

Chugai Enters into a License Agreement for Emicizumab with JW Pharmaceutical

TOKYO, May 10, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has entered into a license agreement with <u>JW Pharmaceutical Corporation</u> for the exclusive marketing right of emicizumab (ACE910) in Korea. Emicizumab is a humanized bispecific antibody currently under development for hemophilia A. Based on the agreement, Chugai will receive upfront, milestone payment and sales-tied royalties.

"We are pleased to sign a license agreement with JW Pharmaceutical for emicizumab in Korea following our collaboration for Actemra," said Osamu Nagayama, Chairman and CEO. "Emicizumab is an antibody drug using Chugai's proprietary antibody engineering technologies and is expected to meet social needs. We are collaborating with JW pharmaceutical to deliver this innovative first-in-class therapeutic agent to patients who are waiting for the drug in Korea."

Emicizumab is under co-development by Chugai, Roche and Genentech, and the four global phase III clinical studies are currently ongoing as follows:

- HAVEN 1: Evaluating emicizumab dosed once weekly in people 12 years of age or older with hemophilia A and inhibitors to factor VIII
- HAVEN 2: Evaluating emicizumab dosed once weekly in children less than 12 years of age with hemophilia A and inhibitors to factor VIII
- HAVEN 3: Evaluating emicizumab dosed once weekly or once every other week in people
 12 years of age or older with hemophilia A without inhibitors to factor VIII
- HAVEN 4: Evaluating emicizumab dosed every four weeks in people 12 years of age or older with hemophilia A with or without inhibitors to factor VIII

Korean patients have been enrolled in both HAVEN 1 and HAVEN 3 studies.

About emicizumab

Emicizumab is an investigational bispecific monoclonal antibody, which was developed using Chugai's proprietary antibody engineering technologies. The drug is designed to bind factors IXa and factors X, and promotes the interaction between factors IXa and factors X. In doing so, emicizumab provides the cofactor function of factor VIII in people with hemophilia A, who either lack or have impaired coagulation function of factor VIII^{1,2)}. In 2015, the drug was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for prophylactic treatment for patients aged 12 years or older with hemophilia A with factor VIII inhibitors.

References

- 1) Kitazawa, et al. Nature Medicine 2012; 18(10): 1570
- 2) Sampei, et al. PLoS ONE 2013; 8: e57479