Alexion's Soliris(R) (eculizumab) Receives Marketing Approval in Australia for All Patients with PNH

CHESHIRE, Conn., Feb 25, 2009 (BUSINESS WIRE) -- Alexion Pharmaceuticals, Inc., (Nasdaq:ALXN) today announced that the Australian Government's Therapeutic Goods Administration has approved the use of Soliris(R) (eculizumab) for the treatment of all patients in Australia with paroxysmal nocturnal hemoglobinuria (PNH), a rare, debilitating and life-threatening blood disorder defined by chronic red blood cell destruction, or hemolysis. Soliris is the first therapy approved in Australia for the treatment of PNH.

"Prior to this positive action by the government, there has not been an approved, safe and effective therapy for the treatment of patients with PNH in Australia," said Professor Jeffrey Szer, M.B., B.S., FRACP, Director of Clinical Haematology, The Royal Melbourne Hospital. "Soliris reduced hemolysis in every patient treated in clinical studies. Regulatory approval is an important step towards providing Australian patients with this debilitating and life-threatening disease access to Soliris, the only approved treatment. With access to Soliris, physicians will be able to prevent the hemolysis that underlies the severe, progressive and life-threatening consequences of PNH."

The marketing application submitted to the Australian regulatory authorities included safety and efficacy data from three multi-national clinical studies: TRIUMPH, a placebo-controlled 26-week Phase 3 study involving 87 PNH patients, (1) SHEPHERD, an open-label 52-week Phase 3 trial involving 97 PNH patients, (2) and E05-001, a long term extension study. (3) Soliris was approved by the United States Food and Drug Administration and the European Commission in 2007, and by Health Canada in 2009, using data from the same studies. Soliris is currently being used to treat patients with PNH in more than 18 countries.

"This marketing approval reflects Australia's recognition of the safety and efficacy of Soliris as a treatment for patients with PNH," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "Our Sydney-based organization will now work with the Australian Federal healthcare authorities to obtain reimbursement for Soliris so that Australian patients with PNH who can benefit from Soliris will have access to it." A decision regarding funding of Soliris therapy for eligible patients is expected by the end of 2009.

About PNH

PNH is a rare blood disorder that strikes people of all ages, with an average age of onset in the early 30s. (4) Approximately 10 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 ranging from one to more than 10 years. (6) The estimated median survival for PNH patients is between 10 and 15 years from the time of diagnosis. (4,6) PNH has been identified more commonly among patients with disorders of the bone marrow, including aplastic anemia (AA) and myelodysplastic syndromes (MDS). (7,8,9) In patients with thrombosis of unknown origin, PNH may be an underlying cause. (5)

More information on PNH is available at www.pnhsource.com.

About Soliris

Soliris has been approved by the U.S. Food and Drug Administration (March 2007), the European Commission (June 2007), Health Canada (January 2009) and Australia's Therapeutic Goods Administration (February 2009) as the first treatment for all patients with PNH, a rare, debilitating and life-threatening blood disorder defined by hemolysis, or the destruction of red blood cells. All four jurisdictions reviewed and approved their respective marketing applications for Soliris under their priority review or accelerated assessment procedures, and all four have designated Soliris as an orphan drug. Prior to these approvals, 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 its own substantial risks of mortality and morbidity. (5,10)

More information on Soliris is available at www.soliris.net.

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. Treatment with Soliris should not alter anticoagulant management because the effect of withdrawal of anticoagulant therapy during Soliris treatment has not been established.

The Australian product label for Soliris also includes a boxed warning: "Soliris increases the risk of meningococcal infections. 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 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. The Registry will be an integral part of Alexion's ongoing commitment to the Australian authorities and will enable monitoring and data collection regarding the safety and effectiveness of Soliris.

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 diseases, cancer, and autoimmune disorders. Soliris is Alexion's first marketed product, approved in the U.S. and Europe in 2007, and Canada and Australia in 2009. 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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Safe Harbor Statement

This news release contains forward-looking statements, including statements related to potential health and medical benefits from Soliris and the timing of regulatory and commercial milestones for Soliris in Australia. 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 regulatory authorities regarding marketing approval or material limitations on the marketing of Soliris, 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 possibility that initial results of commercialization are not predictive of future rates of adoption of Soliris, the risk that third parties won't agree to license any necessary intellectual property to Alexion on reasonable terms or at all, the risk that third party payors will not reimburse for the use of Soliris 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-K for the period ended December 31, 2008, and in Alexion's 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.

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