

## Roche to present new data from its broad oncology portfolio at the European Society for Medical Oncology 2019 Congress

- **First positive results from a Phase III cancer immunotherapy combination study in people with previously untreated advanced bladder cancer**
- **First results from the BFAST study testing Foundation Medicine's FoundationOne® Liquid biopsy assay to identify patients who may be eligible for Alecensa® (alectinib)**
- **First results from the positive Phase III IMpower110 study of Tecentriq® (atezolizumab) monotherapy as an initial treatment for advanced lung cancer**

Basel, 23 September 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that results from a number of studies across its comprehensive oncology portfolio, covering a broad range of cancers including bladder, lung and breast will be presented at the European Society for Medical Oncology (ESMO) 2019 Congress, taking place from 27 September - 1 October in Barcelona, Spain. A total of 100 abstracts and 15 late-breaking abstracts that include a Roche medicine will be presented at this year's congress.

"We are excited to present a number of key datasets across a broad range of diseases at ESMO this year, including results from our Tecentriq combination study in people with previously untreated advanced bladder cancer, the first positive Phase III cancer immunotherapy trial in this setting. In addition, we will present data from our Phase III Tecentriq monotherapy study in previously untreated advanced lung cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We will also share data from a study using Foundation Medicine's liquid (blood) biopsy, a more patient-friendly approach to diagnosing and treating cancer. The results of the first cohort of this study involving ALK+ non-small cell lung cancer patients who received Alecensa will be presented at the congress."

Follow Roche on Twitter via @Roche and keep up to date with ESMO 2019 Congress news and updates by using the hashtag #ESMO19.

### Key presentations

#### Bladder cancer:

First results from the Phase III IMvigor130 study will be presented as an oral presentation at the Presidential Symposium on 30 September at 17:53-18:05 CEST (abstract LBA14) and will be featured in the official ESMO press programme at 07:30 CEST on the same day. This study evaluates the efficacy and safety of Tecentriq® (atezolizumab) in combination with platinum-based chemotherapy or alone versus platinum-based chemotherapy in patients with previously untreated locally advanced or mUC, and supports Roche's broad clinical development programme for Tecentriq in bladder cancer.

IMvigor130 met its co-primary endpoint of progression-free survival (PFS). The combination showed a statistically significant reduction in the risk of disease worsening or death in people with previously untreated

locally advanced or metastatic urothelial carcinoma (mUC). Encouraging overall survival (OS) results were observed at this interim analysis, however these results are not yet mature. The study represents the first positive Phase III immunotherapy combination study in patients with previously untreated bladder cancer. Tecentriq monotherapy was the first cancer immunotherapy approved in bladder cancer.

#### **Lung cancer:**

##### **Alecensa® (alectinib)**

Results from the first cohort of the Phase II/III Blood First Assay Screening Trial (BFAST) will be presented at ESMO 2019. BFAST is the first prospective trial to use blood-based next generation sequencing (NGS) as the sole method of identifying and assigning non-small cell lung cancer (NSCLC) patients to targeted therapy based on actionable genetic alterations without the need for tissue biopsy. The study utilised FoundationOne® Liquid, Foundation Medicine's liquid (blood) biopsy assay to detect fusions in circulating tumour DNA (ctDNA) from a simple blood draw to identify anaplastic lymphoma kinase (ALK) status and consequently eligibility for Alecensa.

In addition to BFAST, updated data from the pivotal Phase III ALEX study investigating the efficacy and tolerability of Alecensa in comparison to crizotinib in patients with untreated ALK-positive NSCLC will also be presented at the congress, along with real world data on the use of Alecensa in clinical practice from the Flatiron Health database.

##### **Tecentriq® (atezolizumab)**

Results from the Phase III IMpower110 study evaluating Tecentriq as first-line monotherapy compared with cisplatin or carboplatin and pemetrexed or gemcitabine (chemotherapy) as first-line treatment in patients with advanced squamous and non-squamous NSCLC will be presented. The study met its primary endpoint of OS, demonstrating a statistically significant OS benefit for Tecentriq monotherapy in people with high levels of PD-L1 expression, compared with chemotherapy alone.

In addition, updated OS results from the IMpower133 study will also be presented at ESMO. IMpower133 showed that first-line Tecentriq in combination with chemotherapy helped people with extensive-stage small cell lung cancer (ES-SCLC) live significantly longer compared with chemotherapy alone. This updated data presentation will also feature analysis by PD-L1 subgroup.

##### **Rozlytrek™ (entrectinib)**

Additionally, results from studies in partnership with Flatiron Health will be presented, including validation of the use of NGS data on a broad scale to improve the understanding of clinical outcomes in people with metastatic lung cancer, and results that illustrate how real-world data can be used to supplement evidence from clinical trials comparing Rozlytrek clinical data with a matched cohort treated with current standard of care from the Flatiron database in ROS1-positive lung cancer.

