Media Release

Roche to present new data highlighting comprehensive approach to cancer care at 2019 American Society of Clinical Oncology (ASCO) Annual Meeting

- **Study results across 17 medicines reflect our commitment to personalised care with advances in targeted therapies, immunotherapy, and diagnostics, data and analytics**
- **New pivotal data on fixed-duration combination of Venclexta/Venclyxto plus Gazyva/Gazyvaro in previously untreated chronic lymphocytic leukaemia**
- **New data for entrectinib in paediatric patients with recurrent or refractory solid tumours harbouring NTRK, ROS1 or ALK gene fusions**
- **Key highlights to be shared at Roche's ASCO Media Briefing on 31 May 2019, from 09:00 – 10:30 CDT at the Chicago Marriott Downtown Magnificent Mile, Chicago, IL, US**

Basel, 10 May 2019 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data from clinical trials of 17 approved and investigational medicines across 27 cancer types, including hard-to-treat and rare tumours, will be presented at the 2019 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL, United States, from 31 May– 4 June, 2019. A total of 155 abstracts that include a Roche medicine will be presented at this year's meeting.

"At this year's ASCO meeting, we are excited to present new data with targeted therapies, immunotherapy and pipeline combinations across a broad range of diseases including blood, breast and lung cancers, as well as paediatric tumours treated with our personalised cancer medicine, entrectinib," said Sandra Horning, MD, chief medical officer and head of Global Product Development. "Through pioneering science, strategic partnerships and data and analytics, we're striving to develop transformative medicines that can help improve outcomes for each individual patient."

Further information on Roche's contribution to the ASCO 2019 scientific programme, as well as the latest innovations and developments in Roche's approach to accelerating progress in cancer care, will be featured during the Roche Media Briefing from 09:00 - 10:30 CDT on Friday 31 May at the Chicago Marriott Downtown Magnificent Mile, Chicago, IL, US. This event, independently organised by Roche, is open to journalists from outside the United States who have registered as media with the ASCO 2019 Annual Meeting.

To register for the Roche Media Briefing, please follow this link:
http://roche.cvent.com/d/v6qcp1?ct=94fca666-18b0-4c40-b5f7-6b4b845171c7

Keep up to date on ASCO meeting news and updates by following Roche on Twitter via @Roche and using the hashtag #ASCO19.

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Key presentations in blood cancers
The first data from the pivotal Phase III CLL14 study will be presented at ASCO, evaluating the 12-month, fixed-duration, chemotherapy-free combination of Venclexta®/Venclyxto® (venetoclax) plus Gazyva®/Gazyvaro® (obinutuzumab) compared to Gazyva/Gazyvaro plus chlorambucil in people with previously untreated chronic lymphocytic leukaemia (CLL) and co-existing medical conditions. The CLL14 study is being conducted in cooperation with the German CLL Study Group (GCLLSG), headed by Michael Hallek, MD, University of Cologne.

The US Food and Drug Administration (FDA) is reviewing a supplemental New Drug Application (sNDA) based on results of the CLL14 study under the FDA's Real-Time Oncology Review and Assessment Aid pilot programmes. Venclexta is being developed by AbbVie and Roche. It is jointly commercialised by AbbVie and Genentech, a member of the Roche group, in the US and commercialised by AbbVie outside of the US.

Key presentations in paediatric cancers
The first data from the Phase I/II STARTRK-NG study of the investigational medicine entrectinib in children and adolescents with recurrent or refractory solid tumours harbouring neurotrophic tyrosine receptor kinase (NTRK), ROS1 or anaplastic lymphoma kinase (ALK)-positive tumours, including central nervous system tumours, will be presented. The study enrolled children and adolescents aged 4.9 months through 20 years (median of seven years) across several different cancer types, including some rare tumours. The STARTRK-NG data will be featured as part of ASCO's official press programme on Wednesday, 15 May.

