
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D) OF THE
THE SECURITIES EXCHANGE ACT OF 1934**

Date of report (Date of earliest event reported): January 26, 2006

ALEXION PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

000-27756
(Commission
File Number)

13-3648318
(I.R.S. Employer
Identification No.)

352 Knotter Drive, Cheshire, Connecticut 06410
(Address of Principal Executive Offices) (Zip Code)

Registrant's telephone number, including area code: (203) 272-2596

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 7.01 Regulation FD Disclosure.

On January 26, 2006, Alexion Pharmaceuticals, Inc. issued a press release relating to results from TRIUMPH, its pivotal Phase III efficacy trial with eculizumab in Paroxysmal Nocturnal Hemoglobinuria patients. A copy of the press release is furnished as Exhibit 99.1 to this form 8-K.

Item 9.01 Financial Statements and Exhibits.

(c) Exhibits

99.1 Press Release issued by Alexion Pharmaceuticals, Inc. on January 26, 2006.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALEXION PHARMACEUTICALS, INC.

Date: January 26, 2006

By: /s/ THOMAS I. H. DUBIN
 Name: **Thomas I. H. Dubin**
 Title: **Senior Vice President and General Counsel**

Index to Exhibits

Exhibit No.	Description
99.1	Press Release issued by Alexion Pharmaceuticals, Inc. on January 26, 2006.



FOR IMMEDIATE RELEASE

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Alexion Pharmaceuticals Reports Positive Phase III Results for Eculizumab From Pivotal TRIUMPH Efficacy Trial in Paroxysmal Nocturnal Hemoglobinuria Patients

–Co-Primary Endpoints of Transfusion Rate and Hemoglobin Stabilization Met with Statistical Significance–

–All Secondary Endpoints Achieved with Statistical Significance–

–Soliris™ Announced as Trademark–

–Conference call scheduled for Today, January 26, 2006 at 9:00 a.m. Eastern–

CHESHIRE, Conn., January 26, 2006 – Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today reported positive results from TRIUMPH, its pivotal Phase III placebo-controlled randomized efficacy trial using eculizumab in Paroxysmal Nocturnal Hemoglobinuria (“PNH”) patients. All pre-specified primary and secondary endpoints in the international trial were achieved with statistical significance. The pre-specified, co-primary endpoints were median transfusion rate and hemoglobin stabilization over six months. The median transfusion rate was reduced from 10 units/patient with placebo to 0 units/patient with eculizumab ($p < 0.00000001$). Hemoglobin stabilization was achieved by 49% of eculizumab patients as compared to 0% for placebo ($p < 0.0000001$). The study enrolled 87 patients at 45 sites in the US, Canada, Europe and Australia.

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 prevent red blood cell destruction. Eculizumab, a long-acting C5 terminal complement inhibitor, is a monoclonal antibody drug that selectively blocks terminal complement activation. There currently is no therapy specifically available for treatment of PNH.

“The TRIUMPH study represents an important milestone in the development of eculizumab for PNH and, hopefully, for the patients afflicted with this chronic, severely debilitating, and life-threatening disease,” said Dr. Peter Hillmen, lead investigator and chairman of the TRIUMPH steering committee, and Consultant Haematologist of the General Infirmary at Leeds, Leeds, UK. “Treatment options are extremely limited for PNH and at present there is no approved therapy. Eculizumab is currently the only potential therapy that addresses hemolysis and the associated morbidities in PNH. In the trial, eculizumab arrested the chronic intravascular hemolysis that is due to the genetic deficiency of natural complement inhibitors on PNH red blood cells – a hallmark and underlying cause of PNH’s hemolytic anemia. Many TRIUMPH patients on the eculizumab regimen were able to resume normal activities of daily living after having experienced years of debility. I believe that these results strongly support the potential for eculizumab to markedly improve the lives of patients with PNH.”

All of the pre-specified secondary endpoints in TRIUMPH, including reduction in lactate dehydrogenase (LDH), quality of life as measured by the Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-Fatigue) instrument, and transfusion avoidance, were also achieved with statistical significance. Additionally, eculizumab appeared to be well tolerated with an adverse event profile comparable to placebo. The most frequent adverse events with eculizumab were headache, nasopharyngitis and back pain.

“The compelling results observed with eculizumab in the PNH TRIUMPH efficacy study represent an important accomplishment in the evolution of Alexion toward a commercial entity,” said Leonard Bell, M.D., Chief Executive Officer of Alexion. “As we continue the ongoing SHEPHERD study, we are focused on preparations to meet with U.S. and European regulatory agencies. We are currently targeting submission of marketing applications for eculizumab in PNH during the second half of this year.”

Alexion previously reached an agreement with the FDA on the design of TRIUMPH, a pivotal Phase III efficacy trial with 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 eculizumab in a broader population of hemolytic PNH patients. Efficacy measures will also be 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 review for the approval of a Biologics License Application (BLA) for eculizumab in the PNH indication, as well as the basis of review for a European Marketing Authorization Application (MAA). Eculizumab has been granted Orphan Drug Status from both the U.S. and European regulatory agencies to treat PNH.

Separately, Alexion has selected Soliris™ as the trademark for eculizumab.

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 Western 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 leading cause of death in this disease.

“PNH is a serious and long-overlooked disease and the current treatment options are limited and debilitating,” said Marilyn Baker, Executive Director of the Aplastic Anemia and Myelodysplastic Syndrome Association. “PNH patients are confronted with life-altering symptoms and frequent blood transfusions – often at a time when they are leading active lives. We applaud Alexion’s decision to focus on a therapy for this rare disease. We are extremely pleased that Alexion continues to make progress, and we look forward to a potential, important therapy for PNH patients.”

Alexion expects that the top-line clinical results from TRIUMPH will be presented at an international scientific meeting later this year.

Conference Call/Web cast Information

Alexion will host a conference call/webcast to discuss matters mentioned in this release. The call is scheduled for today, January 26th at 9:00 a.m., Eastern Time. To participate in this call, dial 913-981-5584, confirmation code 1942581, shortly before 9:00 a.m., Eastern Time. A replay of the call will be available for a limited period following the call, beginning at noon today. The replay number is 719-457-0820, confirmation code 1942581. The web cast can be accessed at: www.alexionpharm.com.

About Alexion:

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 and cardiovascular disorders, autoimmune diseases and cancer. Alexion’s two lead product candidates, Soliris™ (eculizumab) and pexelizumab, are currently undergoing evaluation in several clinical development programs, including two Phase III trials of Soliris™ (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™ (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. The Company’s Phase III trial of pexelizumab in coronary artery bypass graft (CABG) surgery patients undergoing cardiopulmonary bypass (CPB) failed to achieve its primary endpoint, and the Company is assessing the impact of this study, known as PRIMO-CABG2, on its ongoing Phase III trial of pexelizumab in acute myocardial infarction (AMI) patients. The pexelizumab trials are conducted in collaboration with Procter and Gamble Pharmaceuticals. Under the SPA process, the FDA has agreed to the design of protocols for the Phase III pexelizumab trials that could, if successful, serve as the primary basis of review for approval of licensing applications for the two indications. Preliminary results from the PRIMO-CABG2 trial of pexelizumab indicate that the trial is unlikely to support filing for licensing approval of pexelizumab in the CABG indication. 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 timing of announcement of clinical trial results, timing of regulatory discussions and decisions, and the progression of Alexion's drug candidates towards commercial sales. Forward- looking statements are subject to factors that may cause Alexion's results and plans to differ from those expected, including 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 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 Annual Report on Form 10-K for the year ended July 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 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.