Media Release

Data at the 2022 ASCO Annual Meeting highlight Roche's continued commitment to innovation in oncology and personalised healthcare

- **Pivotal data on glofitamab, a potential first-in-class CD20xCD3 T-cell engaging bispecific antibody, in heavily pre-treated patients with aggressive lymphoma, will be presented as part of our industry-leading haematology portfolio**
- **Further studies exploring broad genomic testing to support informed treatment decisions for patients and advance cancer care approaches will be presented**

Basel, 24 May 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data from clinical trials of 18 approved and investigational medicines across more than 20 cancer types will be presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, which will be held 3-7 June, 2022. Roche and its partners will present clinical studies across medicines, comprehensive genomic tests, and real-world data at this year's meeting.

"At ASCO this year, progress from our portfolio, partnerships and collaborations showcase our commitment to advance innovation in cancer care," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We're especially pleased to present data from our broad haematology portfolio, including pivotal data for glofitamab, a potential first-in-class bispecific antibody that may improve the lives of people with heavily pre-treated aggressive lymphoma."

Focusing on improving outcomes in non-Hodgkin lymphoma

New and updated data in non-Hodgkin lymphoma will be presented at ASCO. This includes pivotal data from the phase II NP30179 study evaluating glofitamab, an investigational CD20xCD3 T-cell engaging bispecific antibody, in heavily pre-treated patients with diffuse large B-cell lymphoma (DLBCL). DLBCL is an aggressive form of lymphoma, where as many as 40% of patients will relapse, at which point treatment options are limited and survival is shortened.[1,2] Glofitamab is part of Roche's broad bispecific antibody development programme, which may offer a new immunotherapy-based approach to tackle a range of blood cancers. It is being investigated in several clinical trials including the STARGLO phase III study, evaluating glofitamab in combination with gemcitabine and oxaliplatin (GemOx) versus MabThera®/Rituxan® (rituximab) in combination with GemOx in autologous stem-cell transplant ineligible relapsed or refractory DLBCL. In addition, key findings from an analysis of the Asia subpopulation from the pivotal phase III POLARIX study investigating Polivy® (polatuzumab vedotin) in combination with MabThera/Rituxan plus cyclophosphamide, doxorubicin and prednisone (R-CHP) in people with newly diagnosed DLBCL will be featured. Polivy plus R-CHP is the first treatment regimen to significantly improve outcomes in previously untreated DLBCL in more than 20 years, potentially transforming treatment for people with this disease.

Driving innovation in personalised cancer care

More than 20 new pieces of research from partnerships with Foundation Medicine will be presented, which continue to support innovation as well as progress in personalised cancer care. This includes new data from the phase II Profiler02 study,* which investigates the use of a comprehensive genomic profiling testing panel from Foundation Medicine, with the aim of informing possible treatment decisions for patients based on their tumour's unique genomic information.

Data from the imCORE network

Additionally, three abstracts from the Immunotherapy Centers Of Research Excellence (imCORE) Network will be presented at ASCO: a phase I study investigating autogene cevumeran (an mRNA-based individualised neoantigen-specific immunotherapy [iNeST]***) in the adjuvant setting of pancreatic ductal adenocarcinoma;** a data mining study evaluating intermediate endpoints for survival in metastatic breast cancer in the real-world setting;** and a study identifying mechanisms of acquired resistance to immune checkpoint blockade.**

imCORE is an academic-industry network for scientific collaboration. Established by Roche and connecting experts from 26 leading institutions around the globe, imCORE is committed to advancing and accelerating cancer immunotherapy research. imCORE is an example of Roche's dedication to collaborating with the global cancer community to further understand cancer biology and immunology, help inform the development of potential future treatment, and transform patients' lives.

Roche's data presented at ASCO will feature its efforts to drive innovation and commitment to health equity through delivery of pioneering medicines and personalised cancer care that together improve outcomes for every patient while reducing the cost to society, inclusive clinical trials that remove barriers to participation, partnerships that multiply our ability to address challenges in cancer care, and bringing innovation into earlier stages of disease to maximise a chance of cure.

Roche Oncology Newsroom

Roche's Oncology Newsroom will be available to journalists from 24 May and feature exclusive materials providing insights into Roche's vision, the latest data and perspectives on health inequities in cancer care. To access the Newsroom, please register here.

