Investor Update



Basel, 8 May 2018

Roche to present new data from its industry-leading oncology portfolio at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting

- New and updated pivotal combination data from the Tecentriq lung programme, including overall survival (OS) results from IMpower150 and progression free survival (PFS) results from IMpower131
- New, longer follow-up data from the Phase III ALEX study of Alecensa in ALK-positive lung cancer
- Pivotal data from the haematology clinical development programme, including new data for Venclexta and polatuzumab vedotin

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data from its early and late-stage clinical studies, on more than 19 approved and investigational cancer medicines, will be presented at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place from 1-5 June, in Chicago, IL, United States. More than 180 abstracts have been accepted across 13 cancer types, including two "late breakers" and 15 oral presentations.

"New data to be presented from our industry-leading oncology portfolio, including our lung and haematology programmes, will demonstrate how our science-driven approach aims to improve outcomes for people living with cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "At ASCO, we look forward to sharing our progress and commitment to build the future of personalised healthcare in oncology."

An analyst briefing to discuss key data presented on the Roche Group's oncology products and pipeline at ASCO 2018 will take place on Monday 4 June from 5:30 -7:00 pm CDT at the Marriott Downtown Chicago

F. Hoffmann-La Roche Ltd

4070 Basel Switzerland Investor Relations email: investor.relations@roche.com Tel. +41 61 68-88880 Fax +41 61 69-10014 www.roche.com Magnificent Mile. This event, independently organized by Roche, is open to analysts and investors who have registered for the event. **To register for the event**, please follow the <u>link</u> (Password: Analyst2018).

Follow Roche on Twitter via @Roche and keep up to date with ASCO 2018 congress news and updates by using the hashtag #ASCO18.

Key presentations in lung cancer

Key data to be presented at ASCO cover advances from Roche's lung cancer programme, including a combination approach using the cancer immunotherapy, Tecentriq^{*} (atezolizumab) with targeted therapies and a range of different chemotherapies.

Updated OS data and new patient reported outcomes (PROs) data from the Phase III IMpower150 study of Tecentriq plus Avastin^{*} (bevacizumab) and chemotherapy (carboplatin and paclitaxel), in people with previously-untreated, advanced non-squamous non-small cell lung cancer (NSCLC), will be presented. The US Food and Drug Administration (FDA) recently granted Priority Review for this combination in the same patient population.

New PFS results from the Phase III IMpower131 study of Tecentriq plus chemotherapy (carboplatin and Abraxane^{*} [albumin-bound paclitaxel; *nab*-paclitaxel]) as an initial (first-line) treatment for people with advanced squamous NSCLC will also be shared and feature as part of ASCO's official press programme on Saturday, 2 June.

Additional results in lung cancer include longer follow-up results from the Phase III ALEX study of Alecensa^{*} (alectinib) versus crizotinib in people with previously untreated anaplastic lymphoma kinase (ALK)-positive NSCLC. These data build on the primary results from the ALEX study, first presented at ASCO 2017, which demonstrated a significant reduction in the risk of disease progression or death versus crizotinib. New data that utilise the application of a real world endpoint to identify and characterise genetic profiles of people with a poor prognosis in advanced NSCLC will also be presented at the congress.

Additional presentations with cancer immunotherapy

Additional cancer immunotherapy data presentations of note include new Tecentriq plus Avastin PROs from the Phase III IMmotion151 study in advanced renal cell carcinoma (RCC), and Phase Ib data for the combination of Tecentriq plus Avastin in first-line hepatocellular carcinoma (HCC). These studies add to the growing body of evidence that support the use of Tecentriq plus Avastin across multiple tumour types. New tumour mutational burden (TMB) data from two studies of Tecentriq will also be presented, including blood-based TMB data from the Phase II B-F1RST study in advanced NSCLC, and tissue-based TMB data across multiple tumour types including NSCLC, metastatic urothelial carcinoma and melanoma.

