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Results of Global Phase III Study with Chugai's HEMLIBRA® for Hemophilia A without Inhibitors Published in the New England Journal of Medicine

TOKYO, August 30, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) today announced that results of the HAVEN 3 study (NCT02847637), the global phase III study evaluating hemophilia A treatment, HEMLIBRA® (generic name: emicizumab [genetical recombination]), were published in the 30 August 2018 issue of the New England Journal of Medicine (NEJM).
Article: https://www.nejm.org/doi/full/10.1056/NEJMoa1803550
Quick video summary by NEJM: https://www.nejm.org/do/10.1056/NEJMdo005333/full/

The study evaluated the efficacy and safety 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. Detailed results of the study were presented at the World Federation of Hemophilia (WFH) 2018 World Congress held in Glasgow, Scotland on May 21, 2018.

"This is the third time that the clinical data of HEMLIBRA have been published in the NEJM, following the results of the phase I study and the first phase III study. It demonstrates a high medical value that the drug may bring to the treatment of hemophilia A," said Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit, Dr. Yasushi Ito. "We are committed to deliver HEMLIBRA which has been created with our proprietary bispecific antibody technologies, as a new treatment option to people with hemophilia A without inhibitors as early as possible in cooperation with Roche."

In May 2018, HEMLIBRA was launched in Japan 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. An application for an additional indication of the treatment of hemophilia A without factor VIII inhibitors has been filed in April in Japan. Applications for the same additional indication have also been filed in the United States and Europe. In the U.S., the Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation in April, and Priority Review in June, for this line extension. In Europe, the review by the EU Committee for Medicinal Products for Human Use (CHMP) is ongoing.

Reference

Chugai Presents Results of Two Pivotal Phase III Studies for its Bispecific Antibody HEMLIBRA at WFH 2018 (Press release issued on May 21, 2018)
https://www.chugai-pharm.co.jp/english/news/detail/20180521160000.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 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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