Media & Investor Release

Early data suggest Roche's NXT007 may have the potential to provide haemostatic normalisation in people with haemophilia A

- **Positive phase I/II data presented at the 2025 International Society on Thrombosis and Haemostasis (ISTH) Congress show NXT007 achieved no bleeds requiring treatment in the highest dose groups in people with haemophilia A[1]**
- **The NXT007 clinical development programme aims to normalise haemostasis and minimise treatment burden[2,3]**
- **Three phase III clinical studies on NXT007, a next-generation bispecific antibody, set to begin in 2026[1]**

Basel, 23 June 2025 - Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today positive phase I/II data on NXT007 in people with haemophilia A, supporting its progression into phase III clinical development. NXT007 is a next-generation investigational bispecific antibody, engineered by Chugai, a member of the Roche Group. Early data from the NXTAGE study suggest that NXT007 may have the potential to provide haemostatic normalisation in people with haemophilia A (without factor VIII inhibitors). NXT007 showed a tolerable safety profile with no thromboembolic events reported so far.[1] These results were featured as an oral presentation at the 2025 International Society on Thrombosis and Haemostasis (ISTH) Congress, 21-25 June, Washington D.C., United States.[1]

"These NXT007 data are promising for people with haemophilia A and underscore our ongoing commitment to advancing care and addressing the real-world challenges faced by this community," said Levi Garraway, MD, PhD, Roche's Chief Medical Officer and Head of Global Product Development. "Hemlibra established a new standard of care, and our focus is to continue to deliver breakthrough innovation that might ultimately help people with haemophilia to live their lives in a manner unaffected by this condition."

NXT007 leverages the Roche Group's expertise in haemophilia A and bispecific antibody development. Our goal is to bring a next generation prophylactic to our portfolio, offering greater therapeutic choice, sustained, elevated bleed protection and reduced treatment burden with factor independence - to allow patients to experience freedom from constant vigilance and have confidence in bleed protection.

NXT007 will be further evaluated in a robust clinical development programme, including ongoing phase I/II clinical trials, with additional phase II data expected later this year. There are also three phase III studies currently planned for 2026, including a phase III head-to-head study with Roche's Hemlibra, the first available prophylactic treatment that can be administered subcutaneously and with flexible dosing options (every week, two weeks or four weeks).[4,5]

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland
Group Communications
Roche Group Media Relations
Phone +41 61 688 88 88
www.roche.com

Part B of the phase I/II NXTAGE study, conducted by Chugai, in Japan, Taiwan and South Korea, is evaluating the safety, pharmacokinetics, pharmacodynamics and efficacy of prophylaxis with NXT007 in people with haemophilia A without factor VIII inhibitors who had not been previously treated with Hemlibra® (emicizumab).[1] Thirty participants (from 12 to 65 years of age) were enrolled in four cohorts (B-1 to B-4) to receive ascending doses of subcutaneous NXT007 every two-to-four weeks during the maintenance period (following four-to-six weeks of loading doses). In presented data from the primary analysis, no treated bleeds were observed with NXT007 in the highest dose cohorts (B-3 and B-4). NXT007 was well tolerated, with no thromboembolic events observed so far.[1]

About NXT007

NXT007 is a next-generation investigational bispecific antibody, being investigated as a prophylactic (preventive) treatment option for people with haemophilia A.[1,2,3]

NXT007 was engineered by Chugai – a member of the Roche Group – built on Hemlibra® (emicizumab)'s framework, with the aim of optimising factor VIII-mimetic activity and half-life, to further enhance potency, efficacy, dosing and administration convenience. NXT007 brings together factor IXa and factor X, proteins required to activate the natural coagulation cascade.[1,2,3] NXT007 is being studied in a robust clinical development programme exploring its potential to achieve sustained elevated bleed protection equivalent to people who do not have haemophilia A (sustained haemostatic normalisation), and reduced treatment burden with factor independence, offering people living with haemophilia A greater therapeutic choice.[1,2,3]

