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Chugai's HEMLIBRA® Approved in Taiwan for the Treatment of Hemophilia A with Factor VIII Inhibitors

TOKYO, December 4, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Chugai Pharma Taiwan Ltd., a wholly owned subsidiary of Chugai, obtained approval from the Taiwan Food and Drug Administration (TFDA) for Chugai's bispecific monoclonal antibody HEMLIBRA® for routine prophylaxis of bleeding episodes in patients with hemophilia A with factor VIII inhibitors by once weekly subcutaneous injection.

"We are pleased that HEMLIBRA has received regulatory approval for hemophilia A with factor VIII inhibitors now in Taiwan," said Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit, Dr. Yasushi Ito. "Chugai will cooperate with Chugai Pharma Taiwan so that HEMLIBRA may contribute to people with hemophilia A with inhibitors who have limited treatment options."

This approval is based on data from two pivotal studies in people with hemophilia A with factor VIII inhibitors: results of HAVEN 1 study (NCT02622321) in adolescents and adults, and the interim analysis of HAVEN 2 study (NCT02795767) in children.

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 50 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. In Japan, HEMLIBRA is approved for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with congenital factor VIII deficiency (hemophilia A) with factor VIII inhibitors in March 2018, and in May 2018, the product is launched.

References

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

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

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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, mainly focusing on the oncology area.
In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.
The consolidated revenue in 2017 of Chugai totalled 534.2 billion yen and the operating income was 103.2 billion yen (IFRS Core basis).
Additional information is available on the internet at https://www.chugai-pharm.co.jp/english.

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