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Daiichi Sankyo Announces Commencement of Clinical Trials in Japan for Duchenne Muscular Dystrophy Treatment

TOKYO, Japan (February 25, 2016) – Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) announced today that administration of the Duchenne muscular dystrophy (hereafter, DMD) treatment drug DS-5141b (hereafter, the Drug), which is jointly developing with the Orphan Disease Treatment Institute Co., Ltd. (hereafter, ODTI^{*1}), to the first subject has begun in the first clinical trial in Japan.

DMD is known as a disease that affects one in 3,500 new-born males regardless of ethnicity. It is known that DMD occurs because muscle cells do not produce dystrophin, but there is no fundamental therapy available.

Because the Drug induces exon 45 skipping of a dystrophin mRNA to promote incomplete but functional dystrophin production, it is expected to be an effective treatment for DMD. The Drug contains the active ingredient ENA® oligonucleotide*², a modified nucleic acid made using proprietary technology owned by Daiichi Sankyo. Daiichi Sankyo expects to obtain manufacturing and marketing approval by the end of 2020.

Daiichi Sankyo remains committed to meeting the needs of more patients and medical professionals through drug development and contributing to medical care by providing new treatment options.

*1 ODTI

Daiichi Sankyo jointly established the ODTI with the Innovation Network Corporation of Japan and a fund managed by Mitsubishi UFJ Capital Co., Ltd.—see Daiichi Sankyo press release dated February 14, 2013 entitled, Daiichi Sankyo Announces Development of Nucleic Acid Treatment for Duchenne Muscular Dystrophy Utilizing Proprietary Technology.

*2 ENA® oligonucleