Translation

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Name of listed company: Chugai Pharmaceutical Co., Ltd.
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Complete Phase I Results of Chugai's Bispecific Antibody "ACE910" Released at the American Society of Hematology Meeting

December 9, 2014 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama] announced today that the phase I clinical data of anti-factor IXa x anti-factor X humanized bispecific antibody "ACE910," currently being developed for the indication of hemophilia A was presented at the 56th American Society of Hematology Annual Meeting held in San Francisco, CA on December 8.

This trial is the first-in-patient phase I study to investigate safety and exploratory prophylactic efficacy profiles of ACE910 in Japanese hemophilia A patients both with and without FVIII inhibitors. Patients were treated with once-weekly subcutaneous injection of ACE910 under three dosing cohorts for 12 successive weeks.

【Outline of the study】

	Number of patients		Dose
	Patients with inhibitors	Patients without inhibitors	
C-1 cohort	4	2	1*, 0.3** mg/kg
C-2 cohort	4	2	3*, 1** mg/kg
C-3 cohort	3	3	3 mg/kg

*Initial dose,**Continuous dose

【Study results】

SAFETY

- All adverse effects (AEs) were of mild intensity, except for 2 moderate AEs: upper respiratory tract infection and headache. There was no evidence of clinically relevant abnormalities of coagulation as indicated by clinical findings or laboratory tests in all cohorts. No thromboembolic AEs were observed, even when ACE910 was given concomitantly with FVIII products or bypassing agents as on-demand therapy for bleeding events. One patient discontinued ACE910 administration due to injection site erythema of mild intensity. No anti-ACE910 antibodies were observed during the 12 weeks course of administration.

EFFICACY

- Once-weekly subcutaneous injection of ACE910 demonstrated a remarkable prophylaxis efficacy profile in all cohorts irrespective of the presence of inhibitors. Bleeding was completely controlled in 13 patients during the course of ACE910 administration. The mean ABR (Annualized Bleeding Rate) at pre and post administration and the ABR reduction rate in each cohort are as follows:

- The mean ABR and the ABR reduction rate

	The mean ABR (times)		The ABR reduction rate (range)
	Six months prior to the study	Post 12 weeks of administration	
C-1 cohort	37.9	13.5	22.8%-100%
C-2 cohort	19.6	0.7	88.9%-100%
C-3 cohort	15.9	0.7	0%*-100%

**One patient did not report bleeding episodes at baseline nor during the conduct of this study.*