Roche to present new positive data from its broad cancer immunotherapy programme and across a wide range of cancers at the European Society for Medical Oncology (ESMO) 2018 Congress

- First positive Phase III study results for a cancer immunotherapy combination in breast cancer, with Tecentriq plus nab-paclitaxel
- Positive data for both Alecensa in lung cancer and Tecentriq in lung and liver cancers
- New pivotal results from the tumour-agnostic entrectinib study across a broad range of cancer types for people whose tumours have been identified as NTRK gene fusion-positive

Basel, 9 October 2018 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new results from a number of studies across its industry leading oncology portfolio of approved and investigational medicines will be presented at the European Society for Medical Oncology (ESMO) 2018 Congress, taking place from 19-23 October, in Munich, Germany. These data include positive Phase III results from Roche’s cancer immunotherapy development programme across multiple tumour types, positive Alecensa® (alectinib) data from the Phase III ALESIA study and new pivotal data for entrectinib, a tumour-agnostic investigational medicine that targets NTRK gene fusion-positive solid tumours.

“We look forward to presenting the first positive Phase III study of a cancer immunotherapy combination in breast cancer, which showed encouraging results for Tecentriq plus nab-paclitaxel in people with metastatic triple-negative breast cancer, specifically in the PD-L1-positive population,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We will also share new data from our pivotal analysis of entrectinib for people with NTRK gene fusion-positive solid tumours, an example of our continued commitment to developing next-generation personalised treatments.”

An audio webcast for analysts and investors to discuss key data presented on the Roche Group’s oncology portfolio and pipeline during the ESMO 2018 Congress in Munich, will be held on Monday 22 October 2018 from 6:00 - 7:15 pm CEST. Further details are available here.

Follow Roche on Twitter via @Roche and keep up to date with ESMO 2018 Congress news and updates by using the hashtag #ESMO18.

Key Presentations

Breast cancer:
Primary results will be presented from the positive, Phase III, randomised IMpassion130 study investigating Tecentriq® (atezolizumab) plus chemotherapy (Abraxane® [albumin-bound paclitaxel; nab-paclitaxel]) as an initial (first-line) treatment for people with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC), an aggressive type of the disease which currently has limited treatment options. Abstract LBA1_PR (Presidential Symposium 1) Saturday, 20 October, 16:30 -16:45 CEST: Hall A2 – Room 18
As reported earlier this year by Roche, the combination of Tecentriq plus chemotherapy (nab-paclitaxel) significantly reduced the risk of disease worsening or death (progression-free survival, PFS) in the intention-to-treat and the PD-L1-positive populations, and showed an encouraging overall survival (OS) improvement at this interim analysis in people whose disease expresses the PD-L1 protein, a subgroup determined by PD-L1 biomarker testing.

Data from the IMpassion130 study will also be featured as part of ESMO’s press programme on Saturday, 20 October.

**Tumour-agnostic:**
Pivotal data from the positive Phase II STARTRK-2, Phase I STARTRK-1 and Phase I ALKA trials will be presented on entrectinib (RXDX-101) for the treatment of people with NTRK gene fusion-positive solid tumours. *Abstract LBA17 (oral) – Sunday, 21 October, 11:24 – 11:36 CEST: Hall B3 – Room 22*

Molecular profiling and next-generation sequencing will play a critical role in identifying people most likely to benefit from entrectinib. Roche is combining comprehensive genomic profiling with precision medicines, like entrectinib, in order to offer patients more personalised healthcare solutions.

Entrectinib has been granted Breakthrough Therapy Designation (BTD) by the US Food and Drug Administration (FDA); Priority Medicines (PRIME) designation by the European Medicines Agency (EMA); and Sakigake Designation by the Japan Ministry of Health, Labour and Welfare for the treatment of NTRK gene fusion-positive, locally advanced or metastatic solid tumours in adult and paediatric patients who have either progressed following prior therapies or have no acceptable standard therapies.

**Lung cancer:**
Key data to be presented at ESMO cover advances from Roche’s lung cancer programme, including a combination approach using the cancer immunotherapy Tecentriq with targeted therapies and a range of different chemotherapies.

