CHMP Adopts Positive Opinion for Alexion's Soliris™ in Europe

- CHMP recommends marketing authorization for Soliris(TM) (eculizumab) to treat all patients with paroxysmal nocturnal hemoglobinuria (PNH) - - First medicinal product to receive positive opinion from CHMP under Accelerated Assessment Procedure -

CHESHIRE, Conn., April 27, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today announced that the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMEA) adopted a positive opinion recommending marketing authorization for Soliris(TM) (eculizumab) for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH). Based upon the CHMP's positive recommendation, marketing authorization by the European Commission is expected in two to three months.

Soliris, a designated orphan medicinal product, is intended to reduce hemolysis (destruction of red blood cells) in patients with paroxysmal nocturnal hemoglobinuria (PNH). The CHMP recommended a broad label for Soliris covering all patients with PNH. According to the adopted CHMP opinion, "Soliris (eculizumab) is indicated for the treatment of patients with paroxysmal nocturnal haemoglobinuria (PNH)." An additional sentence describing the PNH patient population that was studied in the Phase III clinical trials 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 CHMP evaluated Soliris under the European Accelerated Assessment procedure, the fastest evaluation timeframe for full approval awarded by EMEA. According to the EMEA, Soliris is the first medicinal product to receive a positive CHMP opinion within the Accelerated Assessment procedure.

There are no therapies specifically available for the treatment of PNH in Europe. PNH is 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).

"Soliris brings real hope to people who live daily with the devastating effects of PNH," said Leonard Bell, MD, chief executive officer of Alexion Pharmaceuticals. "The positive opinion adopted by CHMP is an important step in Alexion's mission to improve PNH patients' lives in Europe and around the globe. Importantly, the adopted CHMP opinion recommends marketing authorization for Soliris to treat all patients with PNH."

CHMP based its opinion 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.

A summary of the CHMP opinion can be accessed at http://www.emea.europa.eu .

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.

In the United States, the 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 in the United States, and following approval 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 at www.soliris.net.

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 Europe and North America. Approximately ten percent of all patients first develop symptoms at 21 years of age or younger. 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. PNH has been identified more commonly among patients with diseases of the bone marrow, including aplastic anemia (AA) and myelodysplastic syndrome (MDS). In patients with thromboses of unknown origin, PNH may be an underlying cause.

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 high-risk and painful procedure used as a last resort.

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. 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 the timing and anticipated results of regulatory authorities' decisions with respect to marketing applications for Soliris, potential benefits and commercial potential of Soliris, and estimates of the number of PNH patients. Forward-looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including requests by 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 regulatory authorities not to approve (or to materially limit) marketing of Soliris, 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, 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 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 Annual Report on Form 10-K for the year ended December 31, 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.

SOURCE Alexion Pharmaceuticals, Inc.

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