Genentech and Biogen Idec Submit Applications to the FDA for Rituxan for Most Common Type of Adult Leukemia

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-- Applications Based on Data from Nearly 1,500 Patients in Two of the Largest Studies Ever Conducted in Chronic Lymphocytic Leukemia --

SOUTH SAN FRANCISCO, Calif.& CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genentech, Inc. and Biogen Idec (Nasdaq:BIIB) today announced that the companies submitted two supplemental Biologics License Applications (sBLAs) to the U.S. Food and Drug Administration (FDA) for Rituxan® (rituximab) plus standard chemotherapy for people with previously untreated or treated chronic lymphocytic leukemia (CLL). The companies will request a priority review, and if granted, anticipate the FDA will make a decision within six months.

CLL is the most common type of adult leukemia, accounting for one-third of all leukemias in the U.S. It is a slow-growing disease that occurs when too many abnormal white blood cells develop in the blood and bone marrow. The abnormal cells outnumber the normal white blood cells, making it difficult for the body to fight infection.

The applications are based on positive results from two of the largest global Phase III clinical trials conducted in patients with CLL. The randomized, comparative studies, known as CLL8 and REACH, showed that Rituxan plus standard chemotherapy for CLL extended the time patients lived without the cancer advancing (progression-free survival or PFS) compared to those receiving chemotherapy alone. In CLL8, previously untreated patients who received Rituxan plus chemotherapy had a 69 percent improvement in PFS (41 percent risk reduction, hazard ratio=0.59; p<0.0001; 95% confidence interval: 0.44,0.72) compared to those who received chemotherapy alone. In REACH, patients whose cancer relapsed after previous treatment had a 54 percent improvement in PFS after receiving Rituxan plus chemotherapy compared to patients receiving chemotherapy alone (35 percent risk reduction, hazard ratio=0.65; p=0.0002; 95% confidence interval: 0.51, 0.82). These findings were based on assessments made by the study investigators.

“There is no cure for CLL, and the primary goal of treatment is to keep the cancer from getting worse,” said Cecil Pickett, Ph.D., Biogen Idec’s president of Research and Development. “These data showed that Rituxan was able to extend the period of time before cancer progression by about 10 months for people with newly diagnosed or recurrent disease.”

“Results from these two large studies, which involved nearly 1,500 patients, give us confidence in Rituxan’s efficacy and safety in CLL,” said Hal Barron, M.D., executive vice president, Global Development and chief medical officer, Genentech. “We believe the data support the potential role of Rituxan as both an initial and second-line treatment for CLL, and look forward to working with the FDA during the review period.”

About the CLL8 and REACH Studies

Sponsored by Roche and conducted by the German CLL Study Group, CLL8 was a global, multi-center, randomized, open-label, Phase III study that enrolled 817 patients with previously untreated (first-line) CD20-positive CLL. REACH was a global, multi-center, randomized, open-label, Phase III study that enrolled 552 patients with relapsed CD20-positive CLL sponsored by Genentech, Biogen Idec and Roche. Both studies evaluated Rituxan plus fludarabine and cyclophosphamide chemotherapy compared with fludarabine and cyclosphosphamide alone. The primary endpoint for both studies was progression-free survival and secondary endpoints were overall survival, event-free survival, duration of response, response rate and complete response.

In patients who had not received previous treatment (CLL8), the overall response rate was 93 percent in the Rituxan-treated arm compared to 85 percent in the chemotherapy alone arm. In patients whose cancer had relapsed after previous treatment (REACH), the overall response rate was 70 percent in the Rituxan-treated arm compared to 58 percent in the chemotherapy alone arm. No new safety signals were observed in either of the studies and safety was consistent with previous Rituxan experience.

