SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

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

Date of Report (Date of earliest event reported) June 14, 2004

ALEXION PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**0-27756**	**13-3648318**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

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

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

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Item 5. Other Events and Regulation FD Disclosure.

On June 14, 2004, the Company announced that they and their collaboration partner for pexelizumab, Procter & Gamble Pharmaceuticals, Inc., have received written confirmation from the U.S. Food and Drug Administration indicating agreement with the protocols for two independent pivotal Phase III trials of the investigational drug pexelizumab. A copy of the press release issued by the Company relating thereto is filed herewith as Exhibit 99.1.

Item 7. Financial Statements and Exhibits.

(c) Exhibits.

99.1 Press Release dated June 14, 2004.

SIGNATURES

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: June 15, 2004

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

Special Protocol Assessment Process Completed for PRIMO-CABG-2 and APEX-AMI Trials –

– Conference Call Scheduled for 11 a.m. EDT Today –

CHESHIRE, Conn., June 14 /PRNewswire-FirstCall/—Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) announced today that they and their collaboration partner for pexelizumab, Procter & Gamble Pharmaceuticals, Inc. (P&GP), have received written confirmation from the U.S. Food and Drug Administration (FDA) indicating agreement with the protocols for two independent pivotal Phase III trials of the investigational drug pexelizumab. One Phase III protocol covers patients undergoing coronary artery bypass graft ("CABG") surgery and the second covers a separate program in patients experiencing acute myocardial infarction (AMI) treated with primary percutaneous intervention (PCI). The agreements for the two Phase III protocols for the separate clinical indications were reached under the FDA's Special Protocol Assessment (SPA) process, a procedure by which the FDA provides official evaluation and guidance on proposed protocols for pivotal Phase III clinical trials. It is expected that, if successful, each trial will complete the filing package that will serve as the primary basis of review for the approval of Biologics License Applications for each of these indications.

Alexion will host a conference call and audio webcast to discuss matters mentioned in this release today, June 14th, at 11:00 a.m., Eastern Time. To participate in this call, dial 913-981-5529, confirmation code 796234, shortly before 11:00 a.m. The audio webcast can be accessed at: http://www.alexionpharm.com. A replay of the call will be available for a limited period following the call, beginning at 2:00 p.m., Eastern Time. The replay number is 719-457-0820, confirmation code 796234.

The first pivotal Phase III trial, called PRIMO-CABG-2, will examine the effects of pexelizumab on the composite endpoint of death or myocardial infarction at 30 days post procedure in moderate to high risk CABG surgery patients with or without concomitant valve surgery during cardiopulmonary bypass. The study is expected to enroll approximately 4,000 patients in the US and Europe. Alexion and P&GP are preparing to initiate the study in the near term.

The PRIMO-CABG-2 trial will mark the second pivotal Phase III study performed with pexelizumab in CABG surgery patients. Results of the first trial, known as PRIMO-CABG, were recently reported in the May 19, 2004 issue of the Journal of the American Medical Association. In the first trial, the primary endpoint in the PRIMO-CABG trial was a composite of the incidence of death or myocardial infarction, measured at 30 days post-procedure, in the subpopulation of patients undergoing CABG without concomitant valve surgery. Analysis confirmed that pexelizumab treatment was associated with a reduction in the primary endpoint, although it was not achieved with statistical significance (p=0.069). Additionally, in the 2,000 patient moderate to high risk study population from PRIMO-CABG with more than one pre-specified risk factor, Death/MI at Day 30 was reduced with statistical significance from 16.3% with placebo to 11.7% with pexelizumab (relative reduction 28%, p=0.003). This PRIMO-CABG study population forms the basis for the PRIMO-CABG-2 study. Further, the pexelizumab regimen appeared to be well tolerated.

The second pivotal Phase III trial, called APEX-AMI, will examine the effects of pexelizumab on death at 90 days post procedure in patients

undergoing percutaneous intervention for acute myocardial infarction. The study is expected to enroll approximately 8,500 patients in the U.S., Europe, Australia and New Zealand. Alexion and P&GP are preparing to initiate the study in the near term.

The APEX-AMI trial follows the previously completed large Phase II study called COMMA which examined the effects of pexelizumab in AMI patients treated with PCI. As reported last year in the journal Circulation (September 9, 2003), the primary analysis of the COMMA trial showed that treatment with a bolus of pexelizumab followed by an infusion continuing to 24 hours did not significantly reduce infarct size (the primary endpoint) but was associated with a significant 70% reduction in 90 day mortality (placebo 5.9% vs. pexelizumab bolus/infusion 1.8%, p=.014). Further, the pexelizumab regimen appeared to be well tolerated.

"We are very gratified that by working with the FDA through the SPA process, we and our collaboration partner for pexelizumab, P&GP, have been able to successfully define clear paths forward for pexelizumab in both CABG and AMI patients," said Leonard Bell, M.D., Chief Executive Officer of Alexion. "We are confident that, if successful, the PRIMO-CABG-2 and APEX-AMI trials should provide a solid basis to support separate biological license applications for the CABG and AMI indications. What remains now is to focus on the efficient and timely execution of these large clinical trials."

If approved, pexelizumab would represent the first of a new class of anti-inflammatory therapeutics (terminal complement inhibitors) for patients undergoing CABG surgery and for patients undergoing PCI for acute myocardial infarction.

Alexion is engaged in the discovery and development of therapeutic products aimed at treating patients with a wide array of severe disease states, including cardiovascular and autoimmune disorders, inflammation and cancer. Alexion's two lead product candidates, pexelizumab and eculizumab, are currently undergoing evaluation in several clinical development programs. Alexion has completed a Phase III clinical study with pexelizumab in CABG patients undergoing cardiopulmonary bypass, and two large Phase II studies with pexelizumab in acute myocardial infarction patients. The Phase III trial and the Phase II trials were conducted in collaboration with P&GP. In addition to pexelizumab, eculizumab is in Phase II clinical trials in rheumatoid arthritis and membranous nephritis, and has completed pilot programs for the treatment of paroxysmal nocturnal hemoglobinuria and dermatomyositis. Alexion is planning and expects to initiate over the next several months a pivotal phase III program with eculizumab in PNH patients in the United States and Europe. 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 on the World Wide Web at: http://www.alexionpharm.com.

This news release contains forward-looking statements. Such 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, 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, 2003 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 and other filings 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.

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