



Alexion Pharmaceuticals Reports Positive Interim Safety and Efficacy Results for Soliris (TM) (eculizumab) From the Open-Label Phase III SHEPHERD Safety Trial in Paroxysmal Nocturnal Hemoglobinuria Patients

- Primary Efficacy Endpoint of Intravascular Hemolysis Met with Statistical Significance -

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CHESHIRE, Conn., June 12 -- Alexion Pharmaceuticals, Inc. (Nasdaq:ALXN) today reported positive preliminary six month interim results from SHEPHERD, its second Phase III trial testing Soliris(TM) (eculizumab) in a broader population of Paroxysmal Nocturnal Hemoglobinuria ("PNH") patients. SHEPHERD is an open-label, non-placebo controlled 12 month Phase III PNH study which is primarily focused on examining safety, as well as efficacy measures. Interim results show that Soliris(TM) (eculizumab) appeared to be safe and well tolerated.

All pre-specified primary and secondary efficacy endpoints in the international trial were achieved with statistical significance. The pre-specified primary surrogate of efficacy endpoint was intravascular hemolysis, the underlying disease process and primary clinical manifestation in PNH, as measured by lactate dehydrogenase area under the curve (LDH AUC). The LDH AUC was significantly decreased ($P < 0.00000000001$); LDH was reduced by 87% from a median of 2051 at baseline to 270 U/L after 26 weeks. The most frequent adverse events with Soliris(TM) (eculizumab) were headache, nasopharyngitis, and nausea.

PNH, a rare 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 a monoclonal antibody drug that selectively blocks terminal complement activation. There currently is no approved therapy specifically available for treatment of PNH.

SHEPHERD enrolled 97 patients at 33 sites in the US, Canada, Europe and Australia. Both of the pre-specified secondary efficacy endpoints in SHEPHERD, reduction in mean LDH change from baseline and quality of life as measured by the Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-Fatigue) instrument, were also achieved with statistical significance.

"The preliminary results observed with Soliris in the open-label Phase III SHEPHERD PNH study are comparable to, and support the efficacy and safety observed with Soliris treatment in previous PNH trials," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "The SHEPHERD patients are a very heterogeneous population and the encouraging Soliris results in this population provide important support for the potential utility of Soliris treatment of PNH patients. We continue to target submission of marketing applications for Soliris in PNH during the second half of this year and we look forward to providing a further update this summer regarding our plans with U.S. and European regulatory agencies."

Alexion previously reached an agreement with the FDA on the design of TRIUMPH, a pivotal Phase III efficacy trial with Soliris (TM) (eculizumab) in PNH patients, and the companion Phase III SHEPHERD trial, under the FDA's Special Protocol Assessment (SPA) process. SHEPHERD is an open-label, non-placebo-controlled, multi-center clinical trial primarily aimed at generating safety data with Soliris(TM) (eculizumab) in a broader population of hemolytic PNH patients. Efficacy measures are also being obtained in the study. The SHEPHERD protocol includes 12 months of treatment with a six-month interim analysis. It is expected that data from these trials will serve as the primary basis of FDA review for the approval of a Biologics License Application (BLA) for Soliris(TM) (eculizumab) in the PNH indication, as well as the primary basis of review for a European Marketing Authorization Application (MAA). Soliris(TM) (eculizumab) has been granted Orphan Drug Status from both the U.S. and European regulatory agencies to treat 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 - 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 significant 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 two lead product candidates, Soliris(TM) (eculizumab) and pexelizumab, are currently undergoing evaluation in several clinical development programs, including two Phase III trials of Soliris(TM) (eculizumab) 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 trials of Soliris(TM) (eculizumab) in PNH patients that could, if successful, serve as the primary basis of review for approval of a licensing application for eculizumab in the PNH indication. Results from the PRIMO-CABG2 trial of pexelizumab in coronary artery bypass graft (CABG) surgery patients indicate that the trial is unlikely to support filing for licensing approval of pexelizumab in the CABG indication. The APEX-AMI trial of pexelizumab in acute myocardial infarction patients was conducted pursuant to a protocol approved under the SPA process; however, that trial has ended prior to enrolling the anticipated number of patients. Accordingly, APEX-AMI results are unlikely to be reviewed under the SPA process. The pexelizumab trials are conducted in collaboration with Procter and Gamble Pharmaceuticals. Alexion is engaged in discovering and developing a pipeline of additional antibody therapeutics targeting severe unmet medical needs, through its wholly owned subsidiary, Alexion Antibody Technologies, Inc. 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 characterization of clinical trial results, timing of announcement of clinical trial results, commercial potential of Alexion's drug candidates, the progression of Alexion's drug candidates towards commercial sales and timing for submission of, and 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 ongoing clinical trials, delays in completion of analysis of clinical trial results, timing and evaluation by regulatory agencies of the results of these and other clinical trials, the results of pre-clinical or clinical studies (including termination or delay in clinical programs), the need for additional research and testing, decision of the FDA or other regulatory authorities not to approve (or to materially limit) marketing of one or both of Alexion's two drug candidates, 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 earlier clinical trials are not predictive of safety and efficacy results in later clinical trials, dependence on Procter & Gamble Pharmaceuticals for development and commercialization of pexelizumab, the risk that third parties won't agree to license any necessary intellectual property to us on reasonable terms, 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 Transition Report on Form 10-K/T for the five-month transition period ended December 31, 2005 and in our other filings with the Securities and Exchange Commission. P&GP retains the development rights and the termination rights discussed in Alexion's Form 10-K/T referred to above. 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.