# *Media & Investor Release*

## Roche to present a broad range of data across multiple cancer types at the ESMO Virtual Congress 2020

- **New and updated data from across our broad cancer portfolio including phase III results in breast, lung and prostate cancers**
- **New integrated analyses from our tumour agnostic Rozlytrek® (entrectinib) clinical development programme**
- **Blueprint Medicines will present new data from the registrational phase I/II ARROW trial, investigating Gavreto™ (pralsetinib) for the treatment of people with RET-mutant medullary thyroid cancer**
- **Impact of COVID-19 on cancer care: Roche live virtual panel discussions and Q&As featuring world leading healthcare experts**

Basel, 17 September 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that results from a number of studies across its broad oncology portfolio will be presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020, which will be held 19-21 September, 2020. Results include data from three phase III studies across the Tecentriq® (atezolizumab) triple-negative breast cancer (TNBC) programme. Central nervous system (CNS) efficacy data from integrated analyses of the pivotal phase II Rozlytrek® STARTRK-2, phase I STARTRK-1, and phase I ALKA-372-001 trials will be presented in addition to results from the registrational phase I/II ARROW trial, investigating Gavreto™ for the treatment of people with advanced, RET-mutant medullary thyroid cancer (MTC). Data from the phase III IPATential150 study in patients with metastatic castration-resistant prostate cancer (mCRPC) and whose tumours had PTEN loss will also be shared.

Roche will also be hosting a live roundtable discussion that will focus on COVID-19 and the impact it may have on the outcomes for cancer patients. The discussion will focus on potential solutions and what lessons have been learned from the pandemic so far. Two additional sessions will look into pandemic-related lessons learned with regards to the integration of technology into patient management and the impact of digital tumour board solutions on multidisciplinary meetings.

“Our commitment to transforming the outcomes of people living with cancer remains steadfast, so we are proud to be presenting data at this year’s congress that advances the scientific understanding of multiple complex diseases,” said Levi Garraway, M.D., Ph.D. Roche's Chief Medical Officer and Head of Global Product Development. “As a direct result of the pandemic, many countries are reporting a disruption to cancer care which could potentially result in the premature deaths of tens of thousands of cancer patients. Therefore, we must work together to ensure that we do not swap one health crisis for another: cancer patients simply cannot afford to wait.”

**F. Hoffmann-La Roche Ltd** 4070 Basel Switzerland
Group Communications Roche Group Media Relations
Tel. +41 61 688 88 88 www.roche.com

The pandemic has accelerated the need for collaboration among all stakeholders involved in cancer care to address key gaps and challenges that require urgent action by governments and policy makers. To discuss these issues and call for a course correction for all cancer care services, a live virtual panel discussion and Q&A featuring leading experts from medical societies, academia and the patient group community, will take place on Tuesday 22 September 2020, 15:00 CEST. Join this event on Roche's LinkedIn page here. Two additional sessions will look into related topics in the context of treatment decision making. In the first session, insights will be shared by Italian experts on how the pandemic has affected cancer care and how digital solutions helped them to continue shared decision making remotely. Sign up here for the session on Saturday, 19 September, 16:00-16:30 CEST. The second talk illustrates challenges faced by multidisciplinary teams when convening tumour boards and their real-world experience with a digital tumour board solution in the pandemic. Sign up here for the session on Saturday, 19 September, 16:30-17:00 CEST.

**Roche highlights featured at ESMO Virtual Congress 2020**

**Breast cancer portfolio**
At ESMO, results from recent studies across the Tecentriq TNBC programme (both early and metastatic TNBC) will be presented, including final OS analysis from the phase III IMpassion130 study (Tecentriq in combination with nab-paclitaxel [Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound)] in mTNBC)], results from the IMpassion031 study (Tecentriq in combination with nab-paclitaxel [Abraxane, albumin-bound paclitaxel; nab-paclitaxel; followed by doxorubicin and cyclophosphamide] in the early TNBC setting), and results from the phase III IMpassion131 study (Tecentriq in combination with paclitaxel in mTNBC).

