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Chugai's Hemlibra Approved for Hemophilia A without inhibitors in Taiwan

- Hemlibra was approved for hemophilia A without inhibitors in Taiwan on 22 October 2019

TOKYO, October 30, 2019 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that [Chugai Pharma Taiwan Ltd.](#), a wholly owned subsidiary of Chugai, obtained approval from the Taiwan Food and Drug Administration (TFDA) for Hemlibra® for routine prophylaxis of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors administered once weekly, every two weeks, or every four weeks by subcutaneous injection on 22 October. TFDA has also approved additional dosing options of every two weeks or every four weeks in patients with hemophilia A with factor VIII inhibitors.

About Hemlibra

Hemlibra is a bispecific monoclonal antibody, which was developed using 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)}. Hemlibra is approved in more than 90 countries, since the product has been approved 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 for the first time in the world by the U.S. Food and Drug Administration (FDA) in November 2017.

1) Kitazawa, et al. Nature Medicine 2012; 18(10): 1570

2) Sampei, et al. PLoS ONE 2013; 8: e57479

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About Chugai

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs.

Additional information is available at <https://www.chugai-pharm.co.jp/english>.

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