Basel, 3 November 2016

Roche showcases new clinical data across a variety of blood diseases at American Society of Hematology 2016 Annual Meeting

- New results from the phase III GALLIUM study which compared Gazyva/Gazyvaro (obinutuzumab) plus chemotherapy to Rituxan/ MabThera (rituximab) plus chemotherapy in previously untreated follicular lymphoma will be presented in the Plenary Scientific Session
- New results for Venclexta/Venclyxto (venetoclax) and investigational medicine emicizumab will also be presented at the meeting
- US FDA has accepted the Biologics License Application for a subcutaneous formulation of Rituxan (rituximab/hyaluronidase)

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that more than 60 abstracts featuring nine of its approved or investigational medicines will be presented during the 58th American Society of Hematology (ASH) Annual Meeting from December 3-6 in San Diego. The abstracts include more than 20 oral presentations across a broad range of medicines and combinations.

“The breadth of data we are presenting at ASH this year reflects our deep commitment to people with blood diseases,” said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development. “We are excited to share the results of the pivotal GALLIUM study in previously untreated follicular lymphoma, which showed that people treated with Gazyva/Gazyvaro plus chemotherapy lived significantly longer without their disease worsening than those treated with Rituxan/MabThera plus chemotherapy.”

The results from the phase III GALLIUM study have been selected for presentation during the Plenary Scientific Session, which honours the top six abstracts submitted to the meeting, as determined by the ASH Program Committee. Results from other studies of Gazyva®/Gazyvaro® will also be presented at the meeting, including an overall survival update from the phase III GADOLIN study in Rituxan®/MabThera®-refractory indolent (slow-growing) non-Hodgkin lymphoma (NHL) and the first results from the phase III GOYA study in previously untreated diffuse large B-cell lymphoma (DLBCL).
Updated results from the phase III SABRINA study comparing subcutaneous and intravenous Rituxan/MabThera in previously untreated follicular lymphoma will be presented. The US Food and Drug Administration (FDA) has accepted the company’s Biologics License Application (BLA) for the subcutaneous formulation of Rituxan, with an action date of June 26, 2017.

Early results will be shared for combinations of Venclexta™/Venclyxto™ with either Gazyva/Gazyvaro or Rituxan/MabThera in chronic lymphocytic leukaemia and certain types of non-Hodgkin lymphoma. Further follow-up from early studies in multiple myeloma and acute myeloid leukaemia that support further investigation of Venclexta/Venclyxto in these diseases will also be presented. Venclexta/Venclyxto is being co-developed by AbbVie and Roche.

The first cohort from a non-interventional study of people with haemophilia will be presented, including real world safety and efficacy data from patients with inhibitors to factor VIII replacement therapy treated with current standard of care according to routine clinical practice. Separately, there are currently three pivotal studies underway to explore the safety and efficacy of emicizumab in the treatment of haemophilia A: a phase III study in people 12 years of age or older with haemophilia A with factor VIII inhibitors investigating weekly dosing; a phase III study in people younger than 12 years of age with factor VIII inhibitors investigating weekly dosing; and a phase III study in people 12 years of age or older without factor VIII inhibitors investigating weekly and every other week dosing.

Key abstracts featuring Roche medicines that will be presented at ASH can be found in the table below.

Follow Roche on Twitter via @Roche and keep up to date with ASH Annual Meeting news and updates by using the hashtag #ASH16.
# Overview of key presentations featuring Roche medicines at ASH 2016

