Media Release

Roche to present new pivotal data at ASH 2021 from broad and comprehensive portfolio, challenging treatment standards for people with blood disorders

- **Phase III POLARIX trial showed Polivy plus R-CHP was the first treatment in two decades to significantly improve outcomes in newly diagnosed diffuse large B-cell lymphoma (DLBCL) versus the standard of care[1]**
- **Pivotal data on mosunetuzumab, a potential first-in-class CD20xCD3 T-cell engaging bispecific antibody, showed high response rates in relapsed or refractory follicular lymphoma (FL)[2]**
- **HAVEN 6 phase III interim data demonstrated Hemlibra's favourable safety and efficacy profile in people with moderate or mild haemophilia A[3]**

Basel, 23 November 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that new data from its extensive haematology portfolio will be presented at the American Society of Hematology (ASH) Annual Meeting and Exposition from 11-14 December 2021. Roche molecules will be featured in more than 90 abstracts, including 17 oral presentations, showcasing new immunotherapies, unique treatment combinations, the application of novel endpoints, and fixed-duration regimens.

Results from three pivotal studies will be featured:

- First presentation of efficacy and safety data from the phase III POLARIX study as a late-breaking abstract and in the ASH press programme. POLARIX met its primary endpoint of improving progression-free survival, showing Polivy® (polatuzumab vedotin) plus MabThera®/Rituxan® (rituximab), cyclophosphamide, doxorubicin, and prednisone (R-CHP) reduced the likelihood of disease worsening or death, versus the standard-of-care, MabThera/Rituxan plus cyclophosphamide, doxorubicin, vincristine and prednisone (R-CHOP), for people with newly diagnosed diffuse large B-cell lymphoma (DLBCL). The safety profile was comparable for Polivy plus R-CHP versus R-CHOP.[1] POLARIX is being conducted in collaboration with The Lymphoma Study Association (LYSA) and The Lymphoma Academic Research Organisation (LYSARC).
- Pivotal results from the phase I/II GO29781 study, presented for the first time and featured in the ASH press programme, showing mosunetuzumab, a CD20xCD3 T-cell engaging bispecific antibody immunotherapy, achieved high response rates with a manageable safety profile. These data suggest that it could be a new treatment option for people with relapsed or refractory follicular lymphoma (FL) who have received two or more prior therapies.[2] FL is the most common indolent (slow growing) form of non-Hodgkin lymphoma, a type of blood cancer, which often returns after initial therapy.[4]
- Interim data from the phase III HAVEN 6 study, which demonstrated the favourable safety and efficacy profile of Hemlibra® (emicizumab) in people with moderate or mild haemophilia A without factor VIII inhibitors.[3] This patient population has historically not used prophylactic (preventative) treatments, likely due to delayed or missed diagnosis and a lack of treatments and treatment guidelines, meaning these patients have a significant unmet clinical need.[5,6]

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"For 20 years, we have remained committed to deepening our understanding of many benign and malignant blood disorders in order to better meet the urgent needs of patients with these diseases," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Our data at ASH reinforce our conviction that following the science and developing versatile treatment approaches leads to improved outcomes for patients in increasingly meaningful ways."

Data presented at ASH by Roche span numerous blood diseases, including lymphoma, leukaemia, multiple myeloma and haemophilia. Additional data to be presented include updated results for three T-cell engaging bispecific antibody immunotherapies: glofitamab and mosunetuzumab, targeting CD20 and CD3; and cevostamab, targeting FcRH5 and CD3.

Further information on the key abstracts featuring Roche medicines presented can be found in the table below.

Roche will be hosting a Live Media Event titled: 'Redefining treatment standards to improve outcomes for patients with blood disorders' on Wednesday 15 December, offering an exclusive opportunity to hear from experts about the pivotal data being presented. Register here to access the Roche Haematology Newsroom, available from Friday 26 November, where you'll be able to attend the Live Media Event and find materials to further explain and provide context to Roche's malignant and non-malignant data.

Follow Roche on Twitter via @Roche and LinkedIn and keep up to date with ASH Annual Meeting news and updates by using the hashtag #ASH21.

