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Chugai's Hemlibra approved in Taiwan

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Chugai Pharmaceuticals announced that Chugai Pharma Taiwan, 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.

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.