News Release

NXT007 Suggests Favorable Tolerability and Efficacy in Phase I/II Study Following Direct Switch from Emicizumab without Washout Period

- NXTAGE Part C suggested favorable tolerability in people with hemophilia A with or without factor VIII inhibitors when switching from emicizumab to NXT007 without a washout period
- Similar to Part B in emicizumab-naïve participants, the highest-dose cohorts achieved plasma concentrations expected to provide factor VIII activity within the normal range, with no bleeds requiring treatment
- NXT007 is a Chugai-originated compound currently under development for hemophilia A. Three Phase III studies are planned to be initiated in 2026.

TOKYO, February 9, 2026 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that data from Part C of the Phase I/II NXTAGE study, the first clinical data evaluating NXT007 in people switching from emicizumab without a washout period, were presented at the 2026 European Association for Haemophilia and Allied Disorders (EAHAD) Congress held in Ireland. NXT007 is a next-generation bispecific antibody, based on Hemlibra (generic name: emicizumab), a widely used treatment for hemophilia A is being developed as a subcutaneous treatment for hemophilia A.

“The favorable tolerability observed when switching from emicizumab to NXT007 without a washout period is an important finding, and we view it as a key insight for advancing the safety evaluation during the switching period. We are advancing the development of NXT007 with the higher goal of achieving hemostatic function equivalent to that of people without hemophilia. Working closely with Roche, we focus on advancing three Phase III clinical studies that are planned to start this year, and aim to bring this treatment to patients as soon as possible,” said Dr. Osamu Okuda, Chugai’s President and CEO.

The NXTAGE study is a multicenter Phase I/II study evaluating the safety, pharmacokinetics, pharmacodynamics, and efficacy of NXT007. Data presented were from Part C, , a multiple ascending dose part of the study in people aged 12 to <65 years with hemophilia A with or without factor VIII inhibitors who have been receiving

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continuous emicizumab treatment for at least 12 weeksParticipants were divided into four cohorts and, after receiving at least 12 weeks of emicizumab pretreatment, switched to subcutaneous NXT007 without a washout period. Following a loading dose period of 4 to 6 weeks, maintenance doses at different dose levels per cohort were administered subcutaneously every 4 weeks. This analysis was conducted after at least 3 participants in each cohort (total of 14 participants) had received NXT007 for 16 weeks or longer.

NXT007 was well tolerated when switching from emicizumab. No thromboembolic events were observed, the frequency of adverse events did not increase in a dose-dependent manner, and there were no adverse events leading to treatment discontinuation or NXT007-related serious adverse events. Among NXT007-related adverse events, injection site reactions (14.3%) were most commonly reported, all of which were mild. Anti-drug antibodies affecting NXT007 plasma concentrations were detected in one participant (7.1%) in Cohort C-3; however, NXT007 plasma concentrations were maintained at a consistent level, and the participant continued in the study without bleeding events. NXT007 plasma concentrations increased in a dose-dependent manner, and similar to Part B in emicizumab-naïve participants, the highest dose cohorts (Cohorts C-3 and C-4) achieved plasma concentrations with the potential to provide factor VIII-equivalent activity[1] within the normal range based on nonclinical data. After switching to NXT007, no bleeds requiring treatment were observed in Cohorts C-3 and C-4.

[Reference]

Phase I/II Study in Hemophilia A Suggests NXT007 May Have the Potential to Provide Hemostatic Normalization (News release issued on June 23, 2025)
https://www.chugai-pharm.co.jp/english/news/detail/20250623113001_1165.html

Non-Clinical Research Results of Chugai's NXT007 Published in Journal of Thrombosis and Haemostasis (News release issued on November 7, 2023)
https://www.chugai-pharm.co.jp/english/news/detail/20231107160000_1021.html

About NXT007

NXT007 is a bispecific antibody originated from Chugai, designed with the goal of achieving coagulation activities at a level comparable to individuals without hemophilia,

while optimizing administration convenience. NXT007 is designed to bind factor IXa and factor X, to provide the cofactor function of factor VIII in people with hemophilia A, who either lack or have impaired coagulation function of factor VIII. By applying Chugai's proprietary antibody engineering technology, FAST-Ig™[2] for the first time, the variable region of Hemlibra has been optimized, aiming to further enhance efficacy. ACT-Ig®[3] was also applied, aiming to further improve antibody pharmacokinetics. Roche decided to in-license the investigational drug in August 2022. Phase I/II clinical studies for hemophilia A are currently ongoing, and three Phase III clinical studies are planned to be initiated in2026.

Sources:

1. Koichiro Yoneyama et.al., Blood (2022) 140 (Supplement 1): 11295–11296
2. Hikaru Koga et al. Efficient production of bispecific antibody by FAST-IgTM and its application to NXT007 for the treatment of hemophilia A, mAbs, 15:1
3. Atsuhiko Maeda et al. Identification of human IgG1 variant with enhanced FcRn binding and without increased binding to rheumatoid factor autoantibody, mAbs, 9:5, 844-853

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