Investor Update

Basel, 5 November 2015

Roche showcases pharmaceuticals strategy and emerging new medicines

Launches or pivotal data for up to eight new medicines planned in next three years

- Focus on strong pipeline of differentiated medicines across a range of therapeutic areas
- Strategy focused on innovation and advancing treatment in areas of high medical need
- Efficiency initiatives supporting optimal resource use, R&D productivity and commercial reach
- Molecular information an emerging key element in Roche's personalised healthcare strategy

Roche (SIX: RO, ROG; OTCQX: RHHBY) is today providing an update on its late-stage pipeline at an investor event in London, including promising investigational medicines for multiple sclerosis, asthma, haemophilia, eye disease and cancer. In these and other areas, Roche expects as many as seven major read-outs from clinical trials with new molecular entities or line extensions for existing medicines up to the end of 2017, adding to the seven read-outs already achieved in 2015.

"Thanks to our diversified late-stage portfolio we are well positioned to maintain our leadership in oncology, expand further in the immunology and ophthalmology segments, and potentially offer new treatments to help improve the lives of people with multiple sclerosis and haemophilia," said Daniel O'Day, COO of Roche's Pharmaceuticals Division. "And we are looking to harness the vast increase in molecular information as the next important step in our efforts to develop even better, more personalised treatment solutions."

In addition to presenting updates on Roche's most advanced investigational medicines, executives will brief investors and analysts on the company's strategy, R&D productivity, life-cycle management and approach to new market opportunities. Special breakout sessions will offer insights into Roche's haematology portfolio, plans to exploit the growing depth and breadth of molecular information for drug discovery and development, and an assessment of the emerging biosimilar landscape.

The presentations will be available via live video webcast or conference call (details at the end of this release).

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Addressing unmet need in melanoma, lung cancer and multiple sclerosis

Cotellic is currently undergoing regulatory review in the US and Europe for use in combination with Zelboraf for the treatment of BRAF mutation-positive unresectable metastatic melanoma. Decisions by the FDA and EMA are expected in November and December, respectively. Results from a phase III trial announced by Roche and Exelixis in October showed a statistically significant and clinically meaningful increase in overall survival for patients taking Cotellic plus Zelboraf compared to Zelboraf alone.

Alectinib is an investigational oral medicine for ALK-positive non-small cell lung cancer (NSCLC). After granting Breakthrough Therapy Designation in 2013, the FDA accepted Roche's US marketing application in September 2015 for priority review, assigning a decision date in March 2016. Roche also filed an EU marketing application in September. A phase III study is comparing alectinib to crizotinib as initial treatment for advanced NSCLC identified as ALK-positive by a companion diagnostic test being developed by Roche.

Ocrelizumab is the first investigational medicine to show positive results in both primary progressive and relapsing forms of multiple sclerosis (PPMS, RMS). Based on pivotal study results, ocrelizumab has the potential to change the way MS is treated. Roche plans to submit data to global regulatory authorities in early 2016 to obtain marketing authorisation for ocrelizumab as a potential new treatment for RMS and first approved treatment for PPMS.

Cancer immunotherapy – preparing a multipronged attack on tumours

Roche's industry-leading cancer immunotherapy pipeline currently includes eight new molecular entities and some 30 combinations of immunotherapies and targeted cancer medicines being tested in clinical trials.

Atezolizumab is an investigational monoclonal antibody designed to interfere with PD-L1, a protein expressed on tumour cells and tumour-infiltrating immune cells, preventing it from binding to PD-1 and B7.1 on the surface of T cells. By inhibiting PD-L1, atezolizumab may enable the activation of T cells, restoring their ability to detect and attack tumour cells. Roche has initiated a rolling FDA filing for atezolizumab and expects to finalise the data submissions from its phase II trials in the first quarter of 2016 under Breakthrough Therapy Designations for certain types of metastatic bladder and lung cancer. Roche currently has several ongoing phase III studies of atezolizumab alone or in combination with other medicines for various types of lung, bladder, kidney and breast cancer. All studies include the evaluation of a companion test developed by Roche Diagnostics to determine PD-L1 status.

Atezolizumab plus chemotherapy: Based on encouraging early-stage

results, Roche is conducting a number of randomised phase III studies to evaluate the benefit of atezolizumab when added to standard chemotherapy in first-line NSCLC. First results are expected in 2017.

Atezolizumab combined with targeted therapies or other cancer immunotherapy agents: Roche is also investigating the potential benefit of combining atezolizumab with targeted medicines such as Avastin, Zelboraf, Cotellic, Tarceva, alectinib or Gazyva, as well as with other cancer immunotherapy agents such as anti-CD40, anti-CSF-1R, anti-OX40, IDO inhibitors or anti-CEA-IL2v FP in a range of cancers.

