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Chugai's HEMLIBRA® Subcutaneous Injection Receives Approval for Hemophilia A without Inhibitors and Extension of Dosing Interval

-- HEMLIBRA is now available for Hemophilia A, regardless of inhibitor status --

TOKYO, December 21, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the Ministry of Health, Labour and Welfare (MHLW) has approved the anti-coagulation factor IXa/X humanized bispecific monoclonal antibody / coagulation factor VIII substitute, "HEMLIBRA® Subcutaneous Injection 30 mg, 60 mg, 90 mg, 105 mg, and 150 mg" [generic name: emicizumab (genetical recombination)], for routine prophylactic treatment for people with hemophilia A without inhibitors to factor VIII, administered once weekly, every two weeks, or every four weeks. The MHLW has also approved additional dosing options of every two weeks or every four weeks in people with hemophilia A with factor VIII inhibitors. With this supplemental approval, the indication of HEMLIBRA has been broadened to "routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with congenital factor VIII deficiency."

"HEMLIBRA is a first-in-class antibody created by Chugai's proprietary antibody engineering technologies with an aim to tackle unmet medical needs," said Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit, Dr. Osamu Okuda. "The approval enables subcutaneous injections of HEMLIBRA to be used weekly, every two weeks or every four weeks regardless of the presence of inhibitors to factor VIII. Chugai will continue to focus on providing the best solution to support the proper use of HEMLIBRA in response to the various needs of people with hemophilia A."

This approval is based on the results from HAVEN 3 study (NCT02847637) and HAVEN 4 study (NCT03020160). HAVEN 3 study is a global phase III study evaluating 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 is a global phase III study evaluating 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.

[Drug Information after the Approval]

INDICATIONS:

Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with congenital factor VIII deficiency

<Precautions related to INDICATIONS>

The efficacy of emicizumab irrespective of the presence of an inhibitor against blood coagulation factor VIII has been confirmed.

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DOSAGE AND ADMINISTRATION:

The recommended dose of emicizumab (genetical recombination) is 3 mg/kg (body weight) administered as subcutaneous injection once weekly for the first 4 weeks, followed by subcutaneous injections according to any of the following dosage regimens.

- 1.5 mg/kg (body weight) once weekly
- 3 mg/kg (body weight) once every 2 weeks
- 6 mg/kg (body weight) once every 4 weeks

<Precautions related to DOSAGE AND ADMINISTRATION>

Emicizumab should only be used in a routine administration regimen to prevent or reduce the frequency of bleeding episodes and should not be used for on-demand hemostatic treatment.

[References]

About the results of HAVEN 3 study

Press release issued on November 20, 2017

https://www.chugai-pharm.co.jp/english/news/detail/20171120151500_52.html

About the results of HAVEN 4 study

Press release issued on December 7, 2017

https://www.chugai-pharm.co.jp/english/news/detail/20171207150000_48.html

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