Key presentations in blood cancers

Data from pivotal studies in haematology will also be presented at ASCO. Additional analyses on minimal residual disease (MRD) rates will be shared from the Phase III MURANO study evaluating Venclexta*/Venclyxto[™] (venetoclax) plus MabThera*/Rituxan* (rituximab), compared to bendamustine plus MabThera/Rituxan, in people with relapsed or refractory chronic lymphocytic leukaemia (CLL). A supplemental new drug application (sNDA) based on the MURANO data was granted Priority Review by the FDA, with an action date of 28 June 2018.

Additional data will also be presented from the Phase Ib M14-358 study of Venclexta/Venclyxto plus azacitidine or decitabine in people with previously untreated acute myeloid leukemia (AML) who are ineligible for intensive chemotherapy. Venclexta/Venclyxto is being developed by AbbVie and Roche.

Data from the randomised Phase II study evaluating polatuzumab vedotin in combination with bendamustine chemotherapy and MabThera/Rituxan in people with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) will also be presented at the meeting.

Key presentations in breast cancer

Updates from two investigational medicines in breast cancer will be presented at ASCO. Data includes results from the Phase III SANDPIPER study of taselisib (GDC-0332) and fulvestrant, compared to fulvestrant alone, in estrogen receptor (ER)-positive, PIK3CA-mutant, locally advanced or metastatic breast cancer, and

updated OS data from the LOTUS trial of ipatasertib (GDC-0068, RG7440) and paclitaxel for previously untreated, locally advanced or metastatic, triple-negative breast cancer. The SANDPIPER data will be featured as part of ASCO's official press programme on Saturday, 2 June.

Medicine	Abstract title	Abstract number
Tecentriq	Overall survival (OS) analysis of IMpower150, a	Abstract 9002 (oral)
(atezolizumab)	randomised Phase 3 study of Atezolizumab plus	Monday 04 June
(investigational use)	chemotherapy plus bevacizumab vs	15:45 – 15:57 CDT
	chemotherapy plus bevacizumab in 1L non-	
Avastin (bevacizumab)	squamous NSCLC	
(investigational use)		
Tecentriq	IMpower131: Primary PFS and safety analysis of	Abstract LBA9000 (oral)
(atezolizumab)	a randomised phase III study of atezolizumab +	Monday 04 June
(investigational use)	carboplatin and paclitaxel or nab-paclitaxel vs	15:00 – 15:12 CDT
	carboplatin plus nab-paclitaxel as 1L therapy in	
	advanced squamous NSCLC.	
Alecensa	Updated efficacy and safety data from the global	Abstract 9043 (poster #366)
(alectinib)	phase III ALEX study of alectinib (ALC) vs	Sunday 03 June
	crizotinib (CZ) in untreated advanced ALK+	08:00 – 11:30 CDT
	NSCLC	
Tecentriq	Patient-reported outcomes (PROs) in the	Abstract 9047 (poster #370)
(atezolizumab)	randomised, phase III IMpower150 study of	Sunday 03 June
(investigational use)	Atezolizumab plus chemotherapy plus	08:00 – 11:30 CDT
	bevacizumab vs chemotherapy plus bevacizumab	
Avastin (bevacizumab)	in 1L non-squamous metastatic NSCLC	
(investigational use)		
Tecentriq	Prospective clinical evaluation of blood-based	Abstract 12001 (oral)
(atezolizumab)	tumour mutational burden (bTMB) as a	Tuesday 05 June
(investigational use)	predictive biomarker for atezolizumab in 1L non-	08:12 – 08:24 CDT
	small cell lung cancer (NSCLC): Interim B-	
	F1RST results.	
Tecentriq	Association of high tissue TMB and atezolizumab	Abstract 12000 (oral)
(atezolizumab)	efficacy across multiple tumour types.	Tuesday 05 June
(investigational use)		08:00 – 08:12 CDT

