Roche to present new clinical data across a variety of blood diseases at American Society of Hematology 2015 Annual Meeting

- Gazyva/Gazyvaro (obinutuzumab) and investigational medicines venetoclax and ACE910 among medicines to be featured at the meeting
- Gazyva/Gazyvaro marketing applications submitted to health authorities based on GADOLIN study results; priority review granted by U.S. Food and Drug Administration
- Pivotal data for venetoclax in relapsed/refractory 17p deletion chronic lymphocytic leukaemia submitted to the U.S. Food and Drug Administration

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that more than 45 abstracts featuring eight of its approved or investigational medicines will be presented during the 57th American Society of Hematology (ASH) Annual Meeting from December 5-8 in Orlando. The abstracts include more than 15 oral presentations across a broad range of molecular targets and combinations, as well as different clinical endpoints that Roche is exploring in various blood diseases and lines of treatment.

“Our data at ASH this year showcase the evolution of our haematology portfolio and represent potential future approaches to helping people with blood cancers and blood disorders,” said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development. “We’re particularly excited about studies evaluating new combinations with Gazyva/Gazyvaro and venetoclax, as well as studies examining the potential clinical significance of minimal residual disease negativity.”

Data for Gazyva/Gazyvaro include results from combination studies such as the Phase IIIb GREEN study and the pivotal CLL11 and GADOLIN studies. GREEN results will include data for Gazyva/Gazyvaro in combination with bendamustine in previously untreated chronic lymphocytic leukemia (CLL). Roche will also share updated results from the Phase III CLL11 study, which formed the basis of the Gazyva/Gazyvaro approval in previously untreated CLL in combination with chlorambucil, and further data from the pivotal Phase III GADOLIN study for the investigational use of Gazyva/Gazyvaro in patients with indolent non-Hodgkin’s lymphoma (NHL) that is refractory to MabThera/Rituxan (rituximab)-based treatment, that add...
to the positive results presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June this year.

Roche will also present findings from multiple studies that suggest a potential role for minimal residual disease (MRD)-negativity in the treatment of certain blood cancers. In collaboration with AbbVie, Roche will share new data for investigational medicine venetoclax as a monotherapy or in combinations across a number of blood cancers, including CLL, non-Hodgkin’s lymphoma (NHL), multiple myeloma (MM) and acute myeloid leukemia (AML). Data will also be shown for investigational medicine ACE910, which was recently granted breakthrough therapy designation by the U.S. Food and Drug Administration (FDA) for the prophylactic treatment of people who are 12 years or older with haemophilia A with factor VIII inhibitors.

The table below contains key abstracts featuring Roche medicines that will be presented. Follow Roche on Twitter via @Roche and keep up to date with ASH Annual Meeting news and updates by using the hashtag #ASH2015.

