



Non-Clinical Research Results of Chugai's NXT007 Published in Journal of Thrombosis and Haemostasis

- Non-clinical research results on NXT007, a bispecific antibody using Chugai's proprietary antibody engineering technologies, was accepted for publication in a leading journal in thrombosis and haemostasis
- The potential of NXT007 to maintain coagulation activities at a level comparable to that in individuals without hemophilia A, was suggested in non-clinical research
- Phase I/II clinical trials to investigate NXT007 in hemophilia A are ongoing

TOKYO, November 7, 2023 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that the results of non-clinical research on NXT007, have been published in the online version of the Journal of Thrombosis and Haemostasis (JTH). NXT007 was discovered by Chugai, and Phase I/II clinical studies in hemophilia A are ongoing. JTH is published by the International Society on Thrombosis and Hemostasis (ISTH) and is recognized as a leading journal in thrombosis and haemostasis, reporting innovative preclinical and clinical research in the field.

"A bispecific antibody NXT007 exerts a hemostatic activity in hemophilia A monkeys enough to keep a non-hemophiliac state"

<https://doi.org/10.1016/j.jtha.2023.09.034>

The following findings were demonstrated in this research, which suggests the potential of NXT007 to maintain coagulation activities at a level comparable to that in individuals without hemophilia.

- Creation of NXT007, a new antibody which aimed to enhance factor VIII activity, by applying antibody engineering technologies based on the amino acid sequence of Hemlibra[®], a treatment for hemophilia A
- NXT007 exerted an *in vitro* thrombin generation activity in human hemophilia A plasma corresponding to that at 100 IU/dL* of FVIII
*100 IU/dL corresponds to a level comparable to that in individuals without hemophilia
- NXT007 showed a dose-dependent hemostatic activity *in vivo*
- NXT007 showed a favorable PK profile *in vivo*

About NXT007

NXT007 is a bispecific antibody developed by Chugai, expected to achieve coagulation activities at a level comparable to individuals without hemophilia as well as introducing convenient administration. 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. Chugai's proprietary antibody engineering technologies are applied, including FAST-IgTM,¹ to enhance large-scale production of the bispecific antibody and ACT-Fc[®],² which is expected to improve antibody pharmacokinetics. FAST-Ig

was applied to an antibody project for the first time. Phase I/II clinical trials for hemophilia A are currently ongoing, and Roche decided to in-license the investigational drug in August 2022.

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Sources

1. 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
2. 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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