



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): **February 17, 2005**

**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))
- 
-

## **TABLE OF CONTENTS**

[Item 8.01 Other Events](#)

[Item 9.01 Financial Statements and Exhibits](#)

[SIGNATURES](#)

[EXHIBIT INDEX](#)

[EX-99.1 - Press Release dated February 17, 2005](#)

---

## [Table of Contents](#)

### **Item 8.01 Other Events**

On February 17, 2005, the Registrant publicly disseminated a press release announcing that the Phase 3 TYSABRI® (natalizumab) AFFIRM monotherapy study achieved the two-year primary endpoint of slowing the progression of disability in patients with relapsing forms of multiple sclerosis and that the rate of clinical relapses, the study's primary endpoint at one-year, was sustained over two years and consistent with previously reported one-year results. 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 February 17, 2005.

---

**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: February 22, 2005

---

**EXHIBIT INDEX**

<u>Exhibit Number</u>	<u>Description</u>
99.1	The Registrant's Press Release dated February 17, 2005



**For More Information Contact:**

**MEDIA CONTACTS:**

Biogen Idec	Elan
Amy Brockelman	Anita Kawatra
Ph: 617 914 6524	Ph: 212 407 5740
	800 252 3526

**INVESTOR CONTACTS:**

Biogen Idec	Elan
Elizabeth Woo	Emer Reynolds
Ph: 617 679 2812	Ph: 353 1 709 4000
	800 252 3526

**TYSABRI<sup>®</sup> TWO-YEAR MONOTHERAPY TRIAL DEMONSTRATES  
SIGNIFICANT IMPACT ON DISABILITY PROGRESSION AND RELAPSE  
RATE IN MULTIPLE SCLEROSIS**

**Data Show 42% Reduction in the Risk of Disability Progression and Sustained  
67% Reduction in Relapse Rate**

**Cambridge, MA and Dublin, Ireland – February 17, 2005** – Biogen Idec (NASDAQ: BIIB) and Elan Corporation, plc (NYSE: ELN) announced today that the Phase III TYSABRI<sup>®</sup> (natalizumab) AFFIRM monotherapy trial achieved the two-year primary endpoint of slowing the progression of disability in patients with relapsing forms of multiple sclerosis (MS). TYSABRI treatment led to a 42 percent reduction in the risk of disability progression relative to placebo. These data also demonstrated a 67 percent reduction in the rate of clinical relapses over two years, which was sustained and consistent with the previously reported one-year results.

Other data from AFFIRM at two years, including MRI measures and immunogenicity were similar to previously reported results.

The adverse event profile at two years was also consistent with previously reported results. Common events included headache, fatigue, urinary tract infection, depression,

-MORE-

---

lower respiratory tract infection, limb and joint pain, and pharyngitis. The incidence of infections in TYSABRI-treated and placebo-treated patients was similar. Serious infections occurred in 3.2 percent and 2.6 percent of patients, respectively. These included bacterial infections such as pneumonia and urinary tract infection, which responded appropriately to antibiotics. TYSABRI has also been associated with hypersensitivity reactions, including serious systemic reactions that occurred at an incidence of less than 1 percent of patients.

“TYSABRI, with its significant effect on slowing the progression of disability, offers new hope for patients with MS,” said Burt Adelman, MD, executive vice president, Development, Biogen Idec. “With these data, we gain a more complete understanding of the broad therapeutic benefit of TYSABRI in MS.”

“Results from the two-year monotherapy clinical trial mark a major milestone in the treatment of MS. These two-year data strengthen our belief that TYSABRI will become the leading therapy for MS patients,” said Lars Ekman, MD, executive vice president and president, Research and Development, Elan.

AFFIRM is a two-year, randomized, multi-center, placebo-controlled, double-blind study of 942 patients conducted in 99 sites worldwide, evaluating the effect of TYSABRI on the progression of disability as measured by the Expanded Disability Status Scale (EDSS) and the rate of clinical relapses. Patients were randomized to receive either a 300 mg IV infusion dose of TYSABRI (n=627) or placebo (n=315) every four weeks.

Based on one-year data from AFFIRM and the SENTINEL add-on trial with AVONEX® (Interferon beta-1a), the U.S. Food and Drug Administration (FDA) granted Accelerated Approval for TYSABRI on November 23, 2004, as a treatment for relapsing forms of MS.

The companies anticipate that two-year data from the AFFIRM trial will be presented at the American Academy of Neurology (AAN) meeting in April 2005. The companies expect two-year results from the SENTINEL trial will be available mid-year. Two-year data from both studies will also be submitted to regulatory authorities.

#### **About TYSABRI**

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.

Biogen Idec and Elan are collaborating equally on the development of TYSABRI in MS, Crohn’s disease (CD), and rheumatoid arthritis (RA). Regulatory authorities in Canada and Australia have designated TYSABRI for Priority Review as a treatment for MS, and the European Medicines Agency (EMA) is actively reviewing the application.

-MORE-

---



In September 2004, the companies submitted a Marketing Authorisation Application (MAA) to the EMEA for CD based on Phase III studies. 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 3,200 patients have received TYSABRI in clinical trials.

Information about TYSABRI, including U.S. prescribing information, and its comprehensive support services in the U.S., is available through a single toll-free number (1-800-456-2255), and via [www.TYSABRI.com](http://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.

#### **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 the potential for TYSABRI will not be affected by unexpected new data or technical issues. The potential for TYSABRI may also be influenced by reimbursement and pricing decisions, the impact of competitive products, the pace of market acceptance, or by intellectual property disputes, 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.*

## ## ##