Overview of key presentations featuring Roche medicines

Medicine	Abstract title	Abstract number
Blood cancer		
Glofitamab	Glofitamab in patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) and ≥2 prior therapies: Pivotal phase II expansion results.	#7500
Mosunetuzumab	CELESTIMO: a phase III trial evaluating the efficacy and safety of mosunetuzumab plus lenalidomide versus rituximab plus lenalidomide in patients with relapsed or refractory follicular lymphoma who have received ≥1 line of systemic therapy.	#TPS7588
Polivy	Asia subpopulation analysis from the phase III POLARIX trial.	#7558
	Initial safety run-in results of the phase III POLARGO trial: polatuzumab vedotin plus rituximab, gemcitabine, and oxaliplatin in patients (pts) with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL).	#7551
Lung cancer		
Tiragolumab	SKYSCRAPER-02: primary results of a phase III, randomized, double-blind, placebo-controlled study of atezolizumab (atezo) + carboplatin + etoposide (CE) with or without tiragolumab (tira) in patients (pts) with untreated extensive-stage small cell lung cancer (ES-SCLC).	#LBA8507
Breast cancer		
Giredestrant	Neoadjuvant giredestrant (GDC-9545) plus palbociclib (P) versus anastrozole (A) plus P in postmenopausal women with estrogen receptor-positive, HER2-negative, untreated early breast cancer (ER+/HER2– eBC): final analysis of the	#589

	randomized, open-label, international phase 2 coopERA BC study.	
Inavolisib	Long-term safety of inavolisib (GDC-0077) in an ongoing phase 1/1b study evaluating monotherapy and in combination (combo) with palbociclib (palbo) and/or endocrine therapy in patients (pts) with PIK3CA-mutated, hormone receptor-positive/HER2-negative (HR+/HER2–) metastatic breast cancer (BC).	#1052
Tumour agnostic treatment and personalised healthcare		
Rozlytrek	Efficacy/safety of entrectinib in patients (pts) with *ROS1*-positive (*ROS1*+) advanced/metastatic NSCLC from the Blood First Assay Screening Trial (BFAST).	#LBA9023
Rozlytrek	Trial in progress: a randomised phase 3 study of entrectinib versus crizotinib in patients (pts) with locally advanced/metastatic *ROS1* fusion-positive (fp) NSCLC with or without baseline CNS metastases (mets).	#TPS9141
Comprehensive genomic profiling (IIS, Centre Léon Bérard)	Increasing targeted therapy options for patients with relapsed cancer with broader somatic gene panel analysis from the primary tumor: The Profiler02 randomized phase II trial.*	#3130
Comprehensive genomic profiling	Clinical and genomic characteristics of patients with durable benefit from immune checkpoint inhibitors (ICI) in advanced non-small cell lung cancer (aNSCLC).	#9048
Comprehensive genomic profiling	CtDNA Shed as a Tool to Select Immune Checkpoint Inhibitors (ICPI) with or without Chemotherapy for Patients (pts) with advanced Non-small Cell Lung Cancer (aNSCLC).	#9045
Comprehensive genomic profiling	Trial in progress - LCMC LEADER Neoadjuvant Screening Trial: LCMC4 Evaluation of Actionable Drivers in Early Stage Lung Cancers.	#TPS8596

Real world data	A real-world (rw) evidence study quantifying the clinical value of multi-gene testing in early-stage lung adenocarcinoma (LUAD).	#8525
Real world data	Real-world analysis of quantitative *MET* copy number (CN) as a biomarker in NSCLC (NSCLC).	#9123
Real world data	Ancestry-based differences in gene alterations in non-small cell lung cancer: real-world data using genetic ancestry analysis.	#9125
imCORE, ISR, Roche	Identifying mechanisms of acquired immune escape from sequential, paired biopsies.**	#2519
imCORE ISR, Dana-Farber Cancer Institute	Real-World Progression-Free Survival (rwPFS) and Time to Next Line of Therapy (TTNT) as Intermediate Endpoints for Survival in Metastatic Breast Cancer: a real world Experience.**	#6520
imCORE ISR, Memorial Sloan Kettering Cancer Center	Phase I Trial of Adjuvant Autogene Cevumeran, an Individualized mRNA Neoantigen Vaccine, for Pancreatic Ductal Adenocarcinoma.**	#2516

* IIS, investigator-initiated study
** ISR, institution-sponsored research
*** jointly developed by Roche and BioNTech

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); Tarceva® (erlotinib); Rozlytrek® (entrectinib); Tecentriq® (atezolizumab); Venclexta®/Venclyxto® (venetoclax) in collaboration with AbbVie; 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

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognising our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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.

References

[1] Maurer MJ, Ghesquières H, Jais JP, et al. Event-free survival at 24 months is a robust end point for disease-related outcome in diffuse large B-cell lymphoma treated with immunochemotherapy. J Clin Oncol. 2014;32(10):1066-1073.
[2] Sehn LH, Gascoyne RD. Diffuse large B-cell lymphoma: optimizing outcome in the context of clinical and biologic heterogeneity. Blood. 2015;125(1):22-32.

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