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Launch of HEMLIBRA® Subcutaneous Injection for the Treatment of Hemophilia A

TOKYO, May 22, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has launched its anti-coagulation factor IXa/X humanized bispecific monoclonal antibody / coagulation factor VIII substitute, (brand name, "HEMLIBRA® Subcutaneous Injection 30 mg, 60 mg, 90 mg, 105 mg, 150 mg;" hereafter, "HEMLIBRA") 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. HEMLIBRA received a manufacturing and marketing approval on March 23, 2018 and was listed on the National Health Insurance (NHI) reimbursement price list today.

Congenital hemophilia A is a disorder where a person's blood does not clot properly due to congenital missing or defective factor VIII, leading to serious bleeding symptoms that occur repeatedly. In Japan, it is reported that about 5,000 people have congenital hemophilia A[1]. The current standard treatment for hemophilia A is factor VIII replacement therapy, however, 25-30% of people with severe congenital hemophilia A develop inhibitors (neutralizing antibodies) that reduce the effects of treatment[2].

"We are pleased that HEMLIBRA, which was created with Chugai's proprietary bispecific antibody technologies, is now available as a new approach to the treatment of hemophilia A in Japan following the U.S. and Europe," said Chugai's President & CEO, Tatsuro Kosaka. "Once people with hemophilia A develop inhibitors against the standard treatment, treatment options become limited, and one of the issues encountered in the treatment was that this may lead to the exacerbation of the disorder. HEMLIBRA is a drug with a novel mode of action that prevents or reduces the frequency of bleeding episodes with once-weekly subcutaneous injection. We believe that the drug will make a significant contribution to people with hemophilia A with inhibitors both in terms of preventing or reducing bleeding episodes and improving their quality of life."

HEMLIBRA is a bispecific antibody, which was created with Chugai's proprietary antibody engineering technologies. The drug binds to activated factor IX and factor X, providing the cofactor function of factor VIII in people with hemophilia A, who either lack or have impaired function of factor VIII[3,4]. Through once-weekly subcutaneous injection, which can be self-administered, HEMLIBRA is expected as an antibody drug which can prevent or reduce the frequency of bleeding episodes in people with hemophilia A with inhibitors. The drug was filed for approval for the treatment of hemophilia A without inhibitors in April 2018.

As a leading company in biopharmaceuticals, Chugai will continue to create pharmaceutical products that meet unmet medical needs through the development of innovative technologies and their application, contributing to healthcare and the health of people around the world.

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Drug Information

Product name:	HEMLIBRA® Subcutaneous Injection 30 mg, 60 mg, 90 mg, 105 mg, 150 mg
Generic name:	emicizumab (genetical recombination)
Indication:	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with congenital factor VIII deficiency with factor VIII inhibitors
Dosage and administration:	The usual dosage is 4 once-weekly subcutaneous doses at 3 mg/kg (body weight) emicizumab (genetical recombination) per dose, followed by once-weekly subcutaneous doses at 1.5 mg/kg (body weight). < Precautions related to DOSAGE AND ADMINISTRATION > HEMLIBRA should be used in routine prophylaxis to prevent or reduce the frequency of bleeding episodes and should not be used for on-demand hemostatic treatment.
Date of approval:	March 23, 2018
Date of NHI reimbursement price listing:	May 22, 2018
Date of launch:	May 22, 2018
Shelf life:	2 years

Drug price:	HEMLIBRA® Subcutaneous Injection 30 mg	JPY 376,006 / Vial
	HEMLIBRA® Subcutaneous Injection 60 mg	JPY 692,565 / Vial
	HEMLIBRA® Subcutaneous Injection 90 mg	JPY 989,990 / Vial
	HEMLIBRA® Subcutaneous Injection 105 mg	JPY 1,134,028 / Vial
	HEMLIBRA® Subcutaneous Injection 150 mg	JPY 1,552,824 / Vial

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