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Chugai's HEMLIBRA® Approved by European Commission in Hemophilia A with Inhibitors -- Approved in EU Following the US --

TOKYO, February 28, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that Roche has received regulatory approval from the European Commission for HEMLIBRA® (emicizumab) for routine prophylaxis of bleeding episodes in people with hemophilia A with factor VIII inhibitors.

"Following the US approval, we are very proud of the approval to deliver the first-in-class product HEMLIBRA to people with hemophilia A with inhibitors in the EU as well," said Chugai's President & COO, Tatsuro Kosaka. "By having HEMLIBRA – an additional Chugai originated medicine to the existing product lineup currently marketed in the EU, such as RoACTEMRA® and ALECENSA®, we are continuously committed to resolve unmet medical needs for patients in the EU jointly with Roche."

This approval is based on the two pivotal studies for hemophilia A with inhibitors: the results of HAVEN1 study (NCT02622321) for adolescents and adults, and the interim analysis of HAVEN2 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)]. In November 2017, the drug (US product name: HEMLIBRA®; Genentech) was approved by the U.S. Food and Drug Administration and was marketed 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." In Japan, HEMLIBRA obtained an orphan drug designation in August 2016 from the Ministry of Health, Labour and Welfare for the prevention and reduction of bleeding episodes in patients with congenital factor VIII deficiency (hemophilia A) who developed inhibitors to factor VIII, followed by an application for regulatory approval filed in July 2017.

About the results of HAVEN1 study and HAVEN2 study

Press release issued on June 26, 2017

https://www.chugai-pharm.co.jp/english/news/detail/20170626140000.html

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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 totaled 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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References

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

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