FDA approves Roche’s Gazyva (obinutuzumab) for people with previously untreated chronic lymphocytic leukemia (CLL)

- Gazyva demonstrated an 84 percent reduction in the risk of disease worsening or death when combined with chemotherapy compared to chemotherapy alone
- Gazyva is the first medicine approved with the FDA’s Breakthrough Therapy Designation

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) approved Gazyva (obinutuzumab), also known as GA101, in combination with chlorambucil chemotherapy for the treatment of people with previously untreated chronic lymphocytic leukemia (CLL). Gazyva is the first medicine approved with the FDA’s Breakthrough Therapy Designation and the fifth cancer medicine from Roche approved by the FDA in the past three years.

“Gazyva is an important new medicine for people with newly diagnosed chronic lymphocytic leukemia as based on clinical data, it more than doubled the time people lived without their disease worsening compared to chlorambucil alone,” said Hal Barron, M.D., chief medical officer and head of Global Product Development. “We have spent 20 years researching blood cancer medicines, and we will continue to study Gazyva to assess its efficacy in other types of blood cancers.”

The FDA granted Gazyva Breakthrough Therapy Designation due to the significance of the positive progression-free survival (PFS) results from the Phase III CLL11 trial and the serious and life-threatening nature of CLL.

Today’s FDA approval is based on the outcomes of the CLL11 trial. The trial showed that people who received Gazyva in combination with chlorambucil chemotherapy had significantly reduced risk of disease progression or death (HR=0.16; p<0.0001) and lived significantly longer without their disease getting worse compared to those who received chlorambucil alone (median PFS 23.0 months vs. 11.1 months). The most common Grade 3/4 adverse events for those who received Gazyva in combination with chlorambucil compared to chlorambucil alone were infusion-related reactions during the first infusion (21 percent vs. 0 percent [chlorambucil is an oral medicine]), low platelet count (thrombocytopenia, 11 percent vs. 3 percent)
and low count of certain types of white blood cells (neutropenia, 34 percent vs. 16 percent), though this did not result in an increased rate of infections in the Gazyva arm.

Final data from the CLL11 trial investigating the direct comparison between Gazyva in combination with chlorambucil and MabThera/Rituxan (rituximab) in combination with chlorambucil (Stage 2), will be presented at the American Society of Hematology’s (ASH) 55th Annual Meeting in December 2013.

Marketing applications have also been submitted to other regulatory authorities, including the European Medicines Agency (EMA).

About Chronic Lymphocytic Leukemia (CLL)
CLL is one of the most common forms of blood cancer and in 2013, it is expected that there will be nearly 5,000 deaths from CLL in the United States. Most cases of CLL (95 percent) start in white blood cells called B-cells that have a protein called CD20 on their surface.

About Gazyva
Gazyva is a new monoclonal antibody designed to attach to CD20, a protein found only on B-cells. It attacks targeted cells both directly and together with the body’s immune system.

Gazyva was discovered by Roche Glycart AG, a wholly owned, independent research unit of Roche. In the United States, Gazyva is part of a collaboration between Genentech and Biogen Idec.

Gazyva is now approved in combination with chlorambucil for people with previously untreated chronic lymphocytic leukemia (CLL) and is additionally being investigated in a large clinical programme, including multiple head-to-head Phase III studies compared to MabThera/Rituxan in indolent non-Hodgkin lymphoma (NHL) and diffuse large B-cell lymphoma (DLBCL).

Gazyva Efficacy in CLL
The pivotal Phase III CLL11 trial, conducted in cooperation with the German CLL Study Group (GCLLSG), is a multicentre, open-label, randomised three-arm study investigating the efficacy and safety profile of either Gazyva plus chlorambucil or MabThera/Rituxan plus chlorambucil compared to chlorambucil alone in 781 previously untreated people with CLL and co-existing medical conditions.
The study showed that Gazyva demonstrated a statistically significant 84 percent reduction in the risk of disease worsening or death (PFS; HR=0.16, 95 percent CI 0.11-0.24, p<0.0001) when combined with chlorambucil compared to chlorambucil alone in people with previously untreated CLL and co-existing medical conditions. In the CLL11 study, no new safety signals were detected for Gazyva.

- Gazyva in combination with chlorambucil more than doubled the time people with newly diagnosed CLL lived without their disease getting worse (median PFS: 23.0 vs. 11.1 months).
- 75.9 percent of people responded to Gazyva in combination with chlorambucil (overall response rate, or ORR) compared to 32.1 percent with chlorambucil alone.
- More than a quarter of the people who received Gazyva in combination with chlorambucil achieved a complete response (CR: 27.8 percent vs. 0.9 percent).

**About Roche in hematology**

For more than 20 years, Roche has been developing medicines that redefine treatment in hematology. Today, we’re investing more than ever in our effort to bring innovative treatment options to people with cancers of the blood.

In addition to Gazyva, Roche’s pipeline of potential hematology medicines includes two antibody-drug conjugates (anti-CD79b [RG7596] and anti-CD22 [RG7593]), a small molecule antagonist of MDM2 (RG7112) and in collaboration with AbbVie, a small molecule BCL-2 inhibitor (RG7601/GDC-0199/ABT-199).

**About Roche**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche’s personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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