Separately, the FDA has accepted for priority review the company’s supplemental Biologics License Application (sBLA) for Gazyva/Gazyvaro in the treatment of patients with follicular lymphoma (FL) who relapsed after, or are refractory to a rituximab-containing regimen, based on GADOLIN study results. Marketing applications for Gazyva/Gazyvaro have also been submitted to other health authorities, including the European Medicines Agency, for approval consideration in the treatment of patients with FL who did not respond or who progressed during or up to 6 months after treatment with rituximab or a rituximab-containing regimen. In addition, AbbVie has submitted a New Drug Application (NDA) for venetoclax to the FDA under breakthrough therapy designation, based in part on results of the pivotal Phase II M13-982 study evaluating venetoclax in people with relapsed/refractory CLL harboring the 17p deletion. Roche and AbbVie announced positive top-line results from this study earlier this year.
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<th>Medicine/topic</th>
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<tr>
<td>Gazyva/Gazyvaro (investigational use)</td>
<td><strong>GREEN</strong>: Safety and Efficacy of Obinutuzumab Plus Bendamustine in Previously Untreated Patients with Chronic Lymphocytic Leukemia: subgroup analysis of the GREEN study</td>
<td>#493 (Oral Presentation) Monday, Dec. 7 7:00 AM ET</td>
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<td><strong>GADOLIN</strong>: Analysis of Minimal Residual Disease in Follicular Lymphoma Patients in GADOLIN, a Phase III Study of Obinutuzumab plus Bendamustine versus Bendamustine in Relapsed/Refractory Indolent Non-Hodgkin Lymphoma</td>
<td>#3978 (Poster discussion) Monday, Dec. 7 6:00-8:00 PM ET</td>
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<td><strong>GADOLIN</strong>: Primary Results of the Health-Related Quality of Life Assessment from the Phase III GADOLIN Study of Obinutuzumab Plus Bendamustine Compared with Bendamustine Alone in Patients with Rituximab-Refractory, Indolent Non-Hodgkin Lymphoma</td>
<td>#1532 (Poster discussion) Saturday, Dec. 5 5:30-7:30 PM ET</td>
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<td>Gazyva/Gazyvaro (approved use)</td>
<td><strong>CLL11</strong>: Updated Survival Analysis from the CLL11 Study: Obinutuzumab Versus Rituximab in Chemoimmunotherapy Treated Patients with Chronic Lymphocytic Leukemia</td>
<td>#1733 (Poster discussion) Saturday, Dec. 5 5:30-7:30 PM ET</td>
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<td>Minimal Residual Disease (MRD)</td>
<td>A Model for Predicting Effect of Treatment on Progression-Free Survival Using Minimal Residual Disease As a Surrogate Endpoint in Chronic Lymphocytic Leukemia</td>
<td>#720 (Oral Presentation) Monday, Dec. 7 4:00 PM ET</td>
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<td>Venetoclax (GDC-0199/ABT-199) (investigational)</td>
<td><strong>GP28331</strong>: Safety and Efficacy of a Combination of Venetoclax (GDC0199/ABT199) and Obinutuzumab in Patients with Relapsed/Refractory or Previously Untreated Chronic Lymphocytic Leukemia Results from a Phase 1b Study (GP28331)</td>
<td>#494 (Oral Presentation) Monday, Dec. 7 7:15 AM ET</td>
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<td><strong>CLL14</strong>: Results of the Safety Run in Phase of CLL14 (BO25323): A Prospective, Open Label, Multicenter Randomized Phase III Trial to Compare the Efficacy and Safety of Obinutuzumab and Venetoclax (GDC0199/ABT199) with Obinutuzumab and Chlorambucil in Patients with Previously Untreated CLL and Coexisting Medical Conditions</td>
<td>#496 (Oral Presentation) Monday, Dec. 7 7:45 AM ET</td>
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<td><strong>M13-365</strong>: Deep and Durable Responses Following Venetoclax (ABT-199 / GDC-0199) Combined with Rituximab in Patients with Relapsed/Refractory Chronic Lymphocytic Leukemia: Results from a Phase 1b Study</td>
<td>#830 (Oral Presentation) Monday, Dec. 7 4:45 PM ET</td>
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**M12-630:** A Dose-Escalation Study of Venetoclax (ABT-199/GDC-0199) in Combination with Bendamustine and Rituximab in Patients with Relapsed or Refractory Non-Hodgkin's Lymphoma

**M14-358:** A Phase 1b Study of Venetoclax (ABT-199/GDC-0199) in Combination with Decitabine or Azacitidine in Treatment-Naive Patients with Acute Myelogenous Leukemia Who Are Greater Than or Equal to 65 Years and Not Eligible for Standard Induction Therapy

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**About Roche in haematology**

For more than 20 years, Roche has been developing medicines that redefine treatment in haematology. Today, we’re investing more than ever in our effort to bring innovative treatment options to people with diseases of the blood. In addition to approved medicines MabThera/Rituxan (rituximab) and Gazyva/Gazyvaro (obinutuzumab), Roche’s pipeline of investigational haematology medicines includes an anti-PDL1 antibody (atezolizumab/MPDL3280A), an anti-CD79b antibody drug conjugate (polatuzumab vedotin/RG7596), a small molecule antagonist of MDM2 (idasanutlin/RG7388) and in collaboration with AbbVie, a small molecule BCL-2 inhibitor (venetoclax/RG7601/GDC-0199/ABT-199). Roche’s dedication to developing novel molecules in haematology expands beyond oncology, with the development of the investigational haemophilia A treatment ACE910.

**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, immunology, infectious diseases, ophthalmology 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 diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.
In 2014, the Roche Group employed 88,500 people worldwide, invested 8.9 billion Swiss francs in R&D and posted sales of 47.5 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 roche.com.

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