The FDA recently granted Priority Review for entrectinib for the treatment of paediatric and adult patients with NTRK fusion-positive, locally advanced or metastatic solid tumours who have either progressed following prior therapies or as initial therapy when there are no acceptable standard therapies, and for the treatment of people with metastatic, ROS1-positive non-small cell lung cancer (NSCLC). These NDAs are based on results from the integrated analysis of the pivotal Phase II STARTRK-2, Phase I STARTRK-1 and Phase I ALKA-372-001 trials, and data from the STARTRK-NG study. The FDA is expected to make a decision on the approval by 18 August 2019.

Key presentations in breast cancers
Key data to be presented at ASCO include updates from Roche's breast cancer programme across multiple subtypes of the disease, including the second interim analysis of overall survival (OS) results, updated safety data and patient-reported outcomes (PROs) from the Phase III IMpassion130 study of Tecentriq® (atezolizumab) plus chemotherapy (Abraxane® [paclitaxel protein-bound particles for injectable suspension (albumin-bound); nab-paclitaxel]) for the treatment of PD-L1-positive, metastatic triple-negative breast cancer (TNBC). This combination was recently granted accelerated approval from the FDA based on progression-free survival (PFS) for the treatment of adults with unresectable locally advanced or metastatic TNBC in people whose tumours express PD-L1, as determined by an FDA-approved test.

Additional data include an eight-year, end-of-study analysis from the Phase III CLEOPATRA study of Perjeta® (pertuzumab) plus Herceptin® (trastuzumab) and chemotherapy for first-line treatment of HER2-positive metastatic breast cancer.

Key presentations in lung cancers

Key data from Roche's broad lung cancer programme will be presented across different types of the disease, including results from the Phase III IMpower150 trial of Tecentriq plus Avastin® (bevacizumab) and chemotherapy (carboplatin and paclitaxel) in chemotherapy-naïve people previously untreated for metastatic NSCLC whose cancer has spread to the liver, which affects approximately 20% of people with the disease. Additionally, results from studies in partnership with Flatiron Health will be presented, including validation of the use of next-generation sequencing 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 in rare tumour types such as ROS1-positive lung cancer.

Key presentations featuring Roche medicines at ASCO 2019

Medicine	Abstract title	Abstract number
Blood cancer		
Venclexta/Venclyxto (venetoclax) Gazyva/Gazyvaro (obinutuzumab)	Effect of fixed-duration venetoclax plus obinutuzumab (VenG) on progression-free survival (PFS), and rates and duration of minimal residual disease negativity (MRD–) in previously untreated patients (pts) with chronic lymphocytic leukemia (CLL) and comorbidities	Abstract 7502 (oral) Tuesday 04 June 10:09 – 10:21 CDT
Venclexta/Venclyxto	Safety and activity of venetoclax in combination with high-dose cytarabine in children with relapsed or refractory acute myeloid leukemia	Abstract 10004 (oral) Friday 31 May 15:57 – 16:09 CDT
polatuzumab vedotin	Polatuzumab vedotin (Pola) + obinutuzumab (G) and lenalidomide (Len) in patients (pts) with relapsed/refractory (R/R) follicular lymphoma (FL): Interim analysis of a Phase Ib/II trial	Abstract 7505 (oral) Tuesday 04 June 11:33 – 11:45 CDT
Tumour agnostic		
entrectinib	Phase I/II trial to assess the activity of entrectinib in children and adolescents with recurrent or refractory solid tumors including central nervous system (CNS) tumors	Abstract 10009 (oral) Sunday 02 June 8:00 – 8:12 CDT
entrectinib	Efficacy of entrectinib in patients (pts) with solid tumors and central nervous system (CNS) metastases: Integrated analysis from three clinical trials	Abstract 3017 (poster) Saturday 01 June 8:00 – 11:00 CDT

