Genentech and Biogen Idec Announce Top-Line Results from a Phase II/III Clinical Trial of Rituxan in Primary-Progressive Multiple Sclerosis

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SOUTH SAN FRANCISCO, Calif. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genentech, Inc. (NYSE:DNA) and Biogen Idec, Inc. (Nasdaq:BIIB) today announced that a Phase II/III study of Rituxan® (rituximab) for primary-progressive multiple sclerosis (PPMS) did not meet its primary endpoint as measured by the time to confirmed disease progression during the 96-week treatment period. Genentech and Biogen Idec will continue to analyze the study results and will submit the data for presentation at an upcoming medical meeting.

“We are disappointed in the outcome of the primary endpoint, but not surprised given the significant clinical challenges presented by PPMS,”said Hal Barron, M.D., Genentech senior vice president, development and chief medical officer. “There was some evidence of biologic activity, and we will continue to review all the data to better understand the role of B cells in MS.”

“While the primary results are not what we had hoped, we continue to believe in the potential of B cell therapy for patients living with MS,”said Michael Panzara, M.D., MPH, Vice President and Chief Medical Officer, Neurology Strategic Business Unit, Biogen Idec. “PPMS is widely considered a difficult form of MS to treat and historically no therapy has proven efficacy in this disease state.”

About the Study

This Phase II/III randomized, double-blind, placebo-controlled, multi-center study was designed to evaluate the efficacy, safety and tolerability of four courses of Rituxan in patients with PPMS. A total of 439 patients from approximately 60 sites in the U.S. and Canada were randomized 2:1 to receive either four treatment courses of Rituxan six months apart or placebo. MRI evaluations were conducted at baseline, weeks 6, 48, 96 and 122.

Detailed safety data from the study is currently being evaluated. The incidence of overall adverse events was comparable between Rituxan and placebo treatment groups. Serious adverse events were 16.4 percent in the Rituxan arm versus 13.6 percent in the placebo arm, with an incidence of serious infections of 4.5 percent compared with <1.0 percent respectively. Infectious events reported in at least 10 percent of patients in either group included upper respiratory and urinary tract infections. Most infectious events in the Rituxan arm were reported as mild to moderate in severity, though events of greater severity were reported more frequently in patients receiving Rituxan. There were more infusion-related reactions with Rituxan, the majority of which were mild to moderate in severity. The companies continue to monitor the long-term safety of Rituxan treatment.

About MS and PPMS

MS is a chronic autoimmune disease where the body’s immune system attacks the myelin sheath causing inflammation and destruction of this fatty, protective substance. The myelin sheath surrounds the body’s nerve fibers in the central nervous system, which includes the brain, optic nerves and spinal cord. There are four generally accepted disease courses of MS with a wide variety of symptoms and variations of disease progression.

Symptoms of the disease vary from patient-to-patient. Neurological disability typically accumulates over time and may include weakness or fatigue; numbness or tingling; blurred vision, impaired color perception or visual loss; poor coordination of muscle movements; difficulty with bladder or bowel control; muscle stiffness (spasticity); speech problems and challenges with cognitive skills.

PPMS affects approximately 10 percent of the MS population and is evident by the slow and continuous progression of the disease. People with PPMS can experience plateaus in the progression of their disability, but generally do not experience distinct periods of relapse or remissions. The progressive nature of PPMS and severe debilitation associated with the disease can have a devastating impact on a patient’s quality of life and ability to function.

About Rituxan

Rituxan, discovered by Biogen Idec, is a therapeutic antibody that first received Food and Drug Administration (FDA) approval in November 1997 for the treatment of relapsed or refractory, low-grade or follicular, CD20-positive, B cell non-Hodgkin's lymphoma (NHL). It was also approved in the European Union under the trade name MabThera® in June 1998. In February 2006, Rituxan also received FDA approval in combination with methotrexate to reduce signs and symptoms and, in January 2008, to slow the progression of structural damage in adult patients with moderately-to-severely active RA who have had an inadequate response to one or more TNF-antagonist therapies. Rituxan is the first treatment for RA that selectively targets immune cells known as CD20-positive B cells. Rituxan does not target the entire immune system.

