Genentech and Biogen Idec Announce Top-Line Results from Phase II/III Clinical Study of Rituxan in Systemic Lupus Erythematosus

April 29, 2008

SOUTH SAN FRANCISCO, Calif. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genentech, Inc. (NYSE:DNA) and Biogen Idec, Inc. (Nasdaq:BIIB) announced today that a Phase II/III study of Rituxan® (rituximab) for systemic lupus erythematosus (SLE, commonly called lupus) did not meet its primary endpoint defined as the proportion of Rituxan treated patients who achieved a major clinical response (MCR) or partial clinical response (PCR) measured by BILAG, a lupus activity response index, compared to placebo at 52 weeks. The study also did not meet any of the six secondary endpoints. 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 results of this Phase II/III study, but we understood from the outset the significant challenges in developing treatments for systemic lupus erythematosus," said Hal Barron, M.D., Genentech senior vice president, development and chief medical officer. “We believe the ongoing Phase III trial in lupus nephritis (LUNAR) remains an important study as it evaluates the potential of Rituxan in a different patient population.”

“There is a critical need to discover new therapeutic pathways in lupus as no new therapy has been approved in more than 30 years. We will analyze the full set of data from this trial in the coming months, share the findings with regulatory authorities, and apply the key insights to our continued research in lupus,” said Evan Beckman, M.D., Senior Vice President, Immunology Research and Development, Biogen Idec.

About the Study

This Phase II/III randomized, double-blind, placebo-controlled, multi-center study was designed to evaluate the efficacy and safety profile of Rituxan in patients with moderate-to-severe SLE on a background immunosuppressant. This study excluded patients with lupus nephritis (LN). A total of 257 patients from approximately 55 sites in the U.S. and Canada were randomized 2:1 to receive Rituxan plus prednisone or placebo plus prednisone in two infusions 15 days apart. The patients were retreated six months later with the same regimen. Patients were evaluated for efficacy every four weeks for 52 weeks. The majority of patients are being monitored to Week 78.

The primary endpoint of the study was the proportion of patients who achieved either a Major Clinical Response (MCR) or Partial Clinical Response (PCR) using the BILAG instrument at 52 weeks. Additional endpoints included: time adjusted area-under-the-curve minus baseline of BILAG score over 52 weeks; proportion of patients who achieve a MCR, and proportion of patients who achieve a PCR (including MCR) at Week 52; proportion of patients who achieve BILAG C or better in all domains at Week 24; time to moderate or severe flare over 52 weeks; change in SLE Expanded Health Survey physical function score from baseline at Week 52; and proportion of subjects who achieve a MCR with < 10 mg prednisone per day from Weeks 24 to 52.

Detailed safety data from the study is currently being evaluated. The incidence of overall adverse events and serious adverse events were comparable between Rituxan and placebo treatment groups. Side effects occurring more frequently in the Rituxan arm included: herpes viral infections (15.4 percent in the Rituxan arm versus 8.0 percent in the placebo arm), and neutropenia (3.6 percent in the Rituxan arm versus 0 percent in the placebo arm). Overall, infusion reactions were mild to moderate in severity. The companies continue to monitor the long-term safety of Rituxan treatment.

The clinical database was locked, the study unblinded and results for the primary and secondary endpoints initially reviewed on April 25, 2008.

This is the first of two studies evaluating the safety and efficacy of Rituxan in patients with lupus. The second, an ongoing Phase III trial (LUNAR) is evaluating Rituxan in patients with active lupus nephritis with results expected in Q1- 2009.

About the BILAG Response Index

The British Isles Lupus Assessment Group (BILAG) index is a validated clinical measure of lupus disease activity. EXPLORER is the first pivotal trial to use BILAG. Unlike other lupus activity indices in which a global score is calculated, the BILAG index reports disease activity in each organ system separately. Physicians evaluate eight organ-based systems (general, mucocutaneous, neurological, musculoskeletal, cardiovascular and respiratory, vascular, renal, and hematological) every 4 weeks when scoring lupus activity using BILAG. Physical exam findings and lab results for each organ system are used to produce a rating that compares the level of disease severity over the past 4 weeks to the previous assessment.

About Lupus

Lupus is an autoimmune disease characterized by inflammation of the joints, skin, kidneys, heart, lungs, blood vessels and the central nervous system. In lupus, the immune system attacks healthy tissues and cells, damaging multiple organs and systems in the body.

Although the signs and symptoms of lupus vary significantly, they commonly include a butterfly-shaped rash across the nose and cheeks, hair loss, sensitivity to light and other skin rashes. Some patients experience more severe symptoms, including fatigue, pain while breathing, joint pain, fever, anemia and ulcers in the mouth and nose. Lupus can cause inflammation of the heart muscle, coronary arteries and the pericardium (a protective layer of tissue enveloping the heart), greatly increasing the risk of cardiovascular disease and heart attack.

While estimates vary widely regarding the number of people affected by lupus, approximately 400,000 patients in the U.S. are believed to have the disease. The course of disease in SLE is highly variable among patients and like other autoimmune diseases, most lupus patients experience periods of illness called flares, and periods of wellness, or remission.

There are several types of lupus, including the most common form of the disease, SLE, which comprises 70 percent of all lupus cases. Women aged 15 to 45 comprise 90 percent of SLE patients. Lupus nephritis is a common and serious complication of SLE that occurs when the disease affects kidneys; approximately one-third of SLE patients will develop lupus nephritis. Currently, there is no cure for lupus.

More information about lupus is available at:
Lupus Foundation of America

http://www.lupus.org

Lupus Research Institute

http://www.lupusresearchinstitute.org

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 rheumatoid arthritis (RA) who have had an inadequate response to one or more TNF-antagonist therapies. 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.

Rituxan has more than 10 years of clinical experience across all indications and more than 1,000,000 patient exposures.

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.

Important Safety Information

Rituxan has been associated with fatal infusion reactions, tumor lysis syndrome (TLS), severe mucocutaneous reactions and progressive multifocal leukoencephalopathy (PML).

There are two reports of PML in Rituxan-treated patients with SLE. These patients had longstanding disease and had received other immunosuppressants including prednisone, azathioprine and cyclophosphamide. It is important to note that patients with SLE are often profoundly immunocompromised either due to their disease or the medications they are taking. While rare, PML is a known risk in severely immunocompromised individuals. A recent analysis showed that many cases of PML in SLE have occurred in patients with minimal immunosuppression, which suggests that SLE itself may predispose patients to PML. A causal relationship between Rituxan and PML has not been established but cannot be ruled out.

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.

Genentech and collaborators are leading research in the field of immunology by developing a pipeline of potential agents for various immune-mediated diseases, with ongoing clinical trials in lupus, RA, MS and antineutrophil cytoplasmic antibody (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 forward-looking statements regarding the potential of Rituxan in lupus and the timing of results in the lupus nephritis study. Such statements are forward looking and involve 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, data analysis or clinical studies, FDA actions or delays, failure to 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.

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