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Chugai's Emicizumab Receives Priority Review Designation by FDA for Hemophilia A with Inhibitors

TOKYO, August 24, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the US Food and Drugs Administration (FDA) has accepted the Biologics License Application (BLA) and has granted Priority Review for an investigational antibody emicizumab prophylaxis (preventative) as a once-weekly subcutaneous treatment for adults, adolescents and children with hemophilia A with factor VIII inhibitors. The FDA is expected to make a decision on approval by February 23, 2018.

"We expect that FDA's review process for emicizumab has been expedited with the Breakthrough Therapy Designation granted in September 2015," said Chugai's Senior Vice President, Head of Project & Lifecycle Management Unit, Dr. Yasushi Ito. "There are limited treatment options for patients with hemophilia A with inhibitors. We are thrilled that the day is approaching when we can deliver this antibody with a novel mode of action to patients given this Priority Review status."

Both the filing and the Priority Review designation were made based on the results of HAVEN 1 study (NCT02622321) and the interim analysis of HAVEN 2 study (NCT02795767), both of which have been conducted under a collaboration between Chugai, Roche and Genentech. HAVEN 1 is for adult and adolescent patients and HAVEN 2 is for pediatric patients.

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. Outside US, emicizumab has been filed in the EU in June 2017 and in Japan in July 2017.

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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 2016 of Chugai totaled 491.8 billion yen and the operating income was 80.6 billion yen (IFRS Core basis).

Additional information is available on the internet at https://www.chugai-pharm.co.jp/english.

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