**Liver cancer (HCC):****Tecentriq + Avastin® (bevacizumab)**

Results will be presented from a Phase Ib study evaluating the efficacy and safety of Tecentriq plus Avastin as a treatment for people with unresectable hepatocellular carcinoma (HCC), the most common form of liver cancer, who have not received prior systemic therapy. Data will be presented underscoring the potential benefit of Tecentriq plus Avastin for HCC patients, as well as randomised data testing the combination versus Tecentriq monotherapy.

**Breast cancer:****Tecentriq**

During ESMO, data from a post-hoc (exploratory) analysis of the IMpassion130 study will be presented, evaluating the performance of VENTANA PD-L1 (SP142) and two other PD-L1 immunohistochemistry (IHC) assays in unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) in predicting clinical activity of Tecentriq plus nab-paclitaxel.

Primary results of IMpassion130 showed that Tecentriq plus nab-paclitaxel reduced the risk of disease worsening or death, and an encouraging OS was observed at interim analysis in people with mTNBC who were tested positive for PD-L1 expression on tumour-infiltrating immune cells compared to nab-paclitaxel alone.

The assessment of PD-L1 on tumour-infiltrating immune cells is essential for identifying the patients with mTNBC benefiting from this Tecentriq combination. PD-L1 expression status in the IMpassion130 study was assessed by the VENTANA PD-L1 (SP142) assay.

**HER2 portfolio/medicines**

Exploratory analysis of the international Phase III, KATHERINE trial – evaluating the efficacy and safety of Kadcyła® (trastuzumab emtansine) versus Herceptin® (trastuzumab) as an adjuvant therapy in people with HER2-positive early breast cancer (eBC) who have residual disease after neoadjuvant taxane and Herceptin-based treatment, have been accepted for oral presentation at this year's congress. This updated analysis examined the association of prior neoadjuvant treatment with characteristics of peripheral neuropathy and thrombocytopenia amongst the study population observed in the KATHERINE trial as well as further data on central nervous system (CNS) recurrences.

Primary results from the Phase III KATHERINE study showed that Kadcyła significantly reduced the risk of invasive breast cancer recurrence or death from any cause (invasive disease-free survival; iDFS) by 50% (Hazard Ratio [HR]=0.50, 95% CI: 0.39-0.64,  $p < 0.0001$ ) compared to Herceptin as an adjuvant treatment in people with HER2-positive eBC who have residual invasive disease after neoadjuvant taxane and Herceptin-based treatment.

Also being presented at ESMO 2019, are data from an epidemiological study looking at the impact of adjuvant Kadcyła on the incidence of metastatic breast cancer (mBC), as well as results from an analysis of data from the Flatiron database, which assessed challenges in determining the effectiveness of HER2-targeted treatment sequencing in the real world.

OS results from the Phase II KATE2 study, evaluating the efficacy and safety of Kadcyła in combination with Tecentriq versus Kadcyła and placebo in people with HER2-positive locally advanced or mBC who have received prior Herceptin and taxane-based therapy, will also be shared in an oral presentation.

#### **Cancer of Unknown Primary Site (CUP):**

Featured in the official ESMO press programme at 08:30 on 28 September will be a retrospective analysis using comprehensive genomic profiling (CGP) of carcinoma of unknown primary origin (CUP) patients that investigated eligibility for molecularly guided targeted or immunotherapy treatment options in the CUPISCO study design. To make that determination, archival tissue from centrally reviewed CUP cases was subjected to CGP using the FoundationOne® CDx test. CUPISCO is a Phase II, randomised, active-controlled, multi-centre study comparing the efficacy and safety of targeted therapy or cancer immunotherapy guided by genomic profiling versus platinum-based chemotherapy in patients with a CUP site.

#### **Overview of key presentations featuring Roche medicines at ESMO 2019**

<b>Medicine</b>	<b>Abstract title</b>	<b>Abstract number (date, time &amp; location of presentation)</b>
<b>Bladder cancer</b>		
Tecentriq	IMvigor130: efficacy and safety from a Phase III study of atezolizumab (atezo) as monotherapy or combined with platinum-based chemotherapy (PBC) vs placebo + PBC in previously untreated locally advanced or metastatic urothelial carcinoma (mUC)	Abstract LBA14_PR (Oral) Monday 30 September 16:30 - 18:15 CEST Barcelona Auditorium (Hall 2)
Tecentriq	Atezolizumab (atezo) vs chemotherapy (chemo) in patients (pts) with platinum-treated locally advanced or metastatic urothelial carcinoma (mUC): a long-term overall survival (OS) and safety update from the Phase III IMvigor211 study	Abstract 918P (Poster) Monday 30 September 12:00 - 13:00 CEST Poster Area (Hall 4)
<b>Lung cancer</b>		
Alecensa	Phase II/III Blood First Assay Screening Trial (BFAST) in patients (pts) with treatment-naïve NSCLC: initial results from the ALK+ cohort	Abstract LBA81_PR (Oral) Monday 30 September 08:30 - 10:00 CEST Madrid Auditorium (Hall 2)

Alecensa	Treatment patterns and outcomes for patients (pts) with anaplastic lymphoma kinase-positive (ALK+) advanced non-small-cell lung cancer (NSCLC) in US clinical practice	Abstract 1546P (Poster) Saturday 28 September 12:00 - 13:00 CEST Poster Area (Hall 4)
Alecensa	Final PFS, updated OS and safety data from the randomised, Phase III ALEX study of alectinib (ALC) versus crizotinib (CRZ) in untreated advanced ALK+ NSCLC	Abstract 1484PD (Poster discussion) Sunday 29 September 16:30 - 17:45 CEST Cordoba Auditorium (Hall 7)
Tecentriq	IMpower110: Interim overall survival (OS) analysis of a Phase III study of atezolizumab (atezo) vs platinum-based chemotherapy (chemo) as first-line (1L) treatment (tx) in PD-L1-selected NSCLC	Abstract LBA78 (Proffered Paper) Friday 27 September 16:00-17:30 CEST Barcelona Auditorium (Hall 2)
Tecentriq	IMpower133: updated overall survival (OS) analysis of first-line (1L) atezolizumab (atezo) + carboplatin + etoposide in extensive-stage SCLC (ES-SCLC)	Abstract 1736O (Proffered Paper) Saturday 28 September 16:30 - 18:00 CEST Cordoba Auditorium (Hall 7)
<b>Liver cancer</b>		
Tecentriq + Avastin	Randomised Efficacy and Safety Results for Atezolizumab (Atezo) + Bevacizumab (Bev) in Patients (pts) With Previously Untreated, Unresectable Hepatocellular Carcinoma (HCC)	Abstract LBA39 (Oral) Friday 27 September 14:00-15:30 CEST Madrid Auditorium (Hall 2)

<b>Breast cancer</b>		
Kadcyla	Peripheral neuropathy (PN), thrombocytopenia (TCP) and central nervous system (CNS) recurrence: an update of the Phase III KATHERINE trial of post-neoadjuvant trastuzumab emtansine (T-DM1) or trastuzumab (H) in patients (pts) with residual invasive HER2-positive breast cancer (BC)	LBA19 (Oral) Monday 30 September 14:45 - 16:15 CEST Cordoba Auditorium (Hall 7)
Kadcyla	Impact of adjuvant trastuzumab emtansine (T-DM1) on incidence of metastatic breast cancer (mBC): an epidemiological model of patients with HER2-positive breast cancer (BC) who did not achieve pathological complete response (pCR) after neoadjuvant treatment (non-pCR)	193P (Poster) Sunday 29 September 12:00 - 13:00 CEST Poster Area (Hall 4)
Kadcyla + Perjeta	Use of trastuzumab emtansine (T-DM1; K) after pertuzumab + trastuzumab (PH) in patients with HER2-positive metastatic breast cancer (mBC): challenges in assessing effectiveness of treatment sequencing in the real world (RW)	356P (Poster) Sunday 29 September 12:00 - 13:00 CEST Poster Area (Hall 4)
Kadcyla + Tecentriq	Overall survival (OS) in KATE2, a Phase II study of programmed death ligand 1 (PD-L1) inhibitor atezolizumab (atezo)+trastuzumab emtansine (TDM1) vs placebo (pbo)+T-DM1 in previously treated HER2+ advanced breast cancer (BC)	305O (Oral) Saturday 28 September 10:15 - 11:45 CEST Barcelona Auditorium (Hall 2)
Tecentriq	Performance of PD-L1 immunohistochemistry (IHC) assays in unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC): post-hoc analysis of IMpassion130	LBA20 (Oral) Saturday 28 September 10:15 - 11:45 CEST Barcelona Auditorium (Hall 2)

<b>Skin</b>		
Tecentriq	Combination treatment with cobimetinib (C) and atezolizumab (A) vs pembrolizumab (P) in previously untreated patients (pts) with BRAFV600 wild type (wt) advanced melanoma: primary analysis from the Phase III IMspire170 trial	Abstract LBA69 (Oral) Saturday 28 September 08:30 - 10:15 CEST Cordoba Auditorium (Hall 7)
<b>Cancer of Unknown Primary Site (CUP)</b>		
Genomic profiling	Comprehensive genomic profiling (CGP) of carcinoma of unknown primary origin (CUP): Retrospective molecular classification of potentially eligible patients (pts) for targeted or immunotherapy treatment (tx) using the prospective CUPISCO trial's criteria	1983PD_PR (Poster discussion) Sunday 29 September 16:30 - 17:45 CEST Alicante Auditorium (Hall 3)

### 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); Kadcyła® (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](http://www.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. 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 2018 employed about 94,000 people worldwide. In 2018, Roche invested CHF 11 billion in R&D and posted sales of CHF 56.8 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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