In HER2-positive breast cancer, results will highlight our focus on improving patients' experience of cancer treatment, looking beyond efficacy outcomes and focusing on more flexible treatment solutions. Data from the phase II PHranceSCa study show the majority of patients prefer treatment with Phesgo™, a subcutaneous (SC) fixed-dose combination of Perjeta® (pertuzumab) and Herceptin® (trastuzumab), compared to standard intravenous formulations. Phesgo was recently approved by the U.S. Food and Drug Administration, about four months earlier than anticipated, for the treatment of early and metastatic HER2-positive breast cancer. Based on the decision of the treating physician and the preference of the patient, it can be administered by a healthcare professional in a treatment centre or in a patient's home.

Data will also be presented for two of our investigational hormone receptor (HR)-positive breast cancer treatments, both of which target the PI3K/AKT signalling pathway, a key driver of cancer cell growth and proliferation. GDC-0077 is our next generation investigational PI3Kα-selective inhibitor and mutant PI3Kα degrader designed to inhibit the growth of tumour cells that have mutations in the *PIK3CA* gene. We will present PI3K pathway biomarker and clinical response data from a phase I/Ib study of GDC-0077 and announce the design of an ongoing phase III study evaluating GDC-0077 in HR-positive, HER2-negative advanced breast cancer. In addition, results will be shared from phase III IPATunity130 cohort B assessing ipatasertib in combination with paclitaxel in patients with *PIK3CA/AKT1/PTEN*-altered HR-positive advanced breast cancer.

**Tecentriq in lung cancer**
Results from an exploratory analysis of characterisation of long-term survivors (LTS), defined in the study as people who survived for longer than 18 months following randomisation, in the IMpower133 trial will be presented in a mini-oral session. The study previously showed that Tecentriq in combination with chemotherapy helped people with extensive-stage small cell lung cancer (ES-SCLC) live significantly longer compared with chemotherapy alone. SCLC is distinguished from other lung cancer subtypes due to its aggressive nature, rapid growth and early development of metastatic disease.

In addition, four-year survival data from the phase II POPLAR and phase III OAK studies, investigating Tecentriq vs docetaxel (chemotherapy) in patients with advanced pre-treated non-small cell lung cancer (NSCLC) will be presented.

**Tumour-agnostic data**
Two sets of CNS efficacy data from integrated analyses of the pivotal phase II STARTRK-2, phase I STARTRK-1, and phase I ALKA-372-001 trials will be presented, including a poster presentation evaluating the efficacy of Rozlytrek in patients with NTRK or ROS1 fusion-positive NSCLC, who have CNS metastases at baseline; and an oral presentation evaluating the intracranial efficacy of Rozlytrek in patients with NTRK fusion-positive solid tumours with baseline CNS metastasis. In addition, an updated integrated analysis of the phase II STARTRK-2, phase I STARTRK-1, and phase I ALKA-372-001 trials, investigating the efficacy and safety of Rozlytrek in locally advanced/metastatic ROS1-positive NSCLC, which evaluated a larger dataset with longer follow-up (15.8 months) will be presented.

**Gavreto in RET-mutant medullary thyroid cancer**
At ESMO, Blueprint Medicines will present results from the registrational phase I/II ARROW trial, investigating Gavreto for the treatment of people with advanced, RET-mutant medullary thyroid cancer. Gavreto is being jointly commercialised by Genentech, a wholly owned member of the Roche Group, and Blueprint Medicines in the U.S. and will be commercialised by Roche outside of the U.S., excluding Greater China (encompasses Mainland China, Hong Kong, Macau and Taiwan). Blueprint Medicines and Gavreto are trademarks of Blueprint Medicines Corporation.

