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Chugai's HEMLIBRA® Receives Regulatory Approval from U.S. FDA for Hemophilia A without Inhibitors

TOKYO, October 5, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the U.S. Food and Drug Administration (FDA) has approved HEMLIBRA® (US generic name: emicizumab-kxwh), a treatment for hemophilia A created by Chugai, for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children, ages newborn and older, with hemophilia A without factor VIII inhibitors, administered once weekly, every two weeks, or every four weeks. The FDA has also approved additional dosing options of every two weeks or every four weeks in adults and children with hemophilia A with factor VIII inhibitors. The US application was submitted by Genentech, a member of Roche Group.

"We are very pleased that HEMLIBRA has obtained its first regulatory approval for people with hemophilia A without inhibitors," said Chugai's President & CEO, Tatsuro Kosaka. "Now people with hemophilia A in the US can be offered flexibility in HEMLIBRA's dosing interval from multiple options depending on their needs, regardless of their inhibitor expression. We anticipate that HEMLIBRA will make an even greater contribution to the advancement of treatment of hemophilia A."

This regulatory approval is based on results from two Phase lll studies HAVEN 3 (NCT02847637) and HAVEN 4 (NCT03020160), conducted jointly with Roche and Genentech. HAVEN 3 study was conducted to evaluate the reduction of bleed rate of HEMLIBRA subcutaneous injection once a week and once every two weeks in people with hemophilia A (12 years of age or older) without inhibitors to factor VIII. HAVEN 4 study was conducted to evaluate efficacy, safety, and pharmacokinetics of HEMLIBRA subcutaneous injection every four weeks in people with hemophilia A (12 years of age or older), with and without inhibitors to factor VIII.

HEMLIBRA was granted Priority Review and Breakthrough Therapy Designation by the FDA in hemophilia A without inhibitors, following the prior designations in hemophilia A with inhibitors. Priority Review designation is granted to medicines that the FDA has determined to have the potential to provide significant improvements in the safety and effectiveness of the treatment, prevention or diagnosis of a serious disease. In Japan and the EU, applications have been filed to regulatory authorities and are currently under review for an additional indication of prophylactic treatment for people with hemophilia A without inhibitors, as well as for additional dosage and administration as a biweekly or every four-week treatment for people with hemophilia A with inhibitors to factor VIII.

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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, 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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