

Studies Show Efficacy and Safety of Alexion's Soliris(TM) in Broad Population of PNH Patients

- Data presented at 12th Congress of European Hematology -

CHESHIRE, Conn., June 11, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today announced results from three analyses of Phase III studies examining Soliris(TM) (eculizumab) for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) at the 12th Congress of European Hematology, organized by The European Hematology Association (EHA) in Vienna. These presentations included:

"The Terminal Complement Inhibitor Eculizumab Reduces Thrombosis in Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH)," presented by Dr. Peter Hillmen of the General Infirmary at the University of Leeds, Leeds, UK.(1) (Abstract No. 0380)

"Safety and Efficacy of the Terminal Complement Inhibitor Eculizumab in Patients with Paroxysmal Nocturnal Hemoglobinuria: SHEPHERD Phase III Clinical Study Results," presented by Dr. Hubert Schrezenmeier of the University Hospital Ulm in Ulm, Germany.(2) (Abstract No. 0378)

"The Clinical Benefit of Eculizumab Is Demonstrable in all Subpopulations of Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) with Hemolysis," presented by Dr. Petra Muus of Radboud University, Nijmegen, Netherlands.(3) (Abstract No. 0379) Subpopulations were diverse and included patients with poor bone marrow function, smaller PNH clone sizes, low levels of hemolysis, less anemia, minimal pre-treatment transfusion requirements and those receiving steroids or erythropoietin.

Dr. Muus noted, "In published clinical trials, Soliris significantly reduced hemolysis in all PNH patients, which led to an improvement in anemia, patient functioning and quality of life, and fewer thrombotic events. Research presented this week at the Congress in Vienna described the impact of Soliris on multiple subgroups of PNH patients and showed that the effect of Soliris was maintained across all subpopulations including in those patients who had as few as only one or no transfusions in the year prior to Soliris treatment."

For the full abstracts of these presentations, please visit the European Hematology Association Web site at http://congress.ehaweb.org/12th.

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. 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).(4)(5)

PNH affects an estimated 8,000 to 10,000 people in North America and Europe.(6) PNH often strikes people in the prime of their lives, with an average age of onset in the early 30's.(7) Ten percent of all patients first develop symptoms at 21 years of age or younger.(5) 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.(8) The estimated median survival for PNH patients is between 10 and 15 years from the time of diagnosis.(6)(8)

PNH has been identified more commonly among patients with disorders of the bone marrow, including aplastic anemia (AA) and myelodysplastic syndrome (MDS).(9)(10)(11)(12) In patients with thrombosis of unknown origin, PNH may be an underlying cause.(5)(13)

There are currently no therapies available in Europe specifically for the treatment of PNH. PNH treatment has been limited to symptom management through periodic blood transfusions, non-specific immunosuppressive therapy and, infrequently, bone marrow transplantations - a procedure that carries considerable mortality risk.(5)(13)

About Soliris

Soliris was approved in March by the U.S. Food and Drug Administration (FDA) as the first treatment for PNH, a rare, debilitating and life- threatening blood disorder defined by hemolysis, or the destruction of red blood cells. In April the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMEA) adopted a positive opinion

recommending marketing authorization for Soliris for the treatment of all patients with PNH. Final EU approval is expected in June or July.

Important Safety Information

Soliris is generally well tolerated. The most frequent adverse events observed in clinical studies were headache, nasopharyngitis (a runny nose), back pain and nausea.(14) 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. Vaccinate patients with a meningococcal vaccine at least 2 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." 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 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 at http://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's lead product, Soliris(TM) (eculizumab), is indicated 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 of the EMEA adopted a positive opinion recommending marketing authorization for Soliris for the treatment of PNH. 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, 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 Hillmen P. The Terminal Complement Inhibitor Eculizumab Reduces Thrombosis in Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH). Study accepted for presentation at the 12th Congress of European Hematology, organized by The European Hematology Association (EHA), on Saturday, June 9 in Vienna, Austria.
- 2 Schrezenmeier H. Safety and Efficacy of the Terminal Complement Inhibitor Eculizumab in Patients with Paroxysmal Nocturnal Hemoglobinuria (PNH): SHEPHERD Phase III Clinical Study Results. Study accepted for presentation at the 12th Congress of European Hematology, organized by The European Hematology Association (EHA), on Saturday, June 9 in Vienna, Austria.
- 3 Muus P. The Clinical Benefit of Eculizumab is Demonstrable in All Subpopulations of Patients with Paroxysmal Nocturnal Hemoglobinuira PNH with Hemolysis. Study accepted for oral presentation at the 12th Congress of European Hematology, organized by The European Hematology Association (EHA), on Saturday, June 9 in Vienna, Austria.
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- 9 Johnson RJ, Hillmen P. Paroxysmal nocturnal hemoglobinemia: Nature's gene therapy? J Clin Path: Mol Pathol. 2002;55:145-152.
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- 13 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.
- 14 Soliris(TM) (eculizumab) prescribing information. Alexion Pharmaceuticals, Inc., 2006.

SOURCE Alexion Pharmaceuticals, Inc.

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