FDA Approves Rituxan for First-Line Maintenance Use in Follicular Lymphoma

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Approval Provides Option That Improves the Length of Time People with Incurable Blood Cancer Live without the Disease Worsening

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) today announced the U.S. Food and Drug Administration (FDA) approved Rituxan® (rituximab) as a maintenance treatment for patients with advanced follicular lymphoma who responded to initial treatment with Rituxan plus chemotherapy (induction treatment). This milestone follows the clearance of Rituxan for this indication by the European Commission in October 2010.

“This approval is important because it shows that maintenance treatment with Rituxan, after initial therapy with Rituxan and chemotherapy, further reduces the risk of relapse in people with follicular lymphoma,” said Hal Barron, M.D., chief medical officer and head, Global Product Development, Roche. “Maintenance use of Rituxan offers people with this incurable disease the opportunity to live longer without their disease getting worse, a primary goal of treatment.”

Follicular lymphoma is considered incurable and is characterized by periods of relapse and remission over a number of years. This approval, based on the Primary Rituxan and Maintenance (PRIMA) study, showed continuing Rituxan administration every two months for two years in patients who responded to initial treatment with Rituxan plus chemotherapy, nearly doubled the likelihood of them living without the disease worsening (progression-free survival or PFS) compared to those who stopped treatment (based on a hazard ratio of 0.54, 95 percent CI, 0.42-0.70; p≤0.0001).

About PRIMA

This approval was based on data from a Phase III study, PRIMA. Sponsored by the Groupe d'Etude des 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 achieved a response (complete or partial) to Rituxan in combination with chemotherapy.

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

The safety profile was consistent with those previously reported in pivotal studies of Rituxan alone or in combination with chemotherapy. Grade ≥ 2 infections were reported more frequently in patients who received Rituxan maintenance compared to the observation arm (37 percent vs. 22 percent). Grade 3-4 adverse reactions occurring at a higher incidence (≥ 2 percent) in the Rituxan group were infections (4 percent vs. 1 percent) and low white blood cell count (4 percent vs. < 1 percent).

About Follicular Lymphoma

Follicular lymphoma, a cancer of the blood, is a common type of non-Hodgkin’s lymphoma (NHL). Follicular lymphoma remains incurable and patients ultimately relapse and relapses require additional treatments. According to the Leukemia and Lymphoma Society, more than 450,000 Americans are living with NHL. Approximately 65,540 Americans were diagnosed with NHL in the United States in 2010. Of those diagnosed with NHL, one in five will have follicular lymphoma.

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 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.

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

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.

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.

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 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. 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 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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