

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) January 23, 2001

ALEXION PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

DELAWARE

(State or Other Jurisdiction
of Incorporation)

0-27756

(Commission
File Number)

13-3648318

(IRS Employer
Identification No.)

352 Knotter Drive, Cheshire, CT

(Address of Principal Executive Offices)

06410

(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

On January 23, 2001, Alexion Pharmaceuticals, Inc. issued the press release filed herewith as Exhibit 99.1.

ITEM 7. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND EXHIBITS.

(c) EXHIBITS.

99.1 Press Release dated January 23, 2001.

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: January 23, 2001

By: /s/ Leonard Bell, M.D.

Name: Leonard Bell, M.D.
Title: President, Chief Executive
Officer, Secretary and Treasurer

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Alexion Reports Initial Analysis of Clinical Safety and Efficacy Data From Phase IIb Cardiopulmonary Bypass Trial

- PEXELIZUMAB SIGNIFICANTLY REDUCED COMPOSITE OF DEATH OR MYOCARDIAL INFARCTION IN CABG PATIENTS -

Cheshire, CT, January 23, 2001 -- Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN) today announced preliminary results of a recently completed Phase IIb trial in patients undergoing cardiac surgery with cardiopulmonary bypass. Alexion's anti-inflammatory C5 Inhibitor monoclonal antibody fragment, pexelizumab, significantly reduced a composite endpoint of death or myocardial infarction at 30 days in patients undergoing coronary artery bypass graft surgery (CABG) with cardiopulmonary bypass (CPB). Alexion is developing pexelizumab in collaboration with Procter & Gamble Pharmaceuticals. Pexelizumab was previously known as 5G1.1-SC.

To more fully discuss these preliminary results, as previously announced, the company will webcast a conference call this morning, January 23, 2001 at 11:00 a.m. eastern time at [HTTP://WWW.ALXN.COM](http://www.alxn.com). The conference call can also be accessed by calling 800-711-5301 (US) or 785-832-0301 (International).

In a double-blind, randomized, placebo-controlled trial which enrolled 914 patients at 62 medical centers in the United States, patients were stratified into two groups, those undergoing only CABG with CPB or patients undergoing CABG with concomitant valve surgery during CPB. Approximately 90% of patients were in the CABG only group (n=796). Patients were treated with placebo, pexelizumab 2.0 mg/kg bolus, or pexelizumab 2.0 mg/kg bolus followed by a 24 hour infusion of pexelizumab at 0.05 mg/kg/hr. Patients were followed for safety and efficacy for 30 days.

Preliminary results show that pexelizumab suppressed complement in CPB patients, with the bolus and bolus plus infusion regimens showing complete suppression for 4 and 24 hours, respectively, and that both regimens appear to be safe and well-tolerated in CPB patients.

"This study provides evidence of benefit for a new approach to limiting myocardial damage during bypass surgery," stated Dr. Robert Califf, Professor of Medicine, Division of Cardiology, Duke University Medical Center and Director of the Duke Clinical Research Institute. "Given the increasing number of high risk patients in need of cardiac surgery, this advance could greatly enhance the value of the procedure. The benefits of this alteration of the immune response to injury may have implications far beyond bypass surgery, including a reduction in myocardial necrosis in patients with acute myocardial infarction."

The results in the CABG only group were noteworthy for the observation that pexelizumab, administered as a bolus plus infusion, was associated with an increasing capacity to reduce increasingly large post CABG myocardial infarctions. Pexelizumab reduced non-Qwave myocardial infarctions (CK-MB (more than sign)100 ng/ml) by 66% (P(less than sign).05) at 30 days. Additionally, at 30 days, pexelizumab reduced the death rate from 1.9% in the placebo group to 0.4%, or a relative reduction of 79% (p=NS). As compared to the placebo group, pexelizumab reduced the composite incidence of death or MI (Qwave or non-Qwave) by 41% (P(less than sign).05) at 30 days. These unanticipated results based on analysis of this selected subgroup are exciting for not only suggesting a clinically meaningful benefit of pexelizumab in CABG only patients, but also for helping select the optimum dosing regimen and ensuring definition of the most relevant efficacy endpoints and patient population for a Phase III study. A full analysis of the safety and efficacy data is expected to be completed this spring and data is expected to be submitted for publication and presentation.