**Subcutaneous formulation of atezolizumab (Tecentriq)**
First data from the phase Ib dose-finding study (Part 1 of IMscin001) of subcutaneous atezolizumab (Tecentriq) in patients with locally advanced or metastatic NSCLC will also be presented. The subcutaneous formulation of atezolizumab (Tecentriq) is being developed to potentially allow faster administration via an injection under the skin, compared to the original intravenous (IV) formulation, thereby significantly reducing a patient's time spent receiving treatment. Based on previous studies of other monoclonal antibodies, subcutaneous is generally a preferred route of administration by patients, physicians, healthcare providers and can be associated with hospital time- and cost-savings.

**PHC symposium**
In light of ESMO's 2020 motto, "bringing innovation to cancer patients", Roche is hosting a symposium that explores what it takes to put personalised healthcare at the heart of clinical practice. Leading experts will

discuss recent innovations in the field of personalised healthcare within oncology like the use of blood based molecular testing. Furthermore, the panelists will also discuss how to accelerate the adoption personalised oncology in healthcare systems. The symposium is tailored for healthcare professionals and includes a virtual live Q&A with the faculty on Friday, 18 September, 17:00-17:30 CEST.

Follow Roche on Twitter via @Roche and keep up to date with ESMO news and updates by using the hashtag #ESMO20.

**Overview of key presentations featuring Roche medicines at ESMO 2020**

| **Medicine** | **Abstract title** | **Abstract number** |
|---|---|---|
| **Triple-negative breast cancer** | | |
| Tecentriq® (atezolizumab) | Primary results from IMpassion131, a double-blind placebo-controlled randomised phase 3 trial of first-line paclitaxel (PAC) +/- atezolizumab (atezo) for unresectable locally advanced/metastatic triple-negative breast cancer (mTNBC) | LBA15 (Oral), Saturday, 19 September, (Channel 1) 16:20-16:32 CEST |
| Tecentriq | IMpassion031: results from a Ph 3 study of neoadjuvant (neoadj) atezolizumab + chemotherapy in early triple-negative breast cancer (TNBC) | LBA11 (Oral), Sunday, 20 September, (Channel 3) 12:30-12:42 CEST |
| Tecentriq | IMpassion130: final OS analysis from the pivotal phase III study of atezolizumab + nab-paclitaxel vs placebo + nab-paclitaxel in previously untreated locally advanced or metastatic triple-negative breast cancer | LBA16 (Oral), Saturday, 19 September, (Channel 1) 16:32-16:44 CEST |
| **HER2-positive breast cancer** | | |
| Phesgo™ (pertuzumab - trastuzumab) | Patient preference for the pertuzumab–trastuzumab fixed-dose combination for subcutaneous use (PH FDC SC) in HER2-positive early breast cancer (EBC): Primary analysis of the open-label, randomised crossover PHranceSCa study | Presentation #165MO (Oral), Friday, 18 September (On-demand) |
| Perjeta® (pertuzumab) and Herceptin® | Final results from PERUSE, a global study of pertuzumab (P), trastuzumab (H) and investigator's chosen taxane as first-line therapy for HER2-positive locally recurrent/metastatic breast cancer (LR/mBC) | Presentation #228P (Poster), Thursday, 17 September (On-demand) |

