FDA Approves Rituxan Plus a Steroid for Use in Severe Forms of Vasculitis

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– First Medicine Ever Approved for Rare Blood Vessel Diseases –

SOUTH SAN FRANCISCO, Calif. & WESTON, Mass.--(BUSINESS WIRE)--Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY) and Biogen Idec (Nasdaq: BIIB) announced today that the U.S. Food and Drug Administration (FDA) approved Rituxan® (rituximab), in combination with corticosteroids, as a new medicine for adults with Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA).

WG and MPA are two severe forms of vasculitis called ANCA-Associated Vasculitis (AAV), a rare autoimmune disease that largely affects the small blood vessels of the kidneys, lungs, sinuses, and a variety of other organs. Both WG and MPA are considered orphan diseases with an estimated prevalence in the United States of approximately three cases per 100,000 people.

"For the first time, people with Wegener's Granulomatosis and Microscopic Polyangiitis have a medicine that the FDA has approved for the treatment of these rare and relapsing diseases," said Hal Barron, M.D., chief medical officer and head, Global Product Development. "We are committed to following the science and focusing on diseases of high unmet medical need, including orphan conditions. Today's approval is an important example of how the scientific community can work together to advance science and treatment options for orphan diseases."

The approval is based on a National Institutes of Health-sponsored study known as RAVE (Rituxan in ANCA-Associated Vasculitis). The study showed that Rituxan was not inferior to the current standard of care, cyclophosphamide (CYC) in inducing disease remission at six months in adults with WG and MPA.

About RAVE

RAVE is a multicenter, randomized, double-blind, active-controlled study. In the study, patients were randomized to receive either Rituxan for four weeks with corticosteroids, or the control treatment of oral CYC with corticosteroids daily for three to six months in the remission induction phase. Once remission was achieved or at the end of the six-month remission induction period, patients in the CYC group were to receive daily azathioprine to maintain remission. Patients in the Rituxan group were not to receive additional therapy to maintain remission. In the Rituxan group, 64 percent (63/99) of patients reached the primary endpoint of complete remission at six months, defined as a zero score on the Birmingham Vasculitis Activity Score for Wegener's Granulomatosis (BVAS/WG) and successfully tapered off corticosteroids, compared with 53 percent (52/98) of patients who received CYC with corticosteroids. The BVAS/WG is an instrument used in clinical trials to define and measure worsening or improvement of AAV disease activity among patients.

Infections were the most commonly reported adverse events and occurred in 62 percent (61/99) of patients in the Rituxan group and 47 percent (46/98) of patients in the control group and were most frequently upper respiratory tract infections. The study evaluated specific serious adverse events of concern in this patient population including deaths, development of certain forms of cancers, blood disorders, infections, cardiovascular events, hospitalizations and infusion reactions. At six months, 33 percent (n=32) of those taking CYC developed one of the adverse events versus 22 percent (n=22) of those on Rituxan.

The six-month data from RAVE was published in the *New England Journal of Medicine* in July 2010, and longer-term efficacy and safety information will be presented at upcoming scientific meetings.

The study was conducted as a collaboration between the Immune Tolerance Network (ITN) and the National Institute of Allergy and Infectious Diseases (part of the National Institutes of Health). Genentech, of South San Francisco, Calif., and Biogen Idec, Inc., of Weston, Mass., provided additional funding as well as Rituxan and placebo treatments for the study.

About Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)

Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA) are two severe forms of a potentially fatal autoimmune disease called AAV which is characterized by inflammation associated with autoantibodies called ANCAs (anti-neutrophil cytoplasm antibodies). ANCAs contribute to inflammation that damages the blood vessel walls in different tissues and organs in the body. In general, WG and MPA both affect the small blood vessels of the kidneys, lungs, sinuses, and a variety of other organs, but the disease is expressed differently from person to person.

