

UNITED STATES
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): November 23, 2004

Biogen Idec Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

0-19311
(Commission
File Number)

33-0112644
(I.R.S. Employer
Identification No.)

14 Cambridge Center, Cambridge, Massachusetts
(Address of principal executive offices)

02142
(Zip Code)

Registrant's telephone number, including area code: **(617) 679-2000**

Not Applicable
(Former name or former address, if changed since last report)

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 8.01 Other Events

On November 23, 2004, the Registrant publicly disseminated a press release announcing the approval of TYSABRI® (natalizumab), formerly referred to as ANTEGREN®, as a treatment for relapsing forms of multiple sclerosis to reduce the frequency of clinical relapses. The FDA granted accelerated approval for TYSABRI following priority review based on one-year data from two Phase III clinical studies, the AFFIRM monotherapy trial and the SENTINEL combination trial with AVONEX® (Interferon beta-1a). The information contained in the press release is incorporated herein by reference and filed as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits

(c) Exhibits.

99.1 The Registrant's Press Release dated November 23, 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.

Biogen Idec Inc.

By: /s/ Anne Marie Cook

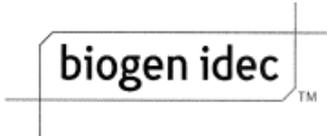
Anne Marie Cook

Vice President, Chief Corporate Counsel

Date: November 30, 2004

EXHIBIT INDEX

Exhibit Number	Description
99.1	The Registrant's Press Release dated November 23, 2004



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FDA GRANTS ACCELERATED APPROVAL OF TYSABRI[®] FORMERLY ANTEGREN[®], FOR THE TREATMENT OF MULTIPLE SCLEROSIS

**Approval of TYSABRI Marks A Major Advancement in the Treatment of MS
Phase III Trials at One Year Demonstrate New Level of Efficacy – 66% Reduction
in Rate of Relapses Seen in AFFIRM Monotherapy Trial**

Cambridge, MA; San Diego, CA; Dublin, Ireland – November 23, 2004 – Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) announced today that the U.S. Food and Drug Administration (FDA) has approved TYSABRI[®] (natalizumab), formerly referred to as ANTEGREN[®], as treatment for relapsing forms of multiple sclerosis (MS) to reduce the frequency of clinical relapses. FDA granted Accelerated Approval for TYSABRI following Priority Review based on one-year data from two Phase III studies, the AFFIRM monotherapy trial and the SENTINEL add-on trial with AVONEX[®] (Interferon beta-1a).

TYSABRI, the first humanized monoclonal antibody approved for the treatment of MS, inhibits adhesion molecules on the surface of immune cells. Research suggests TYSABRI works by preventing immune cells from migrating from the bloodstream into the brain where they can cause inflammation and potentially damage nerve fibers and their insulation.

“TYSABRI is a powerful and innovative therapy that offers new hope for hundreds of thousands of people living with MS,” said James C. Mullen, chief executive officer, Biogen Idec. “We believe TYSABRI will revolutionize the treatment of MS and become the leading choice for patients and physicians.”

“TYSABRI is a significant breakthrough for patients with MS,” said Kelly Martin, president and chief executive officer, Elan. “The approval of TYSABRI, with its unique mechanism of action and new level of efficacy, has the potential to make a genuine difference in the lives of patients and families who struggle with the debilitating effects of this disease.”

Results of the AFFIRM Monotherapy Trial

AFFIRM is a two-year, randomized, multi-center, placebo-controlled, double-blind study of 942 patients conducted in 99 sites worldwide, in which patients were randomized to receive either a fixed 300 mg IV infusion dose of TYSABRI (n=627) or placebo (n=315) every four weeks. TYSABRI reduced the rate of clinical relapses by 66 percent relative to placebo (p<0.001), the primary endpoint at one-year. The annualized relapse rate was 0.25 for TYSABRI-treated patients versus 0.74 for placebo-treated patients.

AFFIRM also met all one-year secondary endpoints, including MRI measures. In the TYSABRI-treated group, 60 percent of patients developed no new or newly enlarging T2 hyperintense lesions compared to 22 percent of placebo-treated patients (p<0.001). On the one-year MRI scan, 96 percent of TYSABRI-treated patients had no gadolinium enhancing lesions compared to 68 percent of placebo-treated patients (p<0.001). The proportion of patients who remained relapse free was 76 percent in the TYSABRI-treated group compared to 53 percent in the placebo-treated group (p<0.001).

Results of SENTINEL Add-on Study

Approval was also based on the results of another Phase III clinical trial, SENTINEL. SENTINEL is a two-year, randomized, multi-center, placebo-controlled, double-blind study of 1,171 AVONEX-treated patients in 123 clinical trial sites worldwide.

In the SENTINEL trial, AVONEX-treated patients who continued to experience disease activity were randomized to add TYSABRI (n=589) or placebo (n=582) to their standard regimen.

SENTINEL achieved its one-year primary endpoint. The addition of TYSABRI to AVONEX resulted in a 54 percent reduction in the rate of clinical relapses over the effect of AVONEX alone ($p < 0.001$). The annualized relapse rate was 0.36 for patients receiving TYSABRI when added to AVONEX versus 0.78 with AVONEX plus placebo.