| | | |
|---|---|---|
| (trastuzumab) | | |
| **HR-positive breast cancer** | | |
| GDC-0077 | Phase III study of GDC-0077 or placebo (pbo) with palbociclib (P) + fulvestrant (F) in patients (pts) with PIK3CA-mutant/hormone receptor-positive/HER2-negative locally advanced or metastatic breast cancer (HR+/HER2– LA/MBC) | Presentation #355TiP (Poster), Thursday, 17 September (On-demand) |
| GDC-0077 | PI3K pathway biomarkers and clinical response in a phase I/Ib study of GDC-0077 in hormone receptor-positive/HER2-negative breast cancer (HR+/HER2– BC) | Presentation #336P (Poster), Thursday, 17 September (On-demand) |
| Ipatasertib | Ipatasertib (IPAT) + paclitaxel (PAC) for *PIK3CA/AKT1/PTEN*-altered hormone receptor-positive (HR+) HER2-negative advanced breast cancer (aBC): Primary results from Cohort B of the IPATunity130 randomised phase 3 trial | Presentation #283MO (Oral), Friday, 18 September (On-demand) |
| **Lung cancer** | | |
| Alecensa® (alectinib) | Blood-based genomic profiling of advanced non-small cell lung cancer (aNSCLC) patients (pts) from Blood First Assay Screening Trial (BFAST) and comparison with real-world data (RWD) | Presentation #1307P (Poster), Thursday, 17 September (On-demand) |
| Alecensa | Blood First Assay Screening Trial (BFAST) in patients (pts) with 1L NSCLC: ALK+ cohort updated biomarker analyses | Presentation #1301P (Poster), Thursday, 17 September (On-demand) |
| Tecentriq | IMpower133: characterisation of long-term survivors treated first-line with chemotherapy ± atezolizumab in extensive-stage small cell lung cancer | Presentation #1781MO (Mini-oral), Friday, 18 September (On-demand) |

| | | |
|---|---|---|
| Tecentriq | 4-year survival in randomised phase II (POPLAR) and phase III (OAK) studies of atezolizumab (atezo) vs docetaxel (doc) in pre-treated NSCLC | Presentation #1271P (Poster), Thursday, 17 September (On-demand) |
| Tecentriq | IMscin001: phase Ib dose-finding study of subcutaneous atezolizumab in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) | Presentation #1270P (Poster), Thursday, 17 September (On-demand) |
| **Flatiron Health data in lung cancer** | | |
| Real world data | Patterns of care and outcomes in carcinoma of unknown primary: A SEER-Medicare study | Presentation #519P (Poster), Thursday, 17 September (On-demand) |
| Real world data | Pan-cancer analysis of homologous recombination (HR)-associated alterations (alts) and genome-wide loss of heterozygosity (gLOH) | Presentation #85MO (Oral), Friday, 18 September (On-demand) |
| **Solid tumours** | | |
| Rozlytrek® (entrectinib) | Efficacy and safety of entrectinib in locally advanced /metastatic ROS1 fusion-positive NSCLC: an updated integrated analysis | Presentation #1287P (Poster), Thursday, 17 September (On-demand) |
| Rozlytrek | Efficacy of entrectinib in patients with NTRK or ROS1 fusion-positive NSCLC with CNS metastases at baseline | Presentation #1288P (Poster), Thursday, 17 September (On-demand) |
| Rozlytrek | Intracranial efficacy of entrectinib in patients with NTRK fusion-positive solid tumours and baseline CNS metastases | Presentation #364O (Oral), |

| | | |
|---|---|---|
| | | Sunday, 20 September, 13:38-13:50 CEST |
| Gavreto™ (pralsetinib) | Results from the registrational phase I/II ARROW trial of pralsetinib (BLU-667) in patients (pts) with advanced RET mutation-positive medullary thyroid cancer (RET+MTC) (Blueprint) | Presentation #1913O (Oral) Sunday, 20 September, 15:21-15:33 CEST |
| **Genitourinary cancers** | | |
| Tecentriq | Patient-reported outcomes (PROs) from IMvigor130: a global, randomised, partially blinded phase III study of atezolizumab (atezo) + platinum-based chemotherapy (PBC) vs placebo (PBO) + PBC in previously untreated locally advanced or metastatic urothelial carcinoma (mUC) | Presentation #698O (Oral), Saturday, 19 September, 17:16-17:28 CEST |
| Perjeta and Herceptin | End-of-study analysis from JACOB: a phase III study of pertuzumab (P) + trastuzumab (H) and chemotherapy (CT) in HER2-positive metastatic gastric or gastro-esophageal junction cancer (mGC/GEJC) | Presentation #1423MO (Oral), Friday, 18 September (On-demand) |
| Ipatasertib | IPATential150: phase III study of ipatasertib (ipat) plus abiraterone (abi) vs placebo (pbo) plus abi in metastatic castration-resistant prostate cancer (mCRPC) | LBA4 (Presidential symposium II), Sunday, 20 September, (Channel 1) 19:02-19:14 CEST |
| **Liver cancer** | | |
| Tecentriq and Avastin® (bevacizumab) | Efficacy of atezolizumab + bevacizumab After Disease Progression With Atezo Monotherapy in Patients With Previously Untreated, Unresectable Hepatocellular Carcinoma (HCC) | Presentation #986P (Poster), Thursday, 17 September (On-demand) |
| Tecentriq and Avastin | IMbrave150: management of adverse events of special interest (AESIs) for atezolizumab and bevacizumab in unresectable HCC | Presentation #1008P (Poster), Thursday, 17 September (On-demand) |

