News Release

Roche Announces New Safety Information of Elevidys for Non-Ambulatory Duchenne Muscular Dystrophy

TOKYO, June 16, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Roche issued a press release on June 15 (local time), regarding new safety information for Elevidys™ in non-ambulatory Duchenne muscular dystrophy (DMD) patients.

In Japan, ELEVIDYS® Intravenous Infusion [generic name: delandistrogene moxeparvovec] (hereinafter, "ELEVIDYS") obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) under the conditional and time-limited approval pathway for ambulatory DMD patients on May 13, 2025.

This new global safety information reports cases of acute liver failure in non-ambulatory DMD patients with fatal outcome. Dosing in the ongoing clinical trial in Japan for non-ambulatory DMD patients will be paused. There is no change to the benefit-risk profile of ELEVIDYS in ambulatory DMD patients.

Chugai will work closely with relevant regulatory authorities, investigators, and healthcare professionals to assure patient safety and will continue to communicate in close collaboration.

Please refer to the link below for details of the press release:
Roche provides safety update on Elevidys™ gene therapy for Duchenne muscular dystrophy in non-ambulatory patients
https://www.roche.com/media/releases/med-cor-2025-06-15

###

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