The peak age range of onset is 65 to 74 years and males are typically affected as often as females. The use of CYC chemotherapy was pioneered by the NIH in the 1970s, and before the use of this drug the mean survival for severely ill patients was approximately five months. CYC is currently the standard of care for treating WG and MPA but doctors wanted an option for patients that works differently and has a different safety profile.

About Rituxan

Rituxan is a therapeutic antibody that binds to a specific protein called CD20 found on the surface of cancerous and normal B-cells. In Non-Hodgkin's Lymphoma (NHL) and rheumatoid arthritis (RA), Rituxan works with the body's own immune system to eliminate CD20-positive B-cells. Stem cells (B-cell progenitors that give rise to B-cells) in bone marrow do not have the CD20 protein allowing B-cells to repopulate after Rituxan treatment.

Rituxan, discovered by Biogen Idec, first received FDA approval in November 1997 for the treatment of relapsed or refractory, low-grade or follicular, CD20-positive, B-cell NHL as a single agent. It was approved in the European Union under the trade name MabThera in June 1998. Rituxan is also approved for the treatment of NHL and chronic lymphocytic leukemia (CLL) as follows:

- Previously untreated follicular, CD20-positive, B-cell NHL in combination with first-line chemotherapy and, in patients achieving a complete or partial response to Rituxan in combination with chemotherapy, as a single-agent maintenance therapy

- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line CVP chemotherapy
- Previously untreated diffuse large B-cell, CD20-positive NHL in combination with CHOP or other anthracycline-based chemotherapy regimens
- Previously untreated and previously treated CD20-positive CLL in combination with fludarabine and cyclophosphamide (FC)

Rituxan received FDA approval for RA in February 2006 and is currently indicated in combination with methotrexate (MTX) in adult patients with moderately-to-severely active RA who have had inadequate response to one or more TNF antagonist therapies. In addition, Rituxan, in combination with glucocorticosteroids, is now approved for the treatment of Wegener's Granulomatosis and Microscopic Polyangiitis in adults.

Rituxan is not recommended for use in patients with severe, active infections.

Important Safety Information

Rituxan can cause serious side effects that can lead to death, including: **infusion reactions, tumor lysis syndrome (kidney failure due to fast breakdown of cancer cells), severe skin and mouth reactions, and progressive multifocal leukoencephalopathy (a rare, serious brain infection).**

Rituxan has also been associated with serious and life-threatening side effects, including: the return of active hepatitis B virus infection with sudden and serious liver problems including liver failure and death, other serious infections that can lead to death, heart problems, kidney problems and stomach and serious bowel problems including blockage and tears in the bowel, that can sometimes lead to death.

The most common side effects of Rituxan seen in patients with NHL were infusion reactions, fever, chills, low white blood cells, infections, body aches and tiredness. The most common side effects of Rituxan in patients with CLL were infusion reactions and low white blood cells. The most common side effects seen in patients with RA were upper respiratory tract infection, nasopharyngitis (nose and throat inflammation), urinary tract infection, and bronchitis. The most common side effects seen in patients with WG and MPA were infections, nausea, diarrhea, headache, muscle spasms, anemia and peripheral edema (swollen hands and feet).

Patients should tell their doctor about any side effect that bothers them or that does not go away. These are not all of the possible side effects with Rituxan.

Patients should read the Rituxan Full Prescribing Information including Boxed Warnings, and the Medication Guide at http://www.rituxan.com.

Genentech and Biogen Idec collaborate on 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 to treat patients with serious or life-threatening medical conditions. The company, a member of the Roche Group, has headquarters in South San Francisco, California. For additional information about the company, please visit http://www.gene.com.

About Biogen Idec

Biogen Idec uses cutting edge science to discover, develop, manufacture and market biological products for the treatment of serious diseases with a focus on neurological disorders. Founded in 1978, Biogen Idec is the world's oldest independent biotechnology company. Patients worldwide benefit from its leading multiple sclerosis therapies, and the company generates more than $4 billion in annual revenues. For product labeling, press releases and additional information about the company, please visit http://www.biogenidec.com.

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