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Positive CHMP opinion for Chugai's Hemlibra

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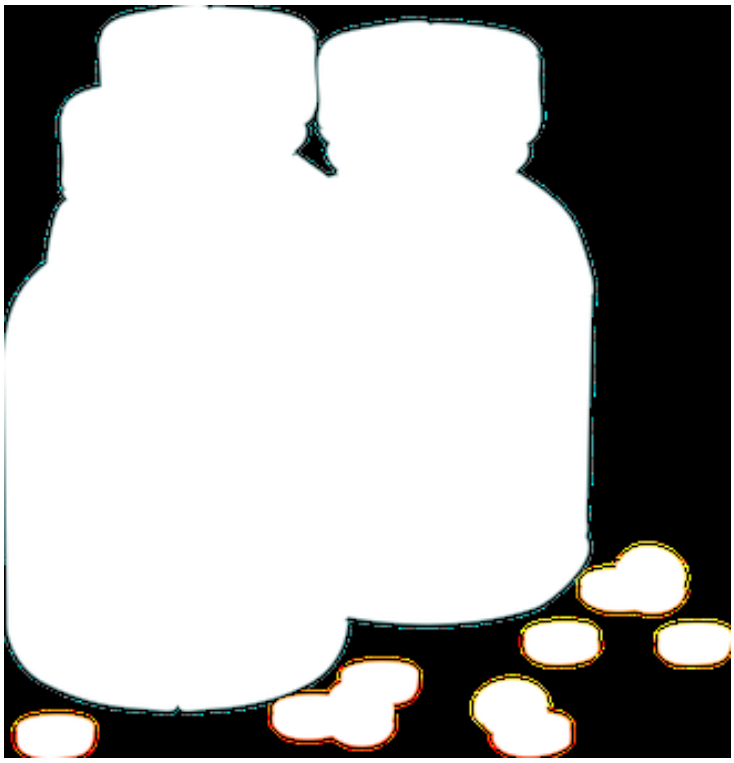

Chugai Pharmaceutical has announced that Roche has received notification that the EU Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for Hemlibra®, a treatment for hemophilia A created by Chugai, for routine prophylaxis of bleeding episodes in adults and children with severe hemophilia A without factor VIII inhibitors, administered once weekly, every two weeks, or every four weeks.

The CHMP has also adopted a positive opinion for additional dosing options of every two weeks or every four weeks in adults and children with hemophilia A with factor VIII inhibitors. "We are thrilled that Hemlibra is expected to be approved shortly for people with severe hemophilia A without inhibitors in the Europe Union (EU). Also, I'm very pleased that people in the EU with hemophilia A will soon be offered multiple options of Hemlibra's dosing interval regardless of their inhibitor expression," said Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit, Dr. Osamu Okuda.

"Hemlibra is co-promoted by Chugai and Roche in Germany, France, and the United Kingdom, as is the case with the anti-rheumatic agent RoActemra®. We are committed to pursue our efforts in collaboration with Roche so that Hemlibra may further contribute to the treatment of hemophilia A." This positive opinion is based on 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 the 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.