



Phase III Study Showed Rituxan in Combination with Chemotherapy Improved Progression-Free Survival in Patients with Relapsed Chronic Lymphocytic Leukemia

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Study is Second Positive Phase III Trial of Rituxan Plus Chemotherapy in Most Common Adult Leukemia

SOUTH SAN FRANCISCO, Calif. & CAMBRIDGE, Mass.--([BUSINESS WIRE](#))--Genentech, Inc. (NYSE:DNA) and Biogen Idec (Nasdaq:BIIB) today announced that a global Phase III study of Rituxan® (rituximab) in combination with fludarabine and cyclophosphamide chemotherapy met its primary endpoint of improving progression-free survival (PFS), as assessed by investigators, in patients with previously treated CD20-positive chronic lymphocytic leukemia (CLL) compared to chemotherapy alone. There were no new or unexpected safety signals reported in the study. An independent review of the primary endpoint is being conducted for U.S. regulatory purposes.

Data from the study, REACH, will be submitted for presentation at a future medical meeting. Earlier this year, another European Phase III study, CLL-8, showed a similar treatment combination improved PFS in patients with CLL who had not previously received treatment.

"REACH, the largest relapsed CLL trial ever conducted, is the first Phase III study of this treatment combination to show an improvement in progression-free survival for patients," said Hal Barron, M.D., Genentech's senior vice president, Development and chief medical officer. "We look forward to collaborating with Biogen Idec to discuss these data with the FDA in the future."

"Patients with CLL currently have few approved treatment options after the disease progresses following initial chemotherapy," said Cecil Pickett, Ph.D., Biogen Idec's president of Research and Development. "The REACH results are promising, and pending confirmation of the results by independent review, we look forward to submitting an application to the FDA for Rituxan's potential approval in this indication."

About the REACH Study

REACH is a multi-center, randomized, open-label, international Phase III study that enrolled 552 patients with previously treated CD20-positive CLL. The study evaluated the efficacy and safety profile of Rituxan in combination with fludarabine and cyclophosphamide chemotherapy versus fludarabine and cyclophosphamide chemotherapy alone. The primary endpoint was PFS, defined as the length of time from the date of treatment randomization to the time of disease progression, relapse or death from any cause. Secondary endpoints included overall survival, event-free survival, duration of response, response rate and complete response.

About Chronic Lymphocytic Leukemia

CLL is the most common type of leukemia in adults. The cancer is a slow-growing type of leukemia in which excess mature B-cells are found in the blood and bone marrow. According to the American Cancer Society, CLL accounts for one-third of all leukemias in the United States. It estimates that 15,000 new cases will be diagnosed and approximately 4,400 people will die from this disease this year.

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

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

In February 2006, Rituxan also received FDA approval in combination with methotrexate (MTX) to reduce signs and symptoms in adult patients with moderately-to-severely active rheumatoid arthritis (RA) who have had an inadequate response to one or more tumor necrosis factor (TNF)-antagonist therapies. Additionally, in January 2008, Rituxan received FDA approval in combination with MTX 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 plasma 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.

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

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.

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 methotrexate 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 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 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>.

This press release contains a forward-looking statement regarding the potential of Rituxan in CLL. Such statement is forward looking 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, data analysis 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.

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