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Abstract title</th>
<th>Abstract number/Presentation details</th>
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| **Gazyva/Gazyvaro**      | Obinutuzumab-Based Induction and Maintenance Prolongs Progression-Free Survival in Patients with Previously Untreated Follicular Lymphoma: Primary Results of the Randomized Phase 3 GALLIUM Study | #6 (Plenary Scientific Session)  
04 Dec 2016  
2.00–4.00pm PT |
|                         | Minimal Residual Disease Assessment in Patients with Follicular Lymphoma Treated with Obinutuzumab or Rituximab as First-Line Induction Immunochemotherapy in the Phase III GALLIUM Study | #613 (Oral presentation)  
05 Dec 2016  
7.00am PT  
(7.00–8.30am PT) |
|                         | Obinutuzumab or Rituximab Plus CHOP in Patients with Previously Untreated Diffuse Large B-Cell Lymphoma: Final Results From an Open Label, Randomized Phase 3 Study (GOYA) | #470 (Oral presentation)  
04 Dec 2016  
4.45pm PT  
(4.30–6.00pm PT) |
| **Gazyva/Gazyvaro**      | Obinutuzumab Plus Bendamustine Followed By Obinutuzumab Maintenance Prolongs Overall Survival Compared With Bendamustine Alone in Patients with Rituximab-Refractory Indolent Non-Hodgkin Lymphoma: Updated Results of the GADOLIN Study | #615 (Oral presentation)  
05 Dec 2016  
7.30am PT  
(7.00–8.30am PT) |
| **Rituxan/MabThera**     | Longer Term Efficacy and Safety of Subcutaneous Compared with Intravenous Rituximab: Updated Results of The Phase III SABRINA Study                                                                               | #1103 (Oral presentation)  
05 Dec 2016  
5.30pm PT  
(4.30–6.00pm PT) |
| **Venclexta/Venclyxto**  | Safety and Efficacy of Venetoclax and Obinutuzumab in Patients with Previously Untreated Chronic Lymphocytic Leukemia (CLL) And Coexisting Medical Conditions: Final Results of The Run-In Phase of the Randomized CLL14 Trial | #2054 (Poster)  
03 Dec 2016  
5.30-7.30pm PT |
|                         | Results of a Phase Ib Study of Venetoclax Plus R- or G-CHOP in Patients with B-cell Non-Hodgkin Lymphoma (CAVALLI)                                                                                             | #3032 (Poster)  
04 Dec 2016  
6.00-8.00pm PT |
|                         | Phase 2 Study of Venetoclax plus Rituximab or Randomized Venetoclax plus                                                                                                                                     | #617 (Oral presentation) |

**Note:** The abstract titles and details are based on the information provided in the image.
<table>
<thead>
<tr>
<th>Title</th>
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<tbody>
<tr>
<td>Bendamustine+Rituximab (BR) versus BR in Patients with Relapsed/Refractory Follicular Lymphoma: Interim Data (CONTRALTO)</td>
<td>05 Dec 2016 8.00am PT (7.00-8.30am PT)</td>
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<tr>
<td>Safety and Efficacy of Venetoclax Plus Low-Dose Cytarabine in Treatment-Naive Patients Aged ≥65 Years with Acute Myeloid Leukemia (M14-387)</td>
<td>#2843 (Oral presentation) 03 Dec. 2016 10:45am PT (9.30–11.00am PT)</td>
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<td><strong>Emicizumab</strong> (investigational)</td>
<td>Bleeding Events and Safety Outcomes in Patients with Hemophilia A with Inhibitors: A Prospective, Multicenter, Non-Interventional Study</td>
<td>#3800 (Poster) 05 Dec 2016 6.00-8.00pm PT</td>
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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 are investing more than ever in our effort to bring innovative treatment options to people with diseases of the blood. In addition to approved medicines Rituxan/MabThera (rituximab), Gazyva/Gazyvaro (obinutuzumab), and Venclexta/Venclyxto (venetoclax) in collaboration with AbbVie, Roche’s pipeline of investigational haematology medicines includes Tecentriq (atezolizumab), an anti-CD79b antibody drug conjugate (polatuzumab vedotin/RG7596) and a small molecule antagonist of MDM2 (idasanutlin/RG7388). Roche’s dedication to developing novel molecules in haematology expands beyond malignancy, with the development of the investigational haemophilia A treatment emicizumab (ACE910).

**About Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives.

Roche is the world’s largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. 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 cancer...
medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. 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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**References**

1 Gazyva is marketed as Gazyvaro in the EU and Switzerland. Genentech, a member of the Roche Group, and Biogen collaborate on Gazyva in the United States.

2 MabThera is marketed as Rituxan in the United States, Japan and Canada. Genentech, a member of the Roche Group, and Biogen collaborate on Rituxan in the United States. Roche markets MabThera in the rest of the world, except Japan, where MabThera is co-marketed by Chugai Pharmaceutical Co., Ltd. and Zenyaku Kogyo Co. Ltd.

3 Emicizumab was created by Chugai Pharmaceutical Co., Ltd. and is being co-developed by Roche.