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Chugai's Hemlibra Receives Approval for Severe Hemophilia A without Factor VIII Inhibitors from the European Commission

- Hemlibra is now available for hemophilia A without inhibitors in the EU, following US and Japan
- Multiple dosing options are available regardless of inhibitor status

TOKYO, March 14, 2019 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that Roche received the decision from the European Commission confirming that Hemlibra® (emicizumab), a hemophilia A treatment originated by Chugai, has EU marketing authorization for routine prophylaxis of bleeding episodes in adults and children with severe hemophilia A (congenital factor VIII deficiency, FVIII <1%) without factor VIII inhibitors. The EU Commission also approved that Hemlibra can be used with multiple dosing options (once weekly, every two weeks, or every four weeks) for all indicated people with hemophilia A, including those with factor VIII inhibitors.

"We are very thrilled that people with severe hemophilia A without inhibitors in the EU can be offered Hemlibra with multiple dosing options," said Chugai's President & CEO, Tatsuro Kosaka. "In addition to its efficacy, the availability of subcutaneous injection has been well accepted especially among children. This approval enables flexibility in Hemlibra's dosing schedule that may better fit into the life of each person with hemophilia A regardless of their inhibitor status. We truly hope that Hemlibra will be widely recognized as a treatment option for hemophilia A, and bring benefits to people with hemophilia A and their caregivers in Europe."

This approval is based on the results from two Phase III 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.

In Japan, Chugai obtained regulatory approval for Hemlibra from the Ministry of Health, Labour and Welfare in December 2018 for an additional indication of prophylactic treatment for people with hemophilia A without inhibitors to factor VIII, 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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Notes

Chugai's HEMLIBRA® Subcutaneous Injection Receives Approval for Hemophilia A without Inhibitors and Extension of Dosing Interval
Press release issued on December 21, 2018
https://www.chugai-pharm.co.jp/english/news/detail/20181221153002_580.html

About Severe Hemophilia A

People with severe hemophilia A is defined as the condition with less than 1% of factor VIII levels[1]. Approximately 50-60% of people with hemophilia A worldwide are expected to have a severe form of the disorder[2].

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

Reference

1) World Federation of Hemophilia : Report on the Annual Global Survey 2017.

2) Marder VJ, et al. Hemostasis and Thrombosis. Basic Principles and Clinical Practice. 6th Edition, 2013. Milwakee, Wisconsin. Lippincott Williams and Wilkin.

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