CD20 is not found on stem cells, pro-B cells (B cell precursors), normal plasma cells, or other normal tissues. Rituxan does not target plasma cells. These cells make antibodies that help fight infections.

Rituxan does not target stem cells in the bone marrow, and B cells can usually regenerate and gradually return to normal levels after treatment with Rituxan in about 12 months for most patients.

In addition, Rituxan received FDA approval in February 2006 for first-line treatment of previously-untreated patients with follicular NHL in combination with CVP (cyclophosphamide, vincristine and prednisolone) chemotherapy and in September 2006, also was approved for the treatment of non-progressing low-grade, CD20-positive, B cell NHL as a single agent, in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy, and for previously untreated diffuse large B cell, CD20-positive, NHL in combination with CHOP or other anthracycline-based chemotherapy regimens.

Over the past ten years, there have been more than 1 million patient exposures to Rituxan.

Important Safety Information

Rituxan has been associated with fatal infusion reactions, tumor lysis syndrome (TLS), severe mucocutaneous reactions and progressive multifocal leukoencephalopathy (PML). Hepatitis B reactivation and cardiac arrhythmias and angina have also been observed. Patients should be closely observed for signs of infection if biologic agents and/or disease modifying anti-rheumatic drugs other than methotrexate are used concomitantly.

Common adverse reactions (≥ 5%): hypertension, nausea, upper respiratory tract infection, arthralgia, pruritus, and pyrexia.

In addition to PPMS, for which there is currently no FDA-approved therapy, Rituxan is also being studied in other autoimmune diseases for significant unmet medical needs, including systemic lupus erythematosus, lupus nephritis and antineutrophil cytoplasmic antibodies (ANCA)-associated vasculitis.

Genentech and Biogen Idec co-market Rituxan in the United States, and Roche markets MabThera in the rest of the world, except Japan, where Rituxan is co-marketed by Chugai and Zenyaku Kogyo Co. Ltd. For a copy of the Rituxan full prescribing information, including Boxed Warning, please call 1-800-821-8590 or visit http://www.gene.com.

About Genentech

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes biotherapeutics for significant unmet medical needs. A considerable number of the currently approved biotechnology products originated from or are based on Genentech science. Genentech manufactures and commercializes multiple biotechnology products and licenses several additional products to other companies. The company has headquarters in South San Francisco, California and is listed on the New York Stock Exchange under the symbol DNA. For additional information about the company, please visit http://www.gene.com.

About Biogen Idec

Biogen Idec creates new standards of care in therapeutic areas with high unmet medical needs. Founded in 1978, Biogen Idec is a global leader in the discovery, development, manufacturing and commercialization of innovative therapies. Patients in more than 90 countries benefit from Biogen Idec's significant products that address diseases such as lymphoma, multiple sclerosis and rheumatoid arthritis. For product labeling, press releases and additional information about the company, please visit http://www.biogenidec.com.

This press release contains a forward-looking statement regarding the potential of B cell therapy for patients living with MS. Such statement is a prediction and involves risks and uncertainties such that actual results may differ materially. Actual results may be affected by a number of factors including, but not limited to, unexpected safety, efficacy or manufacturing issues, the need for additional data or clinical studies, FDA actions or delays, failure to obtain or maintain FDA approval, competition, pricing, reimbursement, the ability to supply product, product withdrawals and new product approvals and launches, and intellectual property or contract rights. Please also refer to the risk factors described in Genentech and Biogen Idec's periodic reports filed with the Securities and Exchange Commission. Genentech and Biogen Idec disclaim, and do not undertake, any obligation to update or revise any forward-looking statements in this press release.

Contact:

Genentech
Media: Nikki Levy, 650-225-1729
Investor: Susan Morris, 650-225-6523
or
Biogen Idec
Media: Shannon Altimari, 617-914-6524
Investor: Eric Hoffman, 617-679-2812