"The results from this study are novel and provide important insight into the management of cardiac surgical patients," commented Stanton K. Shernan, M.D., Assistant Professor of Anesthesia at Harvard Medical School, Director of Cardiac

Anesthesia at Brigham and Women's Hospital, and a lead investigator of the study. "The preliminary results from this important study, suggest that pharmacological inhibition of terminal complement activation can safely and significantly decrease perioperative myocardial injury in patients undergoing coronary artery bypass grafting. Furthermore, morbidity and mortality associated with myocardial ischemia-reperfusion can be reduced, especially in those patients who experience the most severe degree of perioperative myocardial injury."

"The apparently robust profile of cardioprotection observed with pexelizumab in its first large-scale trial in patients with acute cardiovascular disorders substantially surpassed our pre-trial expectations," stated Leonard Bell, M.D., President and Chief Executive Officer of Alexion. "Indeed, we believe that the observed reduction in the incidence of post CABG death or myocardial infarction may provide an important clinical benefit if proven in further studies. We are particularly proud since we believe that this is the first large-scale trial of any novel anti-inflammatory drug to show a significant reduction in the incidence of myocardial infarction in patients. Moreover, this is the first large scale trial to demonstrate that potent and sustained terminal complement inhibition provides clinically important cardioprotection. Pending a full evaluation of the data from this trial, and in conjunction with planned discussions with the FDA and foreign regulatory agencies, we expect to initiate a multi-national pivotal Phase III trial with pexelizumab in CABG patients at the earliest possible opportunity."

"These preliminary results are exciting and if confirmed in a Phase III trial may have a significant impact on CABG patients," said Mark Collar, President - Procter & Gamble Pharmaceuticals, Inc.

According to the American Heart Association, approximately 550,000 coronary artery bypass graft surgery procedures were performed in the U.S. in 1998.

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 are currently in eight clinical development programs. Alexion, in collaboration with Procter & Gamble, has completed this Phase IIb efficacy and safety study in CPB patients, and together the firms are currently conducting two large Phase II studies in acute myocardial infarction patients. Alexion's other lead product candidate, 5G1.1, has recently completed a Phase II efficacy trial for the treatment of rheumatoid arthritis and we expect to release results after completion of the preliminary analysis. 5G1.1 is also in a Phase II efficacy trial for the treatment of membranous nephritis and in Phase Ib pilot studies for treatment of psoriasis, dermatomyositis, and pemphigoid. Through its wholly owned subsidiary, Alexion Antibody Technologies, Inc., Alexion is engaged in discovering and developing a portfolio of additional antibody therapeutics targeting severe unmet medical needs. This press release and further information about Alexion Pharmaceuticals, Inc. can be found on the World Wide Web at: WWW.ALEXIONPHARM.COM.

The Procter & Gamble Company makes and markets 300 brands in 140 countries to nearly five billion consumers. In pharmaceuticals, P&G is focusing on developing and commercializing superior drugs in three therapeutic areas: cardiac, musculo-skeletal, and anti-infective.

This news release contains forward-looking statements. Such statements are subject to certain factors which may cause Alexion's plans to differ or results to vary from those expected including unexpected pre-clinical or clinical results, the need for additional research and testing, delays in manufacturing, access to capital and funding, delays and adverse changes in development of commercial relationships, the risk that the results of earlier clinical trials are not predictive of the safety and efficacy results in larger clinical trials, and a variety of risks set forth from time to time in Alexion's filings with the Securities and Exchange Commission, including but not limited to Alexion's Annual Report on Form 10-K for the year ended July 31, 2000. Except in special circumstances in which a duty to update arises under law when prior disclosure becomes materially misleading in light of subsequent events, Alexion does not intend to update any of these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

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