About haemophilia A

Haemophilia A is an inherited, serious disorder in which a person's blood does not clot properly, leading to uncontrolled and often spontaneous bleeding. Haemophilia A affects around 900,000 people worldwide.[6,7] People with haemophilia A either lack or do not have enough of a clotting protein called factor VIII. In a healthy person, when a bleed occurs, factor VIII brings together the clotting factors IXa- and X, which is a critical step in the formation of a blood clot to help stop bleeding. Depending on the severity of their symptoms, people with haemophilia A can bleed frequently, especially into their joints or muscles.[8] These bleeds can present a significant health concern as they often cause pain and can lead to chronic swelling, deformity, reduced mobility and long-term joint damage.[9] A serious complication of treatment is the development of inhibitors to factor VIII replacement therapies. Inhibitors are antibodies developed by the body's immune system that bind to and block the efficacy of replacement factor VIII, making it difficult, if not impossible, to obtain a level of factor VIII sufficient to control bleeding.[6]

About Roche in haematology

Roche has been developing medicines for people with malignant and non-malignant blood diseases for more than 25 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, Hemlibra® (emicizumab), PiaSky® (crovalimab), Lunsumio® (mosunetuzumab) and Columvi® (glofitamab). Our pipeline of investigational haematology medicines includes T-cell engaging bispecific antibody cevostamab, targeting both FcRH5 and CD3 and Tecentriq® (atezolizumab). 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

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.

For over 125 years, sustainability has been an integral part of Roche's business. As a science-driven company, our greatest contribution to society is developing innovative medicines and diagnostics that help people live healthier lives. Roche is committed to the Science Based Targets initiative and the Sustainable Markets Initiative to achieve net zero by 2045.

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] 1. Shima M, et al. NXT007 Prophylaxis in Emicizumab-Naive Persons with Hemophilia A without Inhibitor: Phase I/II Study (NXTAGE) Presented at International Society on Thrombosis and Haemostasis (ISTH) congress; 2025 June. Abstract OC.20.3.
[2] Shima M, et al. Safety, Pharmacokinetics, and Pharmacodynamics of Single Subcutaneous Injection of NXT007, an Emicizumab-Based Next-Generation Bispecific Antibody, in Healthy Volunteers (NXTAGE Study). Presented at: International Society on Thrombosis and Haemostasis (ISTH) Congress; 2023 July 28. Abstract OC 69.4.
[3] Teranishi-Ikawa Y., et al. A bispecific antibody NXT007 exerts a hemostatic activity in hemophilia A monkeys enough to keep a non-hemophiliac state. Journal of Thrombosis and Haemostasis. 2023; doi: 10.1016/j.jtha.2023.09.034
[4] Hemlibra SmPC [Internet; cited 2025 June] Available from: https://www.medicines.org.uk/emc/product/9043/smpc
[5] FDA Prescribing Information [Internet; cited 2025 June]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761083s002s004lbl.pdf.
[6] Srivastava A, et al. WFH guidelines for the management of hemophilia, 3rd edition. Haemophilia. 2020;26 (Suppl 6): 1-158.
[7] Iorio A, et al. Establishing the Prevalence and Prevalence at Birth of Hemophilia in Males. Ann Intern Med. 2019;171(8):540-546.
[8] NHS. Symptoms of haemophilia [Internet; cited 2025 June]. Available from: https://www.nhs.uk/conditions/haemophilia/symptoms/.
[9] Franchini M, et al. Haemophilia A in the third millennium. Blood Rev. 2013; 179-84.

Roche Global Media Relations

Phone: +41 61 688 8888 / e-mail: media.relations@roche.com

Hans Trees, PhD
Phone: +41 79 407 72 58

Sileia Urech
Phone: +41 79 935 81 48

Nathalie Altermatt
Phone: +41 79 771 05 25

Lorena Corfas
Phone: +41 79 568 24 95

Simon Goldsborough
Phone: +44 797 32 72 915

Karsten Kleine
Phone: +41 79 461 86 83

Nina Mählitz
Phone: +41 79 327 54 74

Kirti Pandey
Phone: +49 172 6367262

Yvette Petillon
Phone: +41 79 961 92 50

Dr Rebekka Schnell
Phone: +41 79 205 27 03

Roche Investor Relations

Dr Bruno Eschli
Phone: +41 61 68-75284
e-mail: bruno.eschli@roche.com

Dr Sabine Borngräber
Phone: +41 61 68-88027
e-mail: sabine.borngraeber@roche.com

Dr Birgit Masjost
Phone: +41 61 68-84814
e-mail: birgit.masjost@roche.com

Investor Relations North America

Loren Kalm
Phone: +1 650 225 3217
e-mail: kalm.loren@gene.com