Alexion Accelerates Plans to Launch Soliris(R) (Eculizumab) in Japan

Increasing Numbers of Patients to Be Served in Japan in Q3 and Q4
2010 Guidance Revised Upward for Revenues and Non-GAAP Net Income; Guidance Narrowed for SG&A

CHESHIRE, Conn. & LAUSANNE, Switzerland, Jun 02, 2010 (BUSINESS WIRE) -- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) and Alexion Pharma International Sàrl today announced that the launch of Soliris (eculizumab) as a treatment for patients with PNH in Japan will begin in the third quarter of 2010, approximately three months earlier than previously expected.

Reimbursement Process in Final Stages

Alexion's accelerated plans for the launch of Soliris in Japan are based on recent approval of the price for Soliris(R) (eculizumab) in Japan by an advisory committee of Japan's Ministry of Health, Labour and Welfare (MHLW). The approval positions the MHLW to list Soliris for reimbursement through Japan's National Health Insurance (NHI) system. Following this listing, Alexion will begin discussions with individual hospital treatment centers to place Soliris on their formularies, a process expected to take an additional one to three months in individual cases.

PNH is an ultra-rare, debilitating and life-threatening blood disorder defined by chronic red blood cell destruction, or hemolysis. Soliris, a first-in-class terminal complement inhibitor, is the first therapy approved in Japan for the treatment of patients with PNH. Soliris received orphan drug designation from the MHLW in 2009 and was approved for marketing under the Ministry's priority review process in April 2010.

"We appreciate the rapid action of the government in Japan, where much of the early research in PNH took place, to finalize the NHI reimbursement and listing for Soliris," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "We expect to provide this life-transforming therapy to increasing numbers of patients throughout Japan in the third and fourth quarters. As we continue to diversify our global access operations, the upcoming launch of Soliris in Japan represents our first major expansion into the Asia-Pacific region."

2010 Guidance Revised Upward for Revenues and Non-GAAP Net Income, and Narrowed for SG&A

In light of the earlier than anticipated commercial launch of Soliris in Japan in the second half of this year, the Company has also announced today that it is raising its previously issued guidance for full-year 2010 revenues and non-GAAP net income. Alexion is revising upward its previously announced guidance for 2010 revenues, from the previous range of $505 to $520 million, now to a higher range of $515 to $530 million. Alexion is also revising upward its non-GAAP earnings per share (EPS) guidance from the previous range of $1.60 to $1.65 for non-GAAP diluted EPS now to a higher range of $1.63 to $1.68. Guidance for non-GAAP Selling, General and Administrative (SG&A) expenses remains within the previously announced range of $185 to $195 million, and is now narrowed to $190 to $195 million, reflecting expenses associated with earlier launch in Japan. Guidance for 2010 R&D expenses remains unchanged; thus, guidance for total operating expenses remains within the previously announced range of $280 to $295 million, but is now narrowed to $285 to $295 million. All other items of previously announced 2010 guidance remain unchanged. Non-GAAP results conform with U.S. GAAP in all regards except that share based compensation and non-cash taxes are excluded in the non-GAAP reporting.

The Company notes that 2010 guidance has been revised upward despite the impact of recent and anticipated measures related to healthcare reimbursement in the U.S. and some European countries, as well as recent weakness in the Euro and the British pound.

About PNH

PNH is a rare blood disorder that strikes people of all ages, with an average age of onset in the early 30s. (1) Approximately 10 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 ranging from one to more than 10 years. (3) It is estimated that approximately one-third of patients with PNH do not survive more than five years from the time of diagnosis. (3) PNH has been identified more commonly among patients with disorders of the bone marrow, including aplastic anemia (AA) and myelodysplastic syndromes (MDS). (4,5,6) In patients with thrombosis of unknown origin, PNH may be an underlying cause. (1) More information on PNH is available at www.pnhsource.com.

About Soliris

Soliris (eculizumab) is a first-in-class terminal complement inhibitor developed from the laboratory through regulatory approval by Alexion. Soliris has been approved by the healthcare authorities in the U.S., European Union, Japan and other countries as the first treatment for patients with PNH, a rare, debilitating and life-threatening blood disorder defined by hemolysis, or the destruction of red blood cells. Prior to these approvals, there was no therapy specifically available for the treatment of PNH.

Patients with PNH in more than 20 countries now have access to Soliris therapy through national or private healthcare providers. As the first terminal complement inhibitor to be approved in countries around the world, Soliris represents a long-sought breakthrough in medical innovation. Alexion's innovative approach to complement inhibition has received some of the pharmaceutical industry's highest honors: the 2008 Prix Galien USA Award for Best Biotechnology Product with broad implications for future biomedical research, and the 2009 Prix Galien France Award in the category of Drugs for Rare Diseases. 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 U.S. product label for Soliris also includes a boxed warning: "Soliris increases the risk of meningococcal infections. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. 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, 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.

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 and kidney diseases, transplant, other inflammatory disorders, and cancer. Soliris is Alexion's first marketed product. 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, the timing of regulatory and commercial milestones for Soliris in Japan, and guidance regarding the anticipated financial results for 2010. 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 published reports or clinical trials are not predictive of safety and efficacy results of Soliris in broader patient populations, the risk that clinical trials may not be completed successfully, 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, 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-Q for the period ended March 31, 2010, 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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