Phase III Study Showed First-Line Maintenance Use of Rituxan® Improved the Likelihood of People with Follicular Lymphoma Living without Their Disease Worsening

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SOUTH SAN FRANCISCO, Calif. & CAMBRIDGE, Mass.--(BUSINESS WIRE)--Genentech, Inc., a wholly owned member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), and Biogen Idec (Nasdaq: BIIB) today announced data from the Phase III PRIMA study. The data showed that continuing Rituxan® (rituximab) for two years in patients who responded to initial treatment with Rituxan plus chemotherapy, doubled the likelihood of them living without their disease worsening (progression-free survival or PFS) compared to those who stopped treatment (based on a hazard ratio of 0.50, 95% CI, 0.39; 0.64; p=<0.0001). The study enrolled patients with previously untreated advanced follicular lymphoma. After two-years of follow-up, 82 percent of patients who received Rituxan maintenance were in remission compared to 66 percent of patients who did not. No new safety signals were observed in this study and the safety profile was consistent with previous experience with Rituxan.

The data were featured during an American Society of Clinical Oncology (ASCO) presscast today. The organization's 46 th Annual Meeting will take place from June 4 to 8, 2010 in Chicago, with more detailed PRIMA results presented on Saturday, June 5.

"Follicular lymphoma is an incurable cancer that may return many times during a person's life and require additional therapy," said Hal Barron, M.D., executive vice president, Global Development and chief medical officer, Roche. "The study is important because in those people who continued Rituxan, the risk of the cancer progressing was half of the risk than in those people who did not receive maintenance Rituxan."

Genentech, Roche and Biogen Idec recently submitted an sBLA (supplemental Biologics License Application) to the U.S. Food and Drug Administration (FDA) and an extension of the Rituxan Marketing Authorization Application to the European Medicines Agency (EMA) based on the PRIMA study data.

"The PRIMA study results add to the body of evidence supporting Rituxan in non-Hodgkin's lymphoma and emphasize the role Rituxan plays in helping people with this cancer that will most likely recur," said Greg Reyes, M.D., Ph.D., senior vice president, Oncology Research and Development, Biogen Idec. "We look forward to discussing these new data with the FDA and European regulatory authorities."

Follicular lymphoma is a type of slow-growing form of non-Hodgkin's lymphoma (NHL). According to the American Cancer Society, an estimated 574,000 Americans have NHL. Of those diagnosed with NHL, approximately 20 to 30 percent of patients have follicular lymphoma. In 2009, approximately 66,000 new cases of NHL were expected to be diagnosed in the United States.

PRIMA: Rituximab Maintenance For Two Years Significantly Improves the Outcome of Patients With Untreated High Tumor Burden Follicular Lymphoma After Response to Immunochemotherapy: Results of the PRIMA Study (Abstract #8004) – Saturday, June 5, 2010, 1:00 p.m. – 1:15 p.m. CDT, Room E354a

Sponsored by the Group d'Etudes de Lymphomes de L'Adulte (GELA), PRIMA is an international, multicenter, randomized, Phase III clinical study that enrolled 1,217 patients with previously untreated advanced follicular lymphoma. The study evaluated the efficacy and safety profile of maintenance Rituxan in patients who responded to initial treatment with Rituxan plus chemotherapy (induction treatment).

In the study, Rituxan plus either CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CVP (cyclophosphamide, vincristine, prednisone) or FCM (fludarabine, cyclophosphamide, mitoxantrone) chemotherapy was used as initial treatment. Patients who responded (1,018/1,217) were randomized to receive Rituxan alone, given once every two months for two years (maintenance), or observation alone.

The safety profile was consistent with those previously reported in pivotal studies of Rituxan alone or in combination with chemotherapy. Serious adverse events (Grade 3 or 4) were reported in 23 percent of patients who received Rituxan maintenance compared to 16 percent who did not, including low white blood cell (neutrophil) counts (4 percent vs. 1 percent) and infections (4 percent vs. 1 percent).

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 NHL and rheumatoid arthritis (RA), Rituxan works with the body's own immune system to eliminate marked CD20-positive B-cells. Stem cells (B-cell progenitors, those cells that give rise to B-cells) in bone marrow do not have the CD20 protein. B-cells usually regenerate after Rituxan treatment and return to normal levels in about 12 months for most patients.

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 CVP chemotherapy.
- 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) to reduce signs and

symptoms and to slow the progression of structural damage in adult patients with moderately-to severely-active RA 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 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.

Other serious, potentially life-threatening side effects seen in RA patients are: hepatitis B infection that may become active again, other infections, heart problems, and low blood cell counts. The most common side effects of Rituxan seen in patients with non-Hodgkin's lymphoma 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. Common side effects in patients with RA include infections and infusion reactions. Patients should talk to their doctor about their medical history before starting treatment with Rituxan.

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.

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 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 worldwide 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.

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