Medicine	Abstract title	Abstract number/presentation details
Polivy	The POLARIX Study: Polatuzumab Vedotin with Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (pola-R-CHP) Versus Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (R-CHOP) Therapy in Patients with Previously Untreated Diffuse Large B-Cell Lymphoma	*#LBA-1 oral presentation* *Session: Late-Breaking Abstracts* *Tuesday 14 December, 2021* *09:00-10:30 ET/15:00-16:30 CET*
Mosunetuzumab	Mosunetuzumab Monotherapy Is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular	*#127 oral presentation* *Session: 623* *Saturday 11 December, 2021* *12:00-13:30 ET/18:00-19:30 CET*

	Lymphoma (FL) Who Have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study	
	Mosunetuzumab Plus Polatuzumab Vedotin Has Promising Efficacy and a Favorable Safety Profile in Patients with Relapsed/Refractory Aggressive B-cell Non-Hodgkin Lymphoma: Updated Results from a Phase Ib/II Study	*#533 oral presentation* *Session: 627* *Sunday 12 December, 2021* *16:30-18:00 ET/22:30-00:00 CET*
	Mosunetuzumab in Combination with Lenalidomide Has a Manageable Safety Profile and Encouraging Activity in Patients with Relapsed/Refractory Follicular Lymphoma: Initial Results from a Phase Ib Study	*#129 oral presentation* *Session: 623* *Saturday 11 December, 2021* *12:00-13:30 ET/18:00-19:30 CET*
	Subcutaneous (SC) Administration of Mosunetuzumab with Cycle 1 Step-Up Dosing Is Tolerable and Active in Patients with Relapsed/Refractory B-Cell Non-Hodgkin Lymphomas (R/R B-NHL): Initial Results from a Phase I/II Study	*#3573 poster presentation* *Session: 626* *Monday 13 December, 2021* *18:00-20:00 ET/00:00-02:00 CET*
Glofitamab	Glofitamab Step-Up Dosing Induces High Response Rates in Patients (pts) With Relapsed or Refractory (R/R) Mantle Cell Lymphoma (MCL), Most of Whom Had Failed Prior Bruton's Tyrosine Kinase Inhibitor (BTKi) Therapy	*#130 oral presentation* *Session: 623* *Saturday 11 December, 2021* *12:00-13:30 ET/18:00-00:00 CET*
	Glofitamab (Glofit) in Combination with Polatuzumab Vedotin (Pola): Phase Ib/II Preliminary Data Support Manageable Safety and Encouraging Efficacy in	*#525 oral presentation* *Session: 626* *Sunday 12 December, 2021* *16:30-18:00 ET/22:30-00:00 CET*

	Relapsed/Refractory (R/R) Diffuse Large B-Cell Lymphoma (DLBCL)	
	Glofitamab As Monotherapy and in Combination with Obinutuzumab Induces High Complete Response Rates in Patients (pts) with Multiple Relapsed or Refractory (R/R) Follicular Lymphoma (FL)	*#128 oral presentation* *Session: 623* *Saturday 11 December, 2021* *12:00-13:30 ET/18:00-00:00 CET*
	Glofitamab Monotherapy Provides Durable Responses After Fixed-Length Dosing in Relapsed/Refractory (R/R) non-Hodgkin Lymphoma (NHL) Patients (pts)	*#2478 poster presentation* *Session: 626* *Sunday 12 December, 2021* *18:00-20:00 ET/00:00-02:00 CET*
	Glofitamab Plus R-CHOP Induces High Response Rates With Minimal Cytokine Release Syndrome (CRS) in Patients (pts) with Relapsed/Refractory (R/R) Non-Hodgkin Lymphoma (NHL) and Previously Untreated (1L) Diffuse Large B-Cell Lymphoma (DLBCL): Preliminary Results From a Dose-Escalation and Safety Run-in Phase Ib Study	*#2479 poster presentation* *Session: 626* *Sunday 12 December, 2021* *18:00-20:00 ET/00:00-02:00 CET*
Cevostamab	Cevostamab Monotherapy Continues to Show Clinically Meaningful Activity and Manageable Safety in Patients with Heavily Pre-Treated Relapsed/Refractory Multiple Myeloma (RRMM): Updated Results from an Ongoing Phase I Study	*#157 oral presentation* *Session: 653* *Saturday 11 December, 2021* *12:00-13:30 ET/18:00-19:30 CET*
Gazyva/Gazyvaro	Obinutuzumab Short Duration Infusion Is Preferred by Healthcare Providers and Has Minimal Impact on	*#1345 poster presentation* *Session: 623* *Saturday 11 December, 2021*

