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Chugai's Hemlibra Approved by the European Commission to Treat People with Moderate Hemophilia A

TOKYO, February 1, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Roche has received notification that the European Commission has extended the marketing authorization for the anti-coagulation factor IXa/X humanized bispecific monoclonal antibody/coagulation factor VIII substitute Hemlibra® [generic name: emicizumab (genetical recombination)] to include routine prophylaxis of bleeding episodes in people with hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, who have moderate disease (FVIII ≥1% and ≤ 5%) with a severe bleeding phenotype. The approval by the European Commission is based on the results from the phase III HAVEN 6 study and real-world data.

[Reference Information]

CHMP recommends expansion of EU label for Hemlibra to include people with moderate haemophilia A (Press release issued by Roche on December 16, 2022)
https://www.roche.com/media/releases/med-cor-2022-12-16

About Hemlibra

Hemlibra is a bispecific monoclonal antibody created with Chugai's proprietary antibody engineering technologies. The drug is designed to bind factor IXa and factor X. In doing so, Hemlibra provides the cofactor function of factor VIII in people with hemophilia A, who either lack or have impaired coagulation function of factor VIII.[1,2] The product was approved by the U.S. Food and Drug Administration (FDA) in November 2017, for the first time in the world, for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors. Hemlibra has been approved in more than 110 countries for congenital hemophilia A with and without factor VIII inhibitors. In Japan, it was first approved in March 2018 for congenital hemophilia A with factor VIII inhibitors, and its indication was later expanded to include congenital hemophilia A without factor VIII inhibitors, and acquired hemophilia A.

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References

1. Kitazawa, et al. Nature Medicine 2012; 18(10): 1570
2. Sampei, et al. PLoS ONE 2013; 8(2): e57479

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