FDA Grants Priority Review for Soliris(TM) (eculizumab) BLA for Treatment of Paroxysmal Nocturnal Hemoglobinuria

CHESHIRE, Conn., Nov. 14 -- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN - News) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the Biologics License Application (BLA) for Soliris(TM) (eculizumab) for the treatment of Paroxysmal Nocturnal Hemoglobinuria (PNH). In addition, the FDA has informed Alexion that it has designated the submission for priority review, which targets an FDA action within six months of the BLA submission date. Alexion submitted the BLA in September 2006. Priority review status is granted by the FDA to products that, if approved, would be a significant improvement over existing therapies.

As previously announced, the European Medicines Evaluation Agency (EMEA) has accepted the Soliris(TM) (eculizumab) application for review under the EMEA's Accelerated Assessment Procedure. Review under the Accelerated Assessment Procedure is provided by the EMEA for medicinal products of major therapeutic interest and shortens the timeframe for review by that agency.

"We are extremely pleased that the FDA has accepted the Soliris BLA for filing and designated it for priority review," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "The priority designation supports our belief in the potential of Soliris for the treatment of PNH. There currently is no therapy specifically available for the treatment of PNH, and we believe that Soliris, if approved, would represent an important option in improving the lives of patients with the disease."

The BLA submission is based on data from the pivotal Phase III TRIUMPH trial which met all pre-specified primary and secondary endpoints with statistical significance. Details regarding the TRIUMPH study results are included in an article published in the September 21, 2006 issue of the New England Journal of Medicine. The BLA submission also includes interim data of at least six months from the open-label Phase III SHEPHERD safety trial. The last patient completed the last visit in the SHEPHERD trial in October 2006 and final 12-month data from the SHEPHERD trial will be submitted to the regulatory applications. The TRIUMPH trial included 87 PNH patients and the SHEPHERD trial has enrolled 97 PNH patients. An additional 11 PNH patients were enrolled in an earlier pilot study.

About PNH and SolirisTM

PNH, a rare and life-threatening form of hemolytic anemia, is an acquired genetic blood disorder characterized by destruction of red blood cells by the body's complement system (a component of the immune system). Patients with PNH lack naturally-occurring complement inhibitors which normally prevent red blood cell destruction. Soliris(TM) (eculizumab), a long-acting C5 terminal complement inhibitor, is an investigational humanized monoclonal antibody drug that is designed to selectively block terminal complement activation and thereby restore complement inhibition in the blood of patients with PNH. Soliris(TM) (eculizumab) has been granted Orphan Drug Status in the PNH indication from both the FDA and European regulatory agencies. There currently is no approved therapy specifically available for treatment of PNH.

Based upon scientific investigations and presentations of the prevalence of patients diagnosed with abnormal PNH cells in their blood, it is currently estimated that approximately 8,000 to 10,000 people in North America and Europe suffer from PNH. Patients with PNH may suffer from severe hemolysis, anemia, chronic fatigue, recurrent pain, pulmonary hypertension and intermittent episodes of dark colored urine, known as hemoglobinuria. Importantly, PNH patients are at increased risk of forming life-threatening blood clots, or thromboses, which are a major cause of death in this disease.

About Alexion

Alexion Pharmaceuticals is a biotechnology 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 and development of therapeutic products aimed at treating patients with a wide array of severe disease states, including hematologic diseases, cancer, and autoimmune disorders. Alexion's lead product candidate, Soliris(TM) (eculizumab), is currently undergoing evaluation in several clinical development programs, including for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). Under the Special Protocol Assessment (SPA) process, the FDA has agreed to the design of protocols for the two phase III trials of Soliris(TM) (eculizumab) in PNH patients. In January, 2006, Alexion announced that the first of those two PNH trials, the TRIUMPH study, achieved its co-primary endpoints with statistical significance. In June 2006, Alexion announced that interim results from the second of those two PNH trials, the SHEPHERD study, showed that eculizumab appeared to be safe and well tolerated and that all primary and secondary efficacy endpoints were achieved with statistical significance. Data from the TRIUMPH and SHEPHERD studies serve as the primary basis of review for approval of the licensing applications for Soliris(TM) (eculizumab) in the PNH indication. Alexion is engaged in discovering and developing a pipeline of additional antibody therapeutics targeting

severe unmet medical needs. This press release and further information about Alexion Pharmaceuticals, Inc. can be found at: http://www.alexionpharm.com/

This news release contains forward-looking statements, including statements related to potential benefits and commercial potential of Soliris(TM), clinical trial results, the timing of submission of additional clinical trial results, estimates of the number of PNH patients, and timing of regulatory authorities' decisions with respect to marketing applications for Soliris(TM) (eculizumab). Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including delays in completion of the SHEPHERD trial, delays in completion of analysis of clinical trial results, requests by the FDA or other regulatory authorities for additional information or data, timing and evaluation by regulatory agencies of our applications, the need for additional research and testing, decision of the FDA or other regulatory authorities not to approve (or to materially limit) marketing of Soliris(TM), delays in arranging satisfactory manufacturing capability, inability to acquire funding on timely and satisfactory terms, delays in developing or adverse changes in commercial relationships, the possibility that results of clinical trials are not predictive of the safety and efficacy of Soliris(TM), the risk that third parties won't agree to license any necessary intellectual property to us on reasonable terms, the risk that third party payors will not reimburse for the use of Soliris(TM) at acceptable rates or at all, the risk that estimates regarding the number of PNH patients are inaccurate 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 quarter ended September 30, 2006, 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.