	Patient-Reported Symptoms Among Patients with Untreated, Advanced Follicular Lymphoma	*17:30-19:30 ET/23:30-01:30 CET*
Venclexta/Venclyxto	Molecular Responses Are Observed across Mutational Spectrum in Treatment-Naïve Higher-Risk Myelodysplastic Syndrome Patients Treated with Venetoclax Plus Azacitidine	*#241 oral presentation* *Session: 637* *Saturday 11 December, 2021* *14:00-15:30 ET/20:00-21:30 CET*
	Outcomes in Patients with Poor-Risk Cytogenetics with or without *TP53* Mutations Treated with Venetoclax Combined with Hypomethylating Agents	*#224 oral presentation* *Session: 617* *Saturday 11 December, 2021* *14:00-15:30 ET/20:00-21:30 CET*
	Chronic Lymphocytic Leukemia (CLL) Clonal Growth Rate Is Slower Following Venetoclax-Rituximab (VenR): Results from a Minimal Residual Disease (MRD) Model from the Randomized Phase 3 Murano Trial	*#1551 poster presentation* *Session: 642* *Saturday 11 December, 2021* *17:30-19:30 ET/23:30-01:30 CET*
Hemlibra	Emicizumab Prophylaxis in Persons with Mild or Moderate Hemophilia A: Results from the Interim Analysis of the HAVEN 6 Study	*#343 oral presentation* *Session: 322* *Sunday 12 December, 2021* *09:30-11:00 ET/15:30-17:00 CET*
	Evaluation of the Safety of Emicizumab Prophylaxis in Persons with Hemophilia A: An Updated Summary of Thrombotic Events and Thrombotic Microangiopathies	*#3186 poster presentation* *Session: 322* *Monday 13 December, 2021* *18:00-20:00 ET/00:00-02:00 CET*
Crovalimab	Two Currently Recruiting Randomized Phase III Trials: COMMODORE 1 and 2 Evaluating Crovalimab vs Eculizumab in Patients With Paroxysmal Nocturnal	*#4313 publication only*

	Hemoglobinuria with or without Current Anti-Complement Therapy	
	Trial in Progress: The Randomized, Double-Blind, Placebo-Controlled Phase Ib CROSSWALK-a Trial Evaluating the Safety of Crovalimab for the Management of Acute Uncomplicated Vaso-Occlusive Episodes (VOEs) in Patients with Sickle Cell Disease (SCD)	*#3108 poster presentation* *Session: 114* *Monday 13 December, 2021* *18:00-20:00 ET/ 00:00-02:00 CET*
	Trial in Progress: The Randomized, Double-Blind, Placebo-Controlled Phase IIa CROSSWALK-c Trial Evaluating the Efficacy of Crovalimab As Adjunct Treatment in the Prevention of Vaso-Occlusive Episodes (VOEs) in Patients with Sickle Cell Disease (SCD)	*#3111 poster presentation* *Session: 114* *Monday 13 December, 2021* *18:00-20:00 ET/00:00-02:00 CET*

About Roche in haematology

Roche has been developing medicines for people with malignant and non-malignant blood diseases for over 20 years; our experience and knowledge in this therapeutic area runs deep. Today, we are investing more than ever in our effort to bring innovative treatment options to patients across a wide range of haematologic diseases. Our approved medicines include MabThera®/Rituxan® (rituximab), Gazyva®/Gazyvaro® (obinutuzumab), Polivy® (polatuzumab vedotin), Venclexta®/Venclyxto® (venetoclax) in collaboration with AbbVie, and Hemlibra® (emicizumab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibodies, glofitamab and mosunetuzumab, targeting both CD20 and CD3, and cevostamab, targeting both FcRH5 and CD3; Tecentriq® (atezolizumab), a monoclonal antibody designed to bind with PD-L1; and crovalimab, an anti-C5 antibody engineered to optimise complement inhibition. Our scientific expertise, combined with the breadth of our portfolio and pipeline, also provides a unique opportunity to develop combination regimens that aim to improve the lives of patients even further.

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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, the company has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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 thirteenth consecutive year, Roche has been recognised as one of the most sustainable companies in the pharmaceutical industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 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 www.roche.com.

References

[1] Tilly H, et al. The POLARIX Study: Polatuzumab Vedotin with Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone (pola-R-CHP) Versus Rituximab, Cyclophosphamide, Doxorubicin, Vincristine and Prednisone (R-CHOP) Therapy in Patients with Previously Untreated Diffuse Large B-Cell Lymphoma. Presentation at: ASH Annual Meeting and Exposition; 2021 Dec 11-14 Abstract #LBA-1.
[2] Budde E, et al. Mosunetuzumab Monotherapy is an Effective and Well-Tolerated Treatment Option for Patients with Relapsed/Refractory (R/R) Follicular Lymphoma (FL) who have Received ≥2 Prior Lines of Therapy: Pivotal Results from a Phase I/II Study. Presentation at ASH Annual Meeting and Exposition; 2021 Dec 11-14 Abstract #127.
[3] Negrier C, et al. Emicizumab Prophylaxis in Persons with Mild or Moderate Hemophilia A: Results from the Interim Analysis of the HAVEN 6 Study. Presentation at ASH Annual Meeting and Exposition; 2021 Dec 11-14 Abstract #343.
[4] Fowler NH. Role of Maintenance Rituximab (Rituxan) Therapy In the Treatment of Follicular Lymphoma. Pharmacy and Therapeutics; 2011; 36:590-598.
[5] Walsh C et al. Identified unmet needs and proposed solutions in mild-to-moderate haemophilia: A summary of opinions from a roundtable of haemophilia experts. Haemophilia. 2021 February 01; 27(S1):25-32.

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