OS and PFS data will be presented for the first time from the positive Phase III IMPower130 study, a multicentre, open-label, randomised study evaluating the efficacy and safety of Tecentriq in combination with chemotherapy (carboplatin and nab-paclitaxel) versus chemotherapy (carboplatin and nab-paclitaxel) alone for advanced non-squamous non-small cell lung cancer (NSCLC). *Abstract LBA53 (oral) – Monday, 22 October, 09:15 – 09:30 CEST: Hall A1 – Room 17*

PFS data will also be presented for the first time from the positive Phase III ALESIA study, a randomised, multicentre, open-label study evaluating the efficacy and safety of Alecensa versus crizotinib in Asian patients with treatment-naïve anaplastic lymphoma kinase (ALK)-positive advanced NSCLC. *Abstract LBA10 (Presidential Symposium 3) – Monday, 22 October, 17:30-17:45 CEST: Hall A2 – Room 18*
Liver cancer:
Updated data will be presented from a Phase Ib study assessing the safety and clinical activity of the combination of Tecentriq and Avastin® as treatment for patients with unresectable or advanced hepatocellular carcinoma (HCC). HCC is an aggressive cancer with limited treatment options and a major cause of cancer deaths worldwide. Earlier this summer the US FDA granted BTD for Tecentriq in combination with Avastin as an initial (first-line) treatment for people with advanced or metastatic HCC. Data at ESMO include longer follow-up and data from patients with hepatitis B virus, a major driver of the disease. Abstract LBA26 (oral) – Sunday, 21 October, 11:54 – 12:09 CEST; Hall A1 – Room 17

