

BIOGEN IDEC INC  
Form 8-K  
December 18, 2006

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**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): December 18, 2006

**BIOGEN IDEC INC.**

(Exact name of registrant as specified in its charter)

DELAWARE

(State or other jurisdiction of incorporation)

0-19311

33-0112644

(Commission File Number)

(IRS Employer Identification No.)

14 Cambridge Center, Cambridge, Massachusetts

02142

(Address of principal executive offices)

(Zip Code)

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

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:

- ☐ 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.**

Biogen Idec Inc. and Genentech, Inc. are issuing a dear healthcare provider letter to physicians and other prescribers, including rheumatologists, neurologists, oncologists, hematologists, dermatologists, nephrologists, oncology nurses and oncology pharmacists, regarding updated safety information for Rituxan®. The letter is currently posted on the Genentech, Inc. website.

The letter informs healthcare providers that two cases of progressive multifocal leukoencephalopathy (PML) resulting in death, have been reported in patients receiving Rituxan® for treatment of Systemic Lupus Erythematosus (SLE). Rituxan is not approved for the treatment of SLE.

PML is a rare, progressive, demyelinating disease of the central nervous system that usually leads to death or severe disability. While rare, PML is a known risk in patients who have immune system suppression either because of their disease or the medications they are taking. PML has been reported in the literature in HIV-positive patients, immunosuppressed cancer patients, transplant patients, and patients with autoimmune disease, including SLE, who were not receiving Rituxan.

The two SLE patients had longstanding SLE with multiple courses of immunosuppressant therapy prior to receiving Rituxan. Rituxan monotherapy was the last treatment administered prior to the diagnosis of PML. PML has also been reported in the literature in patients with SLE receiving prednisone, azathioprine, cyclophosphamide, and other immunosuppressant agents, who were not receiving Rituxan.

Previously, cases of PML have also been reported in patients with hematologic malignancies during or up to one year after completion of Rituxan. The majority of these patients received Rituxan in combination with chemotherapy or as part of a hematopoietic stem cell transplant. A description of cases of PML in patients with hematologic malignancies treated with Rituxan is included in the current US prescribing information.

The Company and Genentech also informed healthcare providers that we are working with FDA to update the Rituxan prescribing information to include the new information.

Rituxan is indicated for the treatment of patients with relapsed or refractory, low-grade or follicular, CD20-positive, B-cell, non-Hodgkin's lymphoma (NHL), and for the first line treatment of follicular, CD20-positive, B-cell NHL in combination with CVP chemotherapy. Rituxan® is also indicated for the treatment of low-grade, CD20-positive, B-cell NHL in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy. Rituxan is also indicated for the first-line treatment of diffuse large B-cell, CD20-positive, NHL in combination with CHOP or other anthracycline-based chemotherapy regimens. Rituxan in combination with methotrexate is also indicated to reduce signs and symptoms in adult patients with moderately- to severely- active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. The safety and effectiveness of Rituxan for the treatment of SLE has not been established and SLE is not an FDA-approved indication.

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**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.

/s/ Susan H. Alexander

Susan H. Alexander

Executive Vice President, General Counsel,  
and Secretary

Date: December 18, 2006