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ASIA EDITION

Sarepta Therapeutics announces commercial launch of ELEVIDYS in Japan for DMD treatment

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Company is eligible to receive a $40 million milestone payment upon first commercial sale in Japan

US-based Sarepta Therapeutics, Inc. has announced the commercial launch of ELEVIDYS (delandistrogene moxeparvovec) in Japan by Chugai Pharmaceutical, following its reimbursement listing on Japan's National Health Insurance (NHI) price list.

Elevidys is the first gene therapy to be launched in Japan for Duchenne muscular dystrophy (DMD). In Japan, ELEVIDYS is available for ambulatory individuals with Duchenne ages 3-to less than 8-years-old, a deletion of any portion or the entirety of exon 8 and/or exon 9 in the DMD gene, and who are negative for anti-AAVrh74 antibodies.

Chugai announced that ELEVIDYS has been launched in Japan following reimbursement listing, enabling access for eligible patients under the conditional and time limited approval granted by Japan's Ministry of Health, Labour and Welfare (MHLW) in May 2025. Chugai will be responsible for postmarketing clinical studies and all case postmarketing surveillance in Japan as part of the Roche Group collaboration to further evaluate long-term efficacy and safety.

As part of a collaboration agreement signed in 2019, Sarepta is working with Roche to transform the future for the Duchenne community, with the goal of enabling those living with the disease to maintain and protect their muscle function. Sarepta is responsible for regulatory approval and commercialisation of ELEVIDYS in the US, as well as manufacturing. Roche is responsible for regulatory approvals and commercialization in territories outside the US Commercialisation of ELEVIDYS in Japan is through Chugai Pharmaceuticals, a member of the Roche Group.

Under Sarepta's collaboration agreement with Roche, the first commercial sale of ELEVIDYS in Japan will trigger a $40 million milestone payment to Sarepta.