SENTINEL also met all secondary endpoints, including MRI measures. In the group treated with TYSABRI plus AVONEX, 67 percent of patients developed no new or newly enlarging T2 hyperintense lesions compared to 40 percent in the AVONEX plus placebo group ($p < 0.001$). On the one-year MRI scan, 96 percent of TYSABRI plus AVONEX-treated patients had no gadolinium-enhancing lesions compared to 76 percent of AVONEX plus placebo-treated patients ($p < 0.001$). The proportion of patients who remained relapse-free was 67 percent in the TYSABRI plus AVONEX-treated group compared to 46 percent in the AVONEX plus placebo-treated group ($p < 0.001$).

“I believe TYSABRI will be an important therapeutic advance for patients with relapsing MS,” said Richard Rudick, MD, lead investigator of the SENTINEL trial and director, Mellen Center for Multiple Sclerosis, Cleveland Clinic Foundation. “Patients who have discontinued therapy, are newly diagnosed with MS, or have persistent active disease despite being on a current therapy will benefit from TYSABRI.”

Safety

Common adverse events associated with TYSABRI include headache, fatigue, urinary tract infection, depression, lower respiratory tract infection, joint pain and abdominal discomfort. The rate of infection in both studies was approximately one per patient-year in both TYSABRI-treated patients and placebo-treated patients.

Serious infections occurred in 1.3 percent of placebo-treated patients and 2.1 percent of TYSABRI-treated patients. Serious infections included bacterial infections such as pneumonia and urinary tract infection, which responded appropriately to antibiotics. TYSABRI has been associated with hypersensitivity reactions, including serious systemic reactions, which occurred at an incidence of less than 1 percent of patients.

Immunogenicity

All biologics have the potential to induce patient antibodies. Analysis of the one-year Phase III MS trials indicate a low level of immunogenicity associated with TYSABRI. Patients were tested for antibodies every 12 weeks in the AFFIRM and SENTINEL trials. Antibodies were detected in approximately 10 percent of patients at least once during treatment, with 6 percent of patients remaining persistently positive. Persistently positive antibodies were associated with a substantial decrease in efficacy and an increase in certain infusion-related adverse events. Almost all patients who tested positive for antibodies did so within the first 12 weeks of treatment.

Two-year Results

AFFIRM and SENTINEL are two-year trials. Two-year results are anticipated beginning in the first half of 2005. Patients who complete these trials are eligible for enrollment in a long-term safety extension study.

“The MS community is pleased that the FDA approval of TYSABRI provides an additional treatment option for people with relapsing forms of MS. There are many people living with MS who may benefit from this different treatment approach,” said Stephen C. Reingold, PhD, vice president for research, the National MS Society.

About TYSABRI

Biogen Idec and Elan are collaborating equally on the development of TYSABRI in MS, Crohn’s disease (CD), and rheumatoid arthritis (RA). In September 2004, a Marketing Authorisation Application (MAA) for CD was filed with the EMEA based on Phase III studies, and another Phase III induction trial for CD is ongoing. A Phase II trial is also underway to evaluate TYSABRI in RA. To date, more than 2,800 patients have received TYSABRI in clinical trials.

Information about TYSABRI, including prescribing information, and its comprehensive support services, will be available through a single toll-free number (1-800-456-2255), and via www.TYSABRI.com.

About Multiple Sclerosis

MS is a chronic disease of the central nervous system that affects approximately 400,000 people in North America and more than one million people worldwide. It is a disease that affects more women than men, with onset typically occurring between 20 and 40 years of age. Symptoms of MS may include vision problems, loss of balance, numbness, difficulty walking and paralysis.

Webcast

The companies will host a joint webcast for the investment community tomorrow at 8:00 a.m. EST, 1:00 p.m. GMT, which can be accessed through the companies' websites. At the conclusion of this call, Elan will have a separate conference call to address any company-specific questions at 9:15 a.m EST, 2:15 p.m. GMT, which can be accessed through the company website.

About Biogen Idec

Biogen Idec creates new standards of care in oncology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, Biogen Idec transforms scientific discoveries into advances in human healthcare. For product labeling, press releases and additional information about the company, please visit <http://www.biogenidec.com>.

About Elan

Elan Corporation, plc is a neuroscience-based biotechnology company. We are committed to making a difference in the lives of patients and their families by dedicating ourselves to bringing innovations in science to fill significant unmet medical needs that continue to exist around the world. Elan shares trade on the New York, London and Dublin Stock Exchanges. For additional information about the company, please visit <http://www.elan.com>.

Safe Harbor/Forward Looking Statements

This press release contains forward-looking statements regarding the potential for TYSABRI. These statements are based on the companies' current beliefs and expectations, and are subject to risks and uncertainties that could cause actual results to differ materially. There is no assurance, for example, that all experiences with TYSABRI will be the same or that TYSABRI will not be affected by unexpected new data or technical issues or by intellectual property disputes. The potential for TYSABRI may also be influenced by reimbursement and pricing decisions, the impact of competitive products, the pace of market acceptance, and any material issues, delays or failures related to its manufacturing and supply. For more detailed information

on the risks and uncertainties associated with TYSABRI and the companies' drug development and other activities, see the periodic and other reports of Biogen Idec Inc. and Elan Corporation, plc filed with the Securities and Exchange Commission. The companies assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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