Phase III Study of Rituxan in Lupus Nephritis Did Not Meet Primary Endpoint

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SOUTH SAN FRANCISCO, Calif. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genentech, Inc. (NYSE:DNA) and Biogen Idec (Nasdaq:BIIB) announced today that a Phase III study of Rituxan® (rituximab) plus mycophenolate mofetil (MMF) and corticosteroids in patients with lupus nephritis did not meet its primary endpoint of significantly reducing disease activity at 52 weeks. The primary endpoint evaluated improvements in kidney response as measured by standard laboratory tests used to assess kidney health. A preliminary analysis of the safety data did not reveal any new or unexpected safety signals in patients receiving Rituxan.

Lupus nephritis is an inflammation of the kidney and a complication of systemic lupus erythematosus (SLE or lupus), an autoimmune disease. Lupus nephritis can lead to a progressive loss of kidney function and may result in kidney failure in the most severe cases. Lupus nephritis occurs in approximately one-third of people with SLE.

“We are disappointed that Rituxan did not show a significant benefit in patients with lupus nephritis, a complex and serious disease. Using the insights from this study, we will continue to look for new approaches to the treatment of lupus,” said Hal Barron, M.D., Genentech's senior vice president, development and chief medical officer.

“We would like to acknowledge the investigators and patients who participated in the LUNAR study for their important contribution to our understanding of this challenging disease,” said Evan Beckman, M.D., Biogen Idec’s senior vice president of Immunology Research and Development. “We plan to analyze the full set of data from this study and share the findings at an upcoming scientific meeting.”

About the Study

This Phase III randomized, double-blind, placebo-controlled, multi-center study included 144 patients with Class III or IV lupus nephritis from approximately 60 sites in the U.S., Canada, Mexico, Argentina and Brazil. Study participants were treated with mycophenolate mofetil (MMF) and corticosteroids and were randomized 1:1 to receive Rituxan or placebo in two infusions, 15 days apart. The patients were retreated six months later with the same regimen. MMF, an immunosuppressive drug, is commonly used in the treatment of lupus nephritis. Patients were evaluated for efficacy at weeks 24 and 52. The majority of patients are being monitored for at least 78 weeks.

The primary endpoint of the study was the proportion of patients who achieved a complete renal response (significant reduction of disease activity from baseline including normalization of kidney function) or partial renal response (reduction of disease activity from baseline including no further loss of kidney function) after 52 weeks of treatment as assessed by improvements in renal function, urinary sediment and proteinuria. Proteinuria refers to an abnormal amount of protein in the urine and is a well-recognized sign of potential kidney damage.

Detailed safety data from the study is currently being evaluated. The incidence of overall adverse events and serious adverse events including infections and infusion reactions was comparable between the Rituxan and placebo treatment groups. Side effects occurring more frequently in the Rituxan arm included: leukopenia (12.3 percent in the Rituxan arm versus 4.2 percent in the placebo arm), neutropenia (5.5 percent in the Rituxan arm versus 1.4 percent in the placebo arm) and hypotension (11.0 percent in the Rituxan arm versus 4.2 percent in the placebo arm). The companies continue to monitor the long-term safety of Rituxan treatment.

About Lupus Nephritis

Lupus nephritis is a frequent and often severe complication of lupus, an autoimmune disease where a person’s own immune system attacks healthy tissues and cells, causing inflammation and damaging multiple organs and systems in the body including the skin, joints, kidneys, and the brain. Lupus nephritis can result in loss of function or complete kidney failure. Lupus nephritis affects approximately 30-40 percent[1] of the 400,000 people with lupus[2]. Most people with lupus nephritis experience periods of illness called flares, and periods of wellness, or remission. Some experience weight gain, high blood pressure, dark urine and swelling (edema) around the eyes, legs, ankles or fingers. Currently, there is no cure for lupus or lupus nephritis.

About Rituxan®

Rituxan, discovered by Biogen Idec, is a therapeutic antibody that first received FDA approval in November 1997 for the treatment of relapsed or refractory, low-grade or follicular, CD20-positive, B-cell non-Hodgkin's lymphoma. It was also approved in the European Union under the trade name MabThera® in June 1998. Rituxan received FDA approval in February 2006 for the treatment of diffuse large B-cell lymphoma (DLBCL) in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens in previously untreated patients.

In February 2006, Rituxan also received FDA approval in combination with MTX to reduce signs and symptoms in adult patients with moderately-to-severely active RA who have had an inadequate response to one or more TNF antagonist therapies. In January 2008, Rituxan was approved 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 retreatment with Rituxan in about 12 months for most patients.

In addition, Rituxan received FDA approval in September 2006 for first-line treatment of previously-untreated patients with follicular NHL in combination with CVP (cyclophosphamide, vincristine, and prednisolone) chemotherapy and also for the treatment of low-grade NHL in patients with stable disease or who achieve a partial or complete response following first-line treatment with CVP chemotherapy.

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

Rituxan is also being studied in other autoimmune diseases with significant unmet medical needs, including antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis.

Rituxan Safety

Rituxan can cause serious side effects, some of which can be life-threatening, including: **Progressive Multifocal Leukoencephalopathy (PML)**, **infusion reactions, Tumor Lysis Syndrome (TLS), and severe skin reactions.** Other serious and life-threatening side effects with Rituxan include: hepatitis B virus reactivation, heart problems, infections, and stomach and bowel problems. Common side effects during Rituxan infusions include: fever, headache, chills and shakes, nausea, itching, hives, cough, sneezing, and throat irritation or tightness.

Please visit http://www.gene.com or call 1-800-821-8590 for the Rituxan full prescribing information, including **Boxed WARNINGS,** Medication Guide**,** and additional important safety information.

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.

About Genentech

Founded more than 30 years ago, Genentech is a leading biotechnology company that discovers, develops, manufactures and commercializes medicines for patients with significant unmet medical needs. 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.

Citations:

1. Wallace DJ. Lupus in the kidney and urinary tract in: The Lupus Book: A Guide for Patients and Families, Third Edition. New York: Oxford University Press, 2005:145-151.

2. Chakravarty EF, Bush TM, Manzi S et al. Prevalence of adult systemic lupus erythematosus in California and Pennsylvania in 2000: estimates obtained using hospitalization data. Arthritis Rheum 2007;56:2092-2096.

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