Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Chugai's HEMLIBRA® Receives Priority Review Status from U.S. FDA for Hemophilia A without Inhibitors - Second Designation following Hemophilia A with inhibitors -

TOKYO, June 5, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the U.S. Food and Drugs Administration (FDA) has accepted the supplemental Biologics License Application (sBLA) and granted Priority Review for HEMLIBRA® [US generic name: emicizumab-kxwh] for adults and children with hemophilia A without factor VIII inhibitors. The FDA is expected to make a decision on approval by 4 October, 2018. In the US, Genentech, Inc, a member of Roche Group is the BLA holder and is engaged in the development and distribution of HEMLIBRA®, which was approved and launched for hemophilia A with inhibitors in November 2017.

"We are very proud that HEMLIBRA has been granted a second Priority Review for hemophilia A without inhibitors following the previous designation for hemophilia A with inhibitors, which underscores the innovation of this drug," said Chugai's Senior Vice President, Co-Head of Project & Lifecycle Management Unit, Dr. Yasushi Ito. "In treatment of hemophilia A without inhibitors, there still remain unmet medical needs in the management of bleeding. Given this Priority Review status, we hope to be able to contribute to people with hemophilia A and their caregivers as soon as possible by providing HEMLIBRA as a new treatment option that can be administered subcutaneously with good bleeding control and eased treatment burden."

The sBLA filing and Priority Review are based on the results of HAVEN 3 study (NCT02847637), which has been conducted with adults and adolescents with hemophilia A without factor VIII inhibitors under a collaboration between Chugai, Roche and Genentech. In EU, Roche has already filed the results to the European Medicines Agency for a supplemental indication of hemophilia A without inhibitors.

Priority Review designation is granted to medicines that the FDA has determined to have the potential to provide significant improvements in safety or effectiveness of the treatment, prevention or diagnosis of a serious disease. In Japan, HEMLIBRA received regulatory approval in March 2018 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 and, in April 2018, was filed to the Ministry of Health, Labour and Welfare for a supplemental indication of hemophilia A without inhibitors.

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL: +81-(0)3-3273-0881 E-mail: pr@chugai-pharm.co.jp
Investor Relations Group TEL: +81-(0)3-3273-0554 E-mail: ir@chugai-pharm.co.jp

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.

Contact:

For Media

Chugai Pharmaceutical Co., Ltd.

Media Relations Group, Corporate Communications Dept.,

Tomoko Shimizu

Tel: +81-3-3273-0881

E-mail: pr@chugai-pharm.co.jp

For US media

Chugai Pharma USA Inc.

Casey Astringer

Tel: +1-908-516-1350

E-mail: pr@chugai-pharm.com

For European media

Chugai Pharma France SAS

Nathalie Leroy

Tel: +33-1-56-37-05-21

E-mail: pr@chugai.eu

For Taiwanese media

Chugai Pharma Taiwan Ltd.

Susan Chou

Tel: +886-2-2715-2000

E-mail: pr@chugai.com.tw

For Investors
Chugai Pharmaceutical Co., Ltd.
Investor Relations Group, Corporate Communications Dept.,
Toshiya Sasai
Tel: +81-3-3273-0554
E-mail: ir@chugai-pharm.co.jp