Overview of key presentations featuring Roche medicines at ASCO 2018

Tecentriq	Patient-reported outcomes (PROs) in	Abstract 4511 (oral)
(atezolizumab)		Sunday 03 June
(investigational use)	-	08:24 – 08:36 CDT
Avastin (bevacizumab)		
(investigational use)		
Tecentriq	Safety and clinical activity of 1L atezolizumab	Abstract 4074 (poster #263)
(atezolizumab)	plus bevacizumab in a phase Ib study in	Sunday 03 June
(investigational use)	hepatocellular carcinoma (HCC).	08:00 – 11:30 CDT
Avastin (bevacizumab)		
(investigational use)		
Tecentriq	1 0	Abstract 4523 (poster #349)
(atezolizumab)	platinum-treated locally advanced or metastatic	Saturday 02 June
		08:00 – 11:30 CDT
	from phase II study IMvigor210.	
Tecentriq		Abstract 4506 (oral)
(atezolizumab)	efficacy of neoadjuvant atezolizumab in muscle	Sunday 03 June
	invasive bladder cancer (ABACUS).	10:00 – 10:12 CDT
(investigator study)		
Tecentriq	Safety and clinical activity results from a phase Ib	
(atezolizumab)	· · · · ·	Friday 01 June
(investigational use)	advanced NSCLC (aNSCLC).	16:42 – 16:54 CDT
Alecensa (alectinib)		
(investigational use)		
Polatuzumab	Randomised phase II trial of polatuzumab	Abstract 7507 (oral)
(investigational use)	vedotin (pola) with bendamustine and rituximab	Sunday 03 June
	(BR) in relapsed/refractory (r/r) FL and DLBCL.	11:45 – 11:57 CDT
Venclexta/Venclyxto	Durable response with venetoclax in	Abstract 7010 (oral)
(investigational use)	combination with decitabine or azacitadine in	Monday 04 June
	elderly patients with acute myeloid leukemia	17:06 – 17:24 CDT
	(AML).	
Venclexta/Venclyxto	High, durable minimal residual disease negativity	Abstract 7508 (oral)
(investigational use)	(MRD–) with venetoclax + rituximab (VenR) in	Sunday 03 June
	relapsed/refractory (R/R) CLL: MRD kinetics	11:57 – 12:09 CDT
	from phase 3 MURANO study.	

Venclexta/Venclyxto	Phase II study of venetoclax plus carfilzomib and	Abstract 8004 (oral)
(investigational use)	dexamethasone in patients with	Friday 01 June
	relapsed/refractory multiple myeloma.	15:57 – 16:09 CDT
Taselisib	Phase III study of taselisib (GDC-0032) +	Abstract LBA1006 (oral)
(investigational use)	fulvestrant (FULV) v FULV in patients	Sunday 03 June
	with estrogen receptor (ER)-positive, PIK3CA-	10:00 – 10:12 CDT
	mutant (MUT), locally advanced or	
	metastatic breast cancer (MBC): Primary analysis	
	from SANDPIPER.	
Ipatasertib	Overall survival (OS) update of the double-blind	Abstract 1008 (oral)
(investigational use)	placebo controlled randomized phase II LOTUS	Sunday 03 June
	trial of first-line ipatasertib plus paclitaxel for	10:24 – 10:36 CDT
	locally advanced/metastatic triple-negative breast	
	cancer (mTNBC).	
Entrectinib	Phase 1 study of entrectinib (RXDX-101), a TRK,	Abstract 10536 (poster #209)
(investigational use)	ROS1, and ALK inhibitor, in children,	Saturday 02 June
	adolescents, and young adults with recurrent or	08:00 – 11:30 CDT
	refractory solid tumours.	
Real World Data	Application of a real world endpoint to identify	Abstract 12006 (oral)
	and characterise genetic profiles of patients (pts)	Tuesday 05 June
	with poor prognosis in advanced non-small-cell	10:00 – 10:12 CDT
	lung cancer (aNSCLC).	

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 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. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry nine 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 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 <u>www.roche.com</u>.

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