Basel, 31 August 2017

Roche to present new data from its oncology portfolio at the 2017 European Society for Medical Oncology (ESMO) Congress

- Data from 18 approved and investigational cancer medicines to be presented at ESMO 2017
- Results for Zelboraf (vemurafenib) as an adjuvant treatment for BRAF V600 mutation-positive melanoma to feature in the ESMO Presidential Symposium
- New data from phase III ALEX and ALUR studies provide additional evidence supporting the use of Alecensa (alectinib) for people with ALK-positive non-small cell lung cancer (NSCLC)
- Multiple clinical, biomarker and real-world data studies across a range of tumour types enhance understanding of cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new results from a number of studies across 18 approved and investigational medicines will be presented during the European Society for Medical Oncology (ESMO) Congress from 8-12 September in Madrid, Spain. These include phase III results from Roche’s targeted medicines portfolio, including Zelboraf® and Alecensa®, updates from our cancer immunotherapy development programme across multiple tumour types and important new insights into the biology of cancer that will help further our understanding of this highly complex disease.

“Progress against cancer is accelerating as our understanding of the disease is enhanced by more sophisticated diagnostics, leading to increasingly tailored treatment approaches,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Continuing this progress will require both incremental and ground-breaking advancements as we collectively pursue cures for the many types of this incredibly complex disease. At ESMO, we are proud to share data from across our broad cancer programme and we look ahead to an unprecedented number of key milestones over the next 12 months.”

First results from the phase III BRIM8 study of Zelboraf for adjuvant (after surgery) treatment of BRAF V600 mutation-positive melanoma will be presented during ESMO’s Presidential Symposium on Monday 11 September 2017.
Additional highlights from the Roche oncology portfolio include new data from the phase III ALEX study investigating Alecensa in anaplastic lymphoma kinase (ALK)-positive NSCLC in the first-line setting. These new data further characterise the impact of Alecensa treatment on lung cancer that has the potential to, or has, spread to the central nervous system, building on the study’s positive primary results that were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting earlier this year. In addition, Roche will present new results from the phase III ALUR study of Alecensa in ALK-positive advanced NSCLC that compared Alecensa to chemotherapy in people who had been previously treated with chemotherapy as well as crizotinib.

Results from the phase II LORELEI study\(^1\) evaluating neoadjuvant (pre-surgery) use of taselisib in HER2-negative/oestrogen receptor (ER)-positive early breast cancer will provide additional insights into the potential role of PI3K inhibition in HER2-negative/ER-positive disease. These data from BRIM8, ALEX, ALUR, and LORELEI are included in the official ESMO press programme.

Roche will also present updates on the progress made in the understanding of the biology and immunology of cancer, including data generated in collaboration with Foundation Medicine. At ESMO, data will be presented for the first time for a blood-based assay that is used to measure tumour mutational burden (TMB). Measuring TMB by comprehensive genomic profiling summarises how many mutations are present in a person’s tumour and may be a way to predict responses to certain cancer immunotherapies. The validation study being presented at ESMO was conducted using samples from the phase II POPLAR and phase III OAK studies of TECENTRIQ\(^\circledR\) (atezolizumab) and provides initial, retrospective evidence of an association between TMB in the blood (bTMB) and TECENTRIQ activity. These early data will inform ongoing and future prospective research to better understand the role of both TMB and bTMB as it relates to treatment with cancer immunotherapy.

Follow Roche on Twitter via @Roche and keep up to date with ESMO 2017 congress news and updates by using the hashtag #ESMO17.

For more information on Roche’s approach to cancer, visit Roche.com.

