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Chugai's Bispecific Antibody "Emicizumab" Global Phase III Data in Patients with Haemophilia A with Inhibitors Published in The New England Journal of Medicine Online

TOKYO, July 10, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the data from HAVEN 1 study (NCT02622321) was published in the online version of The New England Journal of Medicine (NEJM). This global phase III study examined Chugai's bispecific antibody emicizumab in adults and adolescents 12 years of age or older with haemophilia A with inhibitors. Results of HAVEN 1 study and the interim analysis of HAVEN 2 study (NCT02795767), a global phase III study of emicizumab in paediatric patients with haemophilia A with inhibitors, are presented today at the 26th International Society on Thrombosis and Haemostasis (ISTH) Meeting in Berlin.

"HAVEN 1 study is the first global phase III study for emicizumab. This important data provides the body of evidence for the upcoming new drug application," said Chugai's President & COO, Tatsuro Kosaka. "The interim analysis of HAVEN 2 study showed that emicizumab offers benefit for children as well. Chugai is committed to provide a new treatment option as soon as possible for the disease which may severely affect patients' life."

Chugai is currently preparing to file the new drug application in Japan for emicizumab based on the data of HAVEN 1 study and the interim analysis of HAVEN 2 study. These data have been filed with the US Food and Drug Administration (FDA) and the European Medicines Agency by Roche. Emicizumab was designated as a Breakthrough Therapy by the FDA for the prophylactic treatment of people who are 12 years or older with haemophilia A with factor VIII inhibitor in September 2015.

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL: +81-(0)3-3273-0881 E-mail: pr@chugai-pharm.co.jp
Investor Relations Group TEL: +81-(0)3-3273-0554 E-mail: ir@chugai-pharm.co.jp

Contact:
For Media
Chugai Pharmaceutical Co., Ltd.
Media Relations Group, Corporate Communications Dept.,
Koki Harada
Tel: +81-3-3273-0881
E-mail: pr@chugai-pharm.co.jp

For US media
Chugai Pharma USA Inc.
Casey Astringer
Tel: +1-908-516-1350
E-mail: pr@chugai-pharm.com

For European media
Chugai Pharma France SAS
Nathalie Leroy
Tel: +33-1-56-37-05-21
E-mail: pr@chugai.eu

For Taiwanese media
Chugai Pharma Taiwan Ltd.
Susan Chou, Osamu Kagawa
Tel: +886-2-2715-2000
E-mail: pr@chugai.com.tw

For Investors
Chugai Pharmaceutical Co., Ltd.
Investor Relations Group, Corporate Communications Dept.,
Toshiya Sasai
Tel: +81-3-3273-0554
E-mail: ir@chugai-pharm.co.jp