Aiming for treatment advances for blood cancers, asthma, haemophilia and age-related vision loss

Gazyva/Gazyvaro (obinutuzumab), a glycoengineered monoclonal antibody that binds to CD20 (a protein found only on B cells), is designed to attack and destroy targeted B cells directly and together with the immune system. It is currently approved in more than 50 countries in combination with chlorambucil for previously untreated chronic lymphocytic leukaemia. In October the US FDA accepted for priority review Roche's supplemental Biologic License Application for Gazyva in the treatment of patients with follicular lymphoma who relapsed after or are refractory to a rituximab-containing regimen, based on results of the phase III GADOLIN study.

Venetoclax is a small-molecule Bcl-2 inhibitor designed to interfere with a process some cancer cells use to survive, thereby promoting programmed cell death, or apoptosis. Ongoing phase II and III studies are investigating venetoclax alone and in combination with other medicines in certain types of chronic lymphocytic leukaemia (CLL), non-Hodgkin's lymphoma, acute myelogenous leukaemia and multiple myeloma. Earlier this year the US FDA awarded breakthrough designation for venetoclax in the treatment of relapsed or refractory CLL with 17p deletion. Roche's partner AbbVie has completed a submission to the US FDA for approval of venetoclax, based on the results of a positive phase II trial; AbbVie also plans to submit these data to the EMA and other regulatory authorities around the world for approval consideration.

Lebrikizumab is a first-in-class anti-IL-13 monoclonal antibody under investigation for the treatment of severe uncontrolled asthma. Lebrikizumab has been shown in phase II studies to significantly reduce asthma exacerbation rates and improve lung function in patients with high levels of the biomarker periostin. Phase III trial results are expected in the first half of 2016, with global filings planned soon after. Roche is also investigating lebrikizumab as a potential treatment for other types of lung disease and atopic dermatitis.

ACE910 (factor IXa/X biMAb) is an investigational bispecific antibody specifically engineered to support the interaction between factors IXa and X and hence mimic factor VIII, a protein essential to blood clotting. It is

being developed for use in people with haemophilia A, irrespective of inhibitor status. Following encouraging phase I results, Roche plans to initiate a phase III trial of ACE910 in patients with factor VIII inhibitors by the end of 2015, a phase III trial in patients without inhibitors in 2016, and a study in paediatric patients (0–12 years) in 2016.

Lampalizumab (anti-Factor D Fab) is a selective inhibitor of complement-mediated inflammation. It is potentially the first disease-modifying therapy for geographic atrophy (GA), an advanced form of age-related macular degeneration. There are currently no effective therapies approved for GA, a significant cause of irreversible vision loss and blindness in the elderly. A phase II study with lampalizumab was the first to show efficacy in reducing the progression of retinal cell death in GA. Patient recruitment for a phase III program is on track. In addition to efficacy and safety, the studies are assessing the prognostic and predictive roles of a complement factor I profile biomarker. Results are expected in 2017. The US FDA has granted fast-track status to lampalizumab for the treatment of GA secondary to age-related macular degeneration.

Participants at the event are also being briefed on Roche's ongoing efficiency initiatives in areas such as clinical development, pharmaceutical production and commercialisation, part of the Group's commitment to optimising use of resources. One result of these efforts has been a doubling of the number of projects in late-stage clinical development since 2010, with no increase in development spend.

Roche experts will also explain the challenges and opportunities of molecular information and its emerging role in drug development, diagnosis, patient selection and treatment monitoring. A key part of Roche's R&D is directed towards developing new techniques and platforms that can exploit the wealth of molecular data now becoming available in clinical trials and real-world treatment settings. The aim is to use these increasingly detailed data in research and development to help select drug targets and develop new medicines. Molecular information will increasingly be used in routine clinical practice to match patients to the most appropriate treatment and monitor their progress on therapy.

Partners and collaborations

- Cotellic (cobimetinib) is being developed in collaboration with Exelixis.
- Zelboraf (vemurafenib) is developed in collaboration with Plexxikon, a member of the Daiichi Sankyo Group.
- Alectinib (RG7853) is being developed in collaboration with Chugai, a member of the Roche Group.
- Venetoclax (Bcl-2 inhibitor, GDC-0199, RG7601) is being developed in collaboration with AbbVie.
- ACE910 (RG6013) is being co-developed with Chugai, a member of the Roche Group.

Roche Pharma Day presentations – live video webcast and conference call

The Roche Pharma Day takes place in London today. Further details are available › here. Presentations will be held in the morning, starting at 10:30 a.m. GMT and are publicly available via live video webcast at ⧉ http://ir.roche.com. Alternatively, you may dial in to the conference 10–15 min prior to the scheduled start, using the following numbers (listen-only mode, no live-access to speakers):
+41 (0) 58 310 5000 (Europe and ROW)
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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 www.roche.com.

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