Alexion's Soliris(TM) Granted Marketing Approval in Europe for Treatment of All Patients With PNH

- First therapy approved in both Europe and the United States for rare and life-threatening blood disease -
- First medicinal product to receive EU approval under Accelerated Assessment Procedure -

CHESHIRE, Conn., June 22, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today announced that the European Commission (EC) has approved the use of Soliris(TM) (eculizumab) for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH). Soliris is the first therapy approved in Europe for the treatment of PNH, a rare, disabling and life-threatening blood disorder defined by chronic red blood cell destruction, or hemolysis.

Hemolysis can cause one or more of the following symptoms in patients with PNH: severe anemia, disabling fatigue, recurrent pain, shortness of breath, pulmonary hypertension, intermittent episodes of dark colored urine (hemoglobinuria), kidney disease, impaired quality of life and blood clots (thromboses).(1,2)

"As the only therapy approved in both Europe and the United States to treat PNH, EC approval marks another major milestone for Soliris and brings hope to patients living with this debilitating disease," said Leonard Bell, MD, Chief Executive Officer of Alexion Pharmaceuticals. "This approval supports Alexion's mission to improve patients' lives in Europe and around the globe. It will allow European physicians to prescribe Soliris to treat all patients with PNH, and we look forward to making Soliris available throughout Europe as soon as possible."

Alexion is prepared to begin reimbursement discussions with healthcare systems in major European countries immediately, and it expects to introduce Soliris in one or more major European markets by the end of 2007, with additional countries to follow in 2008.

Soliris, a designated orphan medicinal product, reduces hemolysis (destruction of red blood cells) in patients with PNH. The EC has approved labeling for Soliris that covers all patients with PNH, as "Soliris is indicated for the treatment of patients with PNH." Describing the PNH patient population that was studied in the Phase III clinical trials, the label further states, "Evidence of clinical benefit of Soliris in the treatment of patients with PNH is limited to patients with history of transfusions." Soliris was previously approved by the U.S. Food and Drug Administration on March 16, 2007 for the treatment of PNH to reduce hemolysis, and is currently being marketed in the United States.

The European Medicines Evaluation Agency (EMEA) evaluated Soliris under the European Accelerated Assessment Procedure, the fastest evaluation timeframe for approval awarded by the EMEA. According to the EMEA, Soliris is the first medicinal product to receive a positive Committee for Human Medicinal Products (CHMP) opinion and approval within the Accelerated Assessment Procedure.

The EMEA approved Soliris based on clinical data from three multi-national clinical studies involving 195 patients. In these studies Soliris reduced hemolysis in every treated patient, thereby reducing symptoms, stabilizing hemoglobin and significantly reducing transfusions. Soliris patients reported markedly less fatigue and improved health-related quality of life. Additionally, there were fewer thrombotic events during Soliris treatment than during the same period of time prior to treatment.

About PNH

PNH is an acquired genetic blood disorder defined by hemolysis, in which patients' red blood cells are destroyed by complement, a component of the body's immune system. PNH is a rare disease that affects an estimated 8,000 to 10,000 people in North America and Europe.(3) PNH often strikes people in the prime of their lives, with an average age of onset in the early 30's.(4) Approximately ten percent of all patients first develop symptoms at 21 years of age or younger.(2) PNH develops without warning and can occur in men and women of all races, backgrounds and ages. PNH often goes unrecognized, with delays in diagnosis often ranging from one to more than 10 years.(5) The estimated median survival for PNH patients is between 10 and 15 years from the time of diagnosis.(3,5)

PNH has been identified more commonly among patients with disorders of the bone marrow, including aplastic anemia (AA) and myelodysplastic syndrome (MDS).(6,7,8,9) In patients with thrombosis of unknown origin, PNH may be an underlying cause.(2,10)

Prior to approval of Soliris, there were no therapies specifically available for the treatment of PNH. PNH treatment was limited to symptom management through periodic blood transfusions, non-specific immunosuppressive therapy and, infrequently, bone marrow transplantations -- a procedure that carries considerable mortality risk.(2,10)

Important Safety Information

Soliris is generally well tolerated. The most frequent adverse events observed in clinical studies were headache, nasopharyngitis (a runny nose), nausea, pyrexia (fever), myalgia (muscular pain), fatigue and herpes simplex (viral infection). Treatment with Soliris should not alter anticoagulant management.

