients with PNH. The most frequent adverse events observed in clinical studies of patients with PNH were headache, nasopharyngitis (runny nose), back pain and nausea. Treatment with Soliris should not alter anticoagulant management because the effect of withdrawal of anticoagulant therapy during Soliris treatment has not been established.

The U.S. product label for Soliris also includes a boxed warning: "Soliris increases the risk of meningococcal infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Vaccinate patients with a meningococcal vaccine at least two weeks prior to receiving the first dose of Soliris; revaccinate according to current medical guidelines for vaccine use. Monitor patients for early signs of meningococcal infections, evaluate immediately if infection is suspected, and treat with antibiotics if necessary." During PNH clinical studies, two out of 196 vaccinated PNH patients treated with Soliris experienced a serious meningococcal infection. Prior to beginning Soliris therapy, all patients and their prescribing physicians are encouraged to enroll in the PNH Registry, which is part of a special risk-management program that involves initial and continuing education and long-term monitoring for detection of new safety findings.

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, other inflammatory disorders, and cancer. Soliris is Alexion's first marketed product. 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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This news release contains forward-looking statements, including statements related to regulatory approvals of Alexion's Rhode Island Manufacturing Facility in different territories, and supplies of Soliris for commercial and clinical purposes.. 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 global regulatory authorities regarding ARIMF as an approved manufacturing facility for Soliris or other products and Alexion's continued ability to operate ARIMF in a compliant manner, regulatory compliance and production capabilities of third party suppliers, the accuracy of inventory forecasts, market conditions, 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 June 30, 2010 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.

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