\(^1\) LORELEI is conducted in collaboration with the Breast International Group (BIG), the Austrian Breast & Colorectal Cancer Study Group (ABCSG) and the SOLTI Breast Cancer Research Group.
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<th>Medicine</th>
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<td>Alecensa (alectinib) <em>(investigational use)</em></td>
<td>Primary results from the phase III ALUR study of alectinib versus chemotherapy in previously treated ALK + non-small-cell lung cancer (NSCLC)</td>
<td>Abstract 1299O_PR (oral) Monday 11 September 09:15 – 10:45 CEST</td>
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<td>Alecensa (alectinib) <em>(investigational use)</em></td>
<td>Alectinib vs crizotinib in treatment-naïve ALK+ NSCLC: CNS efficacy results from the ALEX study</td>
<td>Abstract 1298O_PR (oral) Monday 11 September 09:15 – 10:45 CEST</td>
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<td>Alecensa (alectinib) <em>(investigational use)</em></td>
<td>CNS efficacy results from the phase III ALUR study of alectinib vs chemotherapy in previously treated ALK+ NSCLC</td>
<td>Abstract 1346P (poster) Saturday 9 September 13:15 – 14:15 CEST</td>
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<td>CEA-TCB <em>(investigational use)</em></td>
<td>Phase I studies of the novel carcinoembryonic antigen T-cell bispecific (CEA-CD3 TCB) antibody as a single agent and in combination with atezolizumab: Preliminary efficacy and safety in patients (pts) with metastatic colorectal cancer (mCRC)</td>
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<td>Perjeta and Herceptin (pertuzumab and trastuzumab) <em>(investigational use)</em></td>
<td>Pertuzumab (P) + trastuzumab (H) + chemotherapy (CT) for HER2-positive metastatic gastric or gastro-oesophageal junction cancer (mGC/GEJC): Final analysis of a Phase III study (JACOB)</td>
<td>Abstract 616O (oral) Friday 8 September 14:00 – 15:30 CEST</td>
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<td>Taselisib <em>(investigational use)</em></td>
<td>Primary results of LORELEI: a phase II randomized, double-blind study of neoadjuvant letrozole (LET) plus tasielsib versus LET plus placebo (PLA) in postmenopausal patients (pts) with ER+/HER2-negative early breast cancer (EBC)</td>
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<td>TECENTRIQ (atezolizumab) <em>(investigational use)</em></td>
<td>Long-term safety and clinical outcomes of atezolizumab in head and neck cancer: Phase Ia trial results</td>
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<td>TECENTRIQ (atezolizumab)</td>
<td>Clinical efficacy of atezolizumab (Atezo) in PD-L1 subgroups defined by SP142 and 22C3 IHC assays in 2L+ NSCLC: Results from the randomized OAK study</td>
<td>Abstract 1296O (oral) Friday 8 September 16:00 – 17:30 CEST</td>
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<td>TECENTRIQ (atezolizumab)</td>
<td>IMMmotion150: Novel radiological endpoints and updated data from a randomized phase II trial investigating atezolizumab (atezo) with or without bevacizumab (bev) vs sunitinib (sun) in untreated metastatic renal cell carcinoma (mRCC)</td>
<td>Abstract LBA39 (poster discussion) Sunday 10 September 14:45 – 16:15 CEST</td>
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**Zelboraf (vemurafenib) (investigational use)**

**BRIM8**: a randomized, double-blind, placebo-controlled study of adjuvant vemurafenib in patients (pts) with completely resected, BRAFV600+ melanoma at high risk for recurrence

**Presidential Symposium Abstract LBA7_PR**
Monday 11 September 16:30 – 17:45 CEST

**Foundation Medicine**

Blood-based biomarkers for cancer immunotherapy: Tumor mutational burden in blood (bTMB) is associated with improved atezolizumab (atezo) efficacy in 2L+ NSCLC (POPLAR and OAK)

**Abstract 1295O (oral)**
Friday 8 September 16:00 – 17:30 CEST

**Foundation Medicine**

Analytic validation of a next generation sequencing assay to identify tumor mutational burden from blood (bTMB) to support investigation of an anti-PD-L1 agent, atezolizumab, in a first line non-small cell lung cancer trial (BFAST)

**Abstract 102P (poster)**
Monday 11 September 13:15 – 14:15 CEST

**Real World Data**

Real-world treatment patterns and outcomes among elderly metastatic triple negative breast cancer patients in the United States

**Abstract 277P (poster)**
Monday 11 September 13:15 – 14:15 CEST

**Real World Data**

Real-world survival outcomes in patients with advanced urothelial cancer in Germany

**Abstract 1117P (poster)**
Sunday 10 September 13:15 – 14:15 CEST

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**About Roche in Oncology**

Roche has been working to transform cancer care for more than 50 years, bringing the first specifically designed anti-cancer chemotherapy drug, fluorouracil, to patients in 1962. Roche’s commitment to developing innovative medicines and diagnostics for cancers remains steadfast.

The Roche Group’s portfolio of innovative cancer medicines includes: Alecensa® (alectinib); Avastin® (bevacizumab); Cotellic® (cobimetinib); Erivedge® (vismodegib); Gazyva®/Gazyvaro® (obinutuzumab); Herceptin® (trastuzumab); Kadcyla® (trastuzumab emtansine); MabThera®/Rituxan® (rituximab); Perjeta® (pertuzumab); Tarceva® (erlotinib); TECENTRIQ® (atezolizumab); Venclexta®/Venclyxto™ (venetoclax); Xeloda® (capecitabine); Zelboraf® (vemurafenib). Furthermore, the Roche Group has a robust investigational oncology pipeline focusing on new therapeutic targets and novel combination strategies.

In addition to Roche's innovative portfolio of cancer medicines, Roche is constantly developing new diagnostic tests that will have a significant impact on disease management for cancer patients. Within the Roche Group there are more than 350 pharmaceutical and diagnostic collaborations, far more than half of which are in the field of oncology.
With a broad portfolio of tumour markers for prostate, colorectal, liver, ovarian, breast, stomach, pancreatic and lung cancer, as well as a range of tissue and molecular oncology tests that contribute to personalised cancer care today, Roche is leading a new era of innovation in the fight against cancer.

**About Roche**

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

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. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. Thirty 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 eight years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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](http://www.roche.com).

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