In Europe, the product label for Soliris includes a special warning: "Due to its mechanism of action, Soliris increases the patient's susceptibility to meningococcal infections (Neisseria meningitidis). To reduce the risk of infection, all patients must be vaccinated at least 2 weeks prior to receiving the first dose of Soliris and must be revaccinated according to current medical guidelines for vaccine use." Moreover, "all patients should be monitored for early signs of meningococcal infections, evaluated immediately if infection is suspected, and treated with antibiotics if necessary. Patients should be informed of these signs and symptoms and steps to take to seek medical care immediately."

Prior to beginning Soliris therapy, all patients and their prescribing physicians in the United States, and following individual member country introduction those in Europe as well, will be enrolled in the Soliris Safety 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.

Please see full prescribing information for Soliris in the United States, including the box warning on meningococcal infection at www.soliris.net.

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 markets Soliris(TM)(eculizumab) in the United States for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). Alexion is engaged in the discovery and development of therapeutic products aimed at treating patients with severe disease states, including hematologic diseases, cancer and autoimmune disorders, and in May 2007, received a corporate leadership award from the National Organization of Rare Disorders (NORD) for the development of Soliris. Alexion applied for marketing authorization with the European Medicines Evaluation Agency (EMEA) for Soliris in September 2006, and in April 2007 the Committee for Human Medicinal Products (CHMP) of the EMEA adopted a positive opinion recommending marketing authorization for Soliris for the treatment of PNH. In June 2007 the EC approved Soliris for the treatment of patients with PNH in Europe. 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 for Soliris, timing for, and potential regulatory decisions with respect to, the marketing applications for Soliris in Europe, timing of first commercialization in different territories, and interest and excitement about Soliris in the physician community. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including for example, requests by regulatory authorities for additional information or data after their review of our submissions, the need for additional research and testing, decision of regulatory authorities not to approve (or to materially limit) marketing of Soliris in Europe or other territories, delays in arranging satisfactory manufacturing capability and establishing commercial infrastructure, delays in developing or adverse changes in commercial relationships, the possibility that results of clinical trials are not predictive of safety and efficacy results of Soliris in broader patient populations, 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 at acceptable rates or at all, the risk that Soliris will not generate interest among physicians, the risk that estimates regarding the number of PNH patients are inaccurate, the risk that pending litigation may be resolved adversely, 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 March 31, 2007 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.

(1) Rother R, Bell L, Hillmen P, Gladwin M. The clinical sequelae of intravascular hemolysis and extracellular plasma hemoglobin. JAMA 2005; 293:1653-1662.

(2) Parker C, Omine M, Richards S, et al. Diagnosis and management of paroxysmal nocturnal hemoglobinuria. Blood 2005; 106:3699-3709.

(3) Hill A, Platts PJ, Smith A et al. The incidence and prevalence of paroxysmal nocturnal hemoglobinuria (PNH) and survival of patients in Yorkshire [abstract]. Blood. 2006;108(11):290a. Abstract 985.

(4) Socie G, Mary J Yves, de Gramont A, et al. Paroxysmal nocturnal haemoglobinuria: long-term follow-up and prognostic factors. Lancet 1996; 348:573-577.
(5) Hillmen P. Lewis SM, Bessler M, Luzzatto L, Dacie JV. Natural history of paroxysmal nocturnal hemoglobinuria. N Engl J Med 1995; 333:1253-1258.
(6) Johnson RJ, Hillmen P. Paroxysmal nocturnal hemoglobinemia: Nature's gene therapy? J Clin Path: Mol Pathol. 2002;55:145-152.
(7) Wang, et al. Clinical significance of a minor population of paroxysmal nocturnal hemoglobinuria-type cells in bone marrow failure syndrome. Blood 2002;100:3897-3902.
(8) Iwanga, et al. Paroxysmal nocturnal haemoglobinuria clones in patients with myelodysplastic syndromes. Brit J Haem. 1998;102:465-474.
(9) Maciejewski, et al. Relationship between bone marrow failure syndromes and the presence of glycophosphatidyl inositol-anchored protein-deficient clones. Brit J Haem. 2001;115:1015-1022.
(10) Hill A, Richards S, Hillmen P. Recent developments in the understanding and management of paroxysmal nocturnal haemoglobinuria. British Journal of Haematology 2007; 137:3, 181-192.

SOURCE Alexion Pharmaceuticals, Inc.

Leonard Bell, M.D., Chief Executive Officer of Alexion Pharmaceuticals, Inc., +1-203-272-2596; Media: David Patti of Makovsky + Company, +1-212-508-9623, dpatti@makovsky.com, for Alexion Pharmaceuticals, Inc.; Investors: Rhonda Chiger of Rx Communications Group, LLC, +1-917-322- 2569, rchiger@rxir.com, for Alexion Pharmaceuticals, Inc.

http://www.alexionpharm.com