| Gynecological cancer | | |
|---|---|---|
| Tecentriq | Primary results from IMagyn050/GOG 3015/ENGOT-OV39, a double-blind placebo (pbo)-controlled randomised phase 3 trial of bevacizumab (bev)-containing therapy +/- atezolizumab (atezo) for newly diagnosed stage III/IV ovarian cancer (OC) | LBA31<br>(Oral)<br>Monday, 21 September, (Channel 3) 16:20-16:32 CEST |

**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); Gavreto™ (pralsetinib); Gazyva®/Gazyvaro® (obinutuzumab); Herceptin® (trastuzumab); Kadcyla® (trastuzumab emtansine); MabThera®/Rituxan® (rituximab); Perjeta® (pertuzumab); Polivy® (polatuzumab vedotin-piiq); Tarceva® (erlotinib); Rozlytrek® (entrectinib); 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. For more information on Roche's approach to cancer, visit www.roche.com.

**About Roche in Personalised Healthcare**
For more than 20 years, Roche has helped lay the scientific groundwork for personalised healthcare with treatments that target the underlying biology of cancer and other diseases. Now, with profound changes in data and technology transforming how medicines are discovered, developed and delivered to patients, we are uniquely positioned to extend this approach across all of healthcare. With our ability to integrate research and development, personalised diagnosis, disease monitoring and treatment access, we are advancing personalised healthcare for every aspect of the patient experience.

Our strategy is rooted in groundbreaking science that can accelerate drug discovery and development. We are also leveraging technologies such as real-world datasets, artificial intelligence, genomic profiling and digital health across our therapeutic portfolio, with an initial emphasis on oncology, neurology, ophthalmology and diagnostics. Through collaborations with academic institutions, industry partners, patients, physicians and regulatory agencies, our goal is to dramatically improve the performance of the entire healthcare ecosystem and the lives of every patient.

**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. More than 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 eleventh consecutive year, Roche has been recognised as one of the most sustainable companies 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.



**Roche Group Media Relations**
Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Dr. Nicolas Dunant
Phone: +41 61 687 05 17

Patrick Barth
Phone: +41 61 688 44 86

Daniel Grotzky
Phone: +41 61 688 31 10

Karsten Kleine
Phone: +41 61 682 28 31

Nina Mählitz
Phone: +41 79 327 54 74

Nathalie Meetz
Phone: +41 61 687 43 05

Barbara von Schnurbein
Phone: +41 61 687 89 67

**Roche Investor Relations**

Dr. Karl Mahler
Phone: +41 61 68-78503
e-mail: karl.mahler@roche.com

Jon Kaspar Bayard
Phone: +41 61 68-83894
e-mail: jon_kaspar.bayard@roche.com

Dr. Sabine Borngräber
Phone: +41 61 68-88027

Dr. Bruno Eschli
Phone: +41 61 68-75284

e-mail: sabine.borngraeber@roche.com

e-mail: bruno.eschli@roche.com

Dr. Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Dr. Gerard Tobin
Phone: +41 61 68-72942
e-mail: gerard.tobin@roche.com

**Investor Relations North America**

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com

Dr. Lisa Tuomi
Phone: +1 650 467 8737
e-mail: tuomi.lisa@gene.com