In CLL8, the most common adverse events that occurred more often in the Rituxan plus chemotherapy arm included blood and lymphatic system disorders, infections and neoplasms. Severe (Grade 3 or greater) events that occurred more often in the Rituxan plus chemotherapy arm included hematologic toxicity (56 percent vs. 39 percent), neutropenia (34 percent vs. 21 percent) and leukocytopenia (24 percent vs. 12 percent). In REACH, the most common adverse events that occurred more often in the Rituxan plus chemotherapy arm included blood and lymphatic system disorders, infections and neoplasms. Grade 3 or greater events such as neutropenia (42 percent vs. 40 percent), febrile neutropenia (15 percent vs. 12 percent) and neoplasms (7 percent vs. 3 percent) occurred more often in the Rituxan plus chemotherapy arm.

Results from both studies were presented at the 50th Annual Meeting of the American Society of Hematology (ASH) in San Francisco in December 2008.

About Chronic Lymphocytic Leukemia

More than an estimated 90,000 Americans are living with the disease. It is largely a disease of older adults and the average age of diagnosis is 72. The American Cancer Society estimates that more than 15,000 new cases will be diagnosed and about 4,500 people will die from CLL this year.

About Rituxan

Rituxan is a therapeutic antibody that binds to a particular protein, the CD20 antigen found on the surface of malignant cells as well as normal B-cells. In non-Hodgkin’s lymphoma and rheumatoid arthritis (RA), Rituxan works with the body’s natural defenses to attack and kill the marked CD20 positive B-cells. Stem cells (B-cell progenitors) in bone marrow lack the CD20 antigen, allowing B-cells to regenerate after treatment and return to normal levels in about 12 months for most patients.

Rituxan 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 as a single agent. It was also approved in the European Union under the trade name MabThera® in June 1998. Rituxan is

also approved for the treatment of non-Hodgkin's lymphoma for the following:

- Previously untreated follicular, CD20-positive, B-cell non-Hodgkin's lymphoma in combination with CVP (cyclophosphamide, vincristine and prednisolone) chemotherapy.
- Non-progressing (including stable disease), low-grade, CD20-positive, B-cell non-Hodgkin's lymphoma as a single agent, after first-line CVP chemotherapy.
- Previously untreated diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma in combination with CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone) or other anthracycline-based chemotherapy regimens.

Rituxan received FDA approval for rheumatoid arthritis in February 2006 and is currently indicated in combination with methotrexate (MTX) to reduce signs and symptoms and to slow the progression of structural damage in adult patients with moderately-to severely-active rheumatoid arthritis who have had inadequate response to one or more TNF antagonist therapies.

Genentech and Biogen Idec co-market Rituxan in the U.S., and Roche markets MabThera in the rest of the world, except Japan, where Rituxan is co-marketed by Chugai and Zenyaku Kogyo Co. Ltd.

Rituxan Safety

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

Hepatitis B reactivation with fulminant hepatitis, other viral infections, cardiovascular events, renal toxicity, and bowel obstruction and perforation have also been observed. Patients should be closely observed for signs of infection if biologic agents and/or disease-modifying anti-rheumatic drugs (DMARDs) other than MTX are used concomitantly.

The most common adverse reactions observed in Rituxan-treated RA patients are hypertension, nausea, upper respiratory tract infection, arthralgia, pruritus and pyrexia.

The most common adverse reactions observed in Rituxan-treated NHL patients (incidence greater than or equal to 25 percent) are infusion reactions, fever, chills, infection, asthenia and lymphopenia.

For additional safety information, please see the full prescribing information, including Boxed Warnings and Medication Guide, at 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 medicines to treat patients with serious or life-threatening medical conditions. The company, a wholly-owned member of the Roche Group, has headquarters in South San Francisco, Calif. For additional information about the company, please visit http://www.gene.com.

About Biogen Idec

Biogen Idec creates new standards of care in oncology, neurology and immunology. As a global leader in the development, manufacturing and commercialization of novel therapies, Biogen Idec transforms scientific discoveries into advances in human healthcare. For product labeling, press releases and additional information about the company, please visit http://www.biogenidec.com.

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