Basel, 24 July 2013

Roche’s obinutuzumab (GA101) delayed disease progression longer than MabThera/Rituxan in people with one of the most common forms of blood cancer

- Phase III CLL11 study showed GA101 plus chlorambucil, a chemotherapy, was superior to MabThera/Rituxan plus chlorambucil in helping people with previously untreated chronic lymphocytic leukemia live longer without their disease worsening
- Final data from the CLL11 study will be submitted to the American Society of Hematology’s 55th Annual Meeting in December 2013

Roche (SIX: RO, ROG; OTCQX: RHHBY): Roche today announced positive results from the phase III CLL11 study. At a pre-planned interim analysis, an independent data monitoring committee determined that the study met its primary endpoint showing that GA101 plus chlorambucil helped people live significantly longer without their disease worsening (progression-free survival; PFS) compared to MabThera/Rituxan plus chlorambucil. The CLL11 study is being conducted in cooperation with the German CLL Study Group (GCLLSG). These final data were reached well ahead of the target completion date in 2014 as a result of the magnitude of difference seen between the two study arms. No new safety signals for GA101 or MabThera/Rituxan were identified in this analysis, and adverse events were similar to those observed in the first stage of the study which was previously reported earlier this year.

"The positive final results from the CLL11 study show the promise that GA101 could hold for people with CLL," said Hal Barron, M.D., Roche’s Chief Medical Officer and Head, Global Product Development. "It is important to explore the potential of this medicine in other types of blood cancer, and our broad development program includes studies in aggressive and indolent lymphoma that compare GA101 with MabThera/Rituxan."

GA101 is the first type II anti-CD20 medicine that is glycoengineered, which means specific sugar molecules in GA101 were modified to change its interaction with the body’s immune cells. This modification creates a unique antibody that is designed to act as an immunotherapy, engaging the patient’s own immune system to help attack the cancerous cells; in addition, GA101 binds to CD20 with the
aim of inducing direct cell death.

These data will be submitted for consideration to the 55th Annual Meeting of the American Society of Hematology (ASH) in New Orleans, which is taking place December 7-10, 2013.

Based on an earlier analysis (stage 1) of the CLL11 study, marketing applications for GA101 were submitted to regulatory authorities including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) in April, 2013. Due to the significance of the positive trial results and the serious and life threatening nature of CLL, the FDA granted the GA101 application both Breakthrough Therapy Designation and Priority Review.

About obinutuzumab (GA101)
GA101 is the first investigational type II, glycoengineered medicine designed to attack cells that have a certain marker (CD20) on their surface. It attacks targeted cells both directly and together with the body’s immune system. GA101 is currently being investigated in a large clinical program, including multiple head-to-head phase III studies versus MabThera/Rituxan in indolent non-Hodgkin lymphoma (NHL) and diffuse large B-cell lymphoma (DLBCL).

In the U.S., GA101 is being developed and will be commercialized in collaboration with Biogen Idec.

About the CLL11 study
CLL11 is a phase III, multicenter, open-label, randomized three-arm study investigating the efficacy and safety profile of either GA101 plus chlorambucil or MabThera/Rituxan plus chlorambucil compared to chlorambucil alone in 781 previously untreated people with CLL and co-existing medical conditions who are in need of therapy. The study included two stages of analysis.

- Stage 1 included 589 patients and compared GA101 plus chlorambucil to chlorambucil alone and MabThera/Rituxan plus chlorambucil to chlorambucil alone. Stage 1 results were reported earlier this year and showed that GA101 plus chlorambucil doubled the time people lived without their disease worsening 23.0 vs. 10.9 months compared to chlorambucil alone (HR=0.14 CI 0.09-0.21 p<0.0001).
- Stage 2 (announced today) enrolled an additional 192 patients to enable the final direct comparison of GA101 versus MabThera/Rituxan, both in combination with chlorambucil.
The primary endpoint of the study was PFS with secondary endpoints including overall response rate (ORR), overall survival (OS), disease-free survival (DFS), minimal residual disease (MRD) and safety profile.

**About the German CLL Study Group (GCLLSG)**

Founded in 1996 and headed by Dr. Michael Hallek, the GCLLSG has been running various phase III, phase II and phase I trials in CLL with the goal to provide optimal treatment to patients suffering from this disease. Among those were landmark trials like the CLL8 trial which led to the current standard of care in CLL. For many years, GCLLSG has been aiming to improve not just the treatment of younger and physically fit patients, but also that of elderly and less fit patients. These patients are generally underrepresented in clinical trials although they constitute the majority of CLL patients treated by doctors in daily practice. The GCLLSG is an independent non-profit research organization supported by the German Cancer Aid (Deutsche Krebshilfe).

**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 GA101, 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
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