Overview of key data featuring Roche medicines at ESMO 2018

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<tr>
<th>Tumour</th>
<th>Abstract title</th>
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<tr>
<td>Breast</td>
<td>IMpassion130: Results from a global, randomised, double-blind, phase 3 study of atezolizumab (atezo) + nab-paclitaxel (nab-P) vs placebo + nab-P in treatment-naive, locally advanced or metastatic triple-negative breast cancer (mTNBC)</td>
<td>Abstract LBA1_PR (Presidential Symposium) Saturday, 20 October 16:30 – 16:45 CEST Hall A2 – Room 18</td>
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<td>Subcutaneous trastuzumab (H SC) with intravenous pertuzumab (P IV) and docetaxel (D IV) in HER2-positive advanced breast cancer (BC): MetaPHER second interim analysis</td>
<td>Abstract 323P (Poster) Monday, 22 October 12:45 – 13:45 CEST Hall A3 – Poster Area</td>
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<td>Pan-cancer assessment of BRCA1/2 genomic alterations (GAs) by comprehensive genomic profiling (CGP) of tissue and circulating tumor DNA (ctDNA)</td>
<td>Abstract 51O (Oral) Saturday, 20 October 09:54 – 10:06 CEST ICM – Room 14b</td>
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<td>Clinical and analytical validation of an FDA approved comprehensive genomic profiling (CGP) assay incorporating multiple companion diagnostics for targeted and immunotherapies</td>
<td>Abstract 79P (Poster) Saturday, 20 October 12:30 – 13:30 CEST Hall A3 – Poster Area</td>
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<td>Lung</td>
<td>IMpower130: Progression-free survival (PFS) and safety analysis from a randomised phase 3 study of carboplatin + nab-paclitaxel (CnP) with or without atezolizumab (atezo) as first-line (1L) therapy in advanced non-squamous NSCLC</td>
<td>Abstract LBA53 (Oral) Monday, 22 October 09:15 – 09:30 CEST Hall A1 – Room 17</td>
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<td>Primary results of ALESIA: A randomised, phase III, open-label study of alectinib vs crizotinib in Asian patients with treatment-naive ALK+</td>
<td>Abstract LBA10 (Presidential Symposium) Monday, 22 October</td>
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| advanced NSCLC| IMpower132: efficacy of atezolizumab (atezo) + carboplatin (carbo)/cisplatin (cis) + pemetrexed (pem) as 1L treatment in key subgroups with stage IV non-squamous non-small cell lung cancer (NSCLC) | 17:30 – 17:45 CEST  
Hall A2 – Room 18  
Abstract LBA54 (Oral)  
Monday, 22 October  
09:30 – 09:45 CEST  
Hall A1 – Room 17 |
|               | IMpower131: Progression-free survival (PFS) and overall survival (OS) analysis of a randomised Phase III study of atezolizumab + carboplatin + paclitaxel or nab-paclitaxel vs carboplatin + nab-paclitaxel in 1L advanced squamous NSCLC |  
Abstract LBA555 (Oral)  
Monday, 22 October  
09:45 – 10:00 CEST  
Hall A1 – Room 17 |
|               | IMpower150: clinical safety, tolerability and immune-related adverse events in a Phase III study of atezolizumab (atezo) + chemotherapy (chemo) ± bevacizumab (bev) vs chemo + bev in 1L nonsquamous NSCLC |  
Abstract 1386PD (Poster Discussion)  
Sunday, 21 October  
16:45 – 17:45 CEST  
ICM – Room 13 |
|               | Analytic validation of tumor mutational burden as a companion diagnostic for combination immunotherapy in non-small cell lung cancer |  
Abstract 56PD (Poster Discussion)  
Saturday, 20 October  
15:00 CEST  
Hall B4 – Room 19 |
| Kidney        | IMmotion151: molecular correlates differentiate response to atezolizumab (atezo) + bevacizumab (bev) vs sunitinib (sun) in untreated metastatic renal cell carcinoma (mRCC) |  
Abstract LBA31 (Oral)  
Saturday, 20 October  
09:15 – 09:27 CEST  
Hall A1 – Room 17 |
|               | Safety and tolerability of atezolizumab (atezo) plus bevacizumab (bev) vs sunitinib (sun) in untreated metastatic renal cell carcinoma (mRCC): pooled analysis of IMmotion150 and IMmotion151 |  
Abstract 873P (Poster)  
Monday, 22 October  
12:45 – 13:45 CEST  
Hall A3 – Poster Area |
| Liver         | Updated safety and clinical activity results from a Phase Ib study of atezolizumab + bevacizumab in hepatocellular carcinoma (HCC) |  
Abstract LBA26 (Oral)  
Sunday, 21 October  
11:54 – 12:09 CEST  
Hall A1 – Room 17 |
| Biomarkers    | Primary efficacy results from B-FIRST, a prospective Phase II trial evaluating blood-based tumour mutational burden (bTMB) as a predictive biomarker for atezolizumab (atezo) in 1L non-small cell lung cancer (NSCLC) |  
Abstract LBA55 (Oral)  
Monday, 22 October  
09:45 – 10:00 CEST  
Hall A1 – Room 17 |
| Colorectal    | Fluoropyrimidine (FP) + bevacizumab (BEV) + atezolizumab vs FP/BEV in BRAFwt metastatic |  
Abstract LBA19 (Oral)  
Monday, 22 October |
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<td>colorectal cancer (mCRC): Findings from Cohort 2 of MODUL – a multicentre, randomized trial of biomarker-driven maintenance treatment following first-line induction therapy</td>
<td>09:27 – 09:39 CEST Hall A2 – Room 18</td>
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<td>Bladder</td>
<td>A phase II study investigating the safety and efficacy of neoadjuvent atezolizumab in muscle invasive bladder cancer (ABACUS) (Investigator initiated study)</td>
<td>Abstract 899P (Poster) Monday, 22 October 12:45 – 13:45 CEST Hall A3 – Poster Area</td>
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<td>Biological features and clinical outcomes in atezolizumab (atezo)-treated patients (pts) with metastatic urothelial cancer (mUC) of the upper vs lower urinary tract (UTUC vs LTUC)</td>
<td>Abstract 902P (Poster) Monday, 22 October 12:45 – 13:45 CEST Hall A3 – Poster Area</td>
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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); Cotellie® (cobimetinib); Erivedge® (vismodegib); Gazyva®/Gazyvaro® (obinutuzumab); Herceptin® (trastuzumab); Kadcyla® (trastuzumab emtansine); MabThera®/Rituxan® (rituximab); Perjeta® (pertuzumab); Tarceva® (erlotinib); Tecentriq® (atezolizumab); Venclaxta®/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.

For more information on Roche’s approach to cancer, visit [Roche.com](http://Roche.com).

**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. Moreover, for the tenth consecutive year, Roche has been recognised as
the most sustainable company in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2017 employed about 94,000 people worldwide. In 2017, Roche invested CHF 10.4 billion in R&D and posted sales of CHF 53.3 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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