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Interim Data from Phase III HAVEN 6 Study Demonstrate Safety and Efficacy Profile of Chugai's Hemlibra in People with Moderate or Mild Hemophilia A

- New data demonstrates Hemlibra's safety profile in people with moderate or mild hemophilia A without factor VIII inhibitors, with no new safety signals identified[1]
- Hemlibra also achieved clinically meaningful bleed control, with 80.3% of participants experiencing no bleeding episodes that required treatment and 90.1% experiencing no joint bleeds that required treatment[1]

TOKYO, December 13 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced results from an interim analysis of the phase III HAVEN 6 study, in which Chugai's anti-coagulation factor IXa/X humanized bispecific monoclonal antibody / coagulation factor VIII substitute Hemlibra® [generic name: emicizumab (genetical recombination)] demonstrated its safety profile and effective bleed control in people with moderate or mild hemophilia A without factor VIII inhibitors.[1] The data were presented at the 63rd American Society of Hematology (ASH) Annual Meeting and Exposition as an oral presentation on December 12 2021.

While the treatment and management of severe hemophilia A is being established, there is less information and treatment guidance on moderate and mild hemophilia A, which can lead to delayed or missed diagnosis of bleeding episodes.[2] Considering this population may not use preventative treatments, they may experience worsened clinical burden, with less than 30% of people with moderate or mild hemophilia A living a bleed-free life.[2,3]

"I am delighted that further data confirmed Hemlibra's potential benefits in treatment of moderate and mild hemophilia A, in which there are still high unmet medical needs in the world," said Chugai's President and CEO, Dr. Osamu Okuda. "Chugai will continue to develop a wide range of data and provide information for proper use so that we may offer a new treatment option for people with hemophilia A further regardless of severity."

HAVEN 6 is a phase III study evaluating the safety, efficacy, pharmacokinetics, and pharmacodynamics of Hemlibra in people with moderate or mild hemophilia A without factor VIII inhibitors. This interim analysis included data from 71 participants (69 men and two women); 20 of whom had mild hemophilia A without factor VIII Inhibitors and 51 had moderate hemophilia A without inhibitors. 37 participants were on factor VIII prophylaxis at baseline.[1]

This interim analysis was conducted after 50 participants with moderate hemophilia A completed at least 24 weeks in the study or withdrew. Data cut-off was on April 16, 2021. These data demonstrate Hemlibra's safety profile and effective bleed control in the HAVEN 6 study, with 80.3% of participants

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experiencing no bleeding episodes that required treatment and 90.1% experiencing no joint bleeds that required treatment.[1]

The most common adverse events (AEs) occurring in 10% or more people in the HAVEN 6 study were headache (14.1%) and local injection site reactions (ISRs) (12.7%). Eleven people (15.5%) reported a Hemlibra-related AE, with ISRs being the most common (12.7%).

Hemlibra is approved to treat people with hemophilia A with factor VIII inhibitors in more than 100 countries worldwide and for people without factor VIII inhibitors in more than 90 countries worldwide, including the US, EU and Japan. Hemlibra has been studied in a clinical trial program including eight phase III studies, in people with hemophilia A with and without factor VIII inhibitors.

About Hemlibra

Hemlibra is a bispecific monoclonal antibody created with 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[4,5]. The product was approved by the U.S. Food and Drug Administration (FDA) in November 2017, for the first time in the world, 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, it was first approved in March 2018, and its indication was later expanded to include congenital hemophilia A without factor VIII inhibitors. Hemlibra has been approved in more than 100 countries for congenital hemophilia A with and without factor VIII inhibitors.

References

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