Breast cancer		
Tecentriq (atezolizumab)	IMpassion130: updated overall survival (OS) from a global, randomized, double-blind, placebo-controlled, Phase III study of atezolizumab (atezo) + *nab*-paclitaxel (nP) in previously untreated locally advanced or metastatic triple-negative breast cancer (mTNBC)	Abstract 1003 (oral) Tuesday 04 June 10:45 – 10:57 CDT
Perjeta (pertuzumab) Kadcyla (ado-trastuzumab emtansine) Herceptin (trastuzumab)	Neoadjuvant trastuzumab (H), pertuzumab (P), and chemotherapy versus trastuzumab emtansine (T-DM1) and P in human epidermal growth factor receptor 2 (HER2)-positive breast cancer (BC): Final outcome results from the Phase III KRISTINE study	Abstract 500 (oral) Monday 03 June 9:45 – 9:57 CDT
Perjeta Herceptin	Genomic correlates of response to adjuvant trastuzumab (H) and pertuzumab (P) in HER2+ breast cancer (BC): Biomarker analysis of the APHINITY trial	Abstract 1012 (clinical science symposium) Saturday 01 June 15:48 – 16:00 CDT
Perjeta Herceptin	End-of-study analysis from the phase III, randomized, double-blind, placebo (Pla)-controlled CLEOPATRA study of first-line (1L) pertuzumab (P), trastuzumab (H), and docetaxel (D) in patients (pts) with HER2-positive metastatic breast cancer (MBC).	Abstract 1020 (poster) Sunday 02 June 8:00 – 11:00 CDT
Tecentriq	IMpassion130: Expanded safety analysis from a P3 study of atezolizumab (A) + nab-paclitaxel (nP) in patients (pts) with treatment (tx)-naïve, locally advanced or metastatic triple-negative breast cancer (mTNBC)	Abstract 1068 (poster) Sunday 02 June 8:00 – 11:00 CDT
Tecentriq	Patient-reported outcomes (PROs) from the Phase III IMpassion130 trial of atezolizumab (atezo) plus nabpaclitaxel (nP) in metastatic triple-negative breast cancer (mTNBC)	Abstract 1067 (poster) Sunday 02 June 8:00 – 11:00 CDT
Kadcyla	Patient-reported outcomes (PROs) from KATHERINE: A Phase III study of adjuvant trastuzumab emtansine	Abstract 513 (poster)

Herceptin	(T-DM1) versus trastuzumab (H) in patients (pts) with residual invasive disease after neoadjuvant therapy for HER2-positive breast cancer	Sunday 02 June 8:00 – 11:00 CDT
Perjeta Herceptin	A phase III, randomized, double-blind, placebo (Pla)-controlled study of pertuzumab (P) + trastuzumab (H) + docetaxel (D) versus Pla + H+ D in previously untreated HER2-positive locally recurrent/metastatic breast cancer (LR/MBC) (PUFFIN).	Abstract 1026 (poster) Sunday 02 June 08:00 – 11:00 CDT
Lung cancer		
Tecentriq	IMpower150: Analysis of efficacy in patients (pts) with liver metastases (mets)	Abstract 9012 (poster discussion) Sunday 02 June 16:30 – 18:00 CDT
Tecentriq	Neoadjuvant atezolizumab in resectable non-small cell lung cancer (NSCLC): Interim analysis and biomarker data from a multicenter study (LCMC3)	Abstract 8503 (oral) Saturday 01 June 14:15 – 14:27 CDT
entrectinib	Time-to-treatment discontinuation (TTD) and real-world progression-free survival (rwPFS) as endpoints for comparative efficacy analysis between entrectinib trial and crizotinib real-world *ROS1* fusion-positive (*ROS1+)* NSCLC patients	Abstract 9070 (poster) Sunday 02 June 8:00 – 11:00 CDT
Alecensa (alectinib)	Final PFS analysis and safety data from the phase III J-ALEX study of Alectinib(ALC) vs. Crizotinib(CRZ) in ALK-inhibitor naïve ALK-positive Non-Small Cell Lung Cancer (ALK+NSCLC)	Abstract: 8569 (poster) Sunday 2 June 8:00 - 11:00 CDT
Genitourinary cancers		
Tecentriq	Clinical outcomes according to PD-L1 status and age in the prospective international SAUL study of atezolizumab (atezo) for locally advanced or metastatic urothelial carcinoma (UC) or non-UC of the urinary tract	Abstract 4519 (poster) Monday 03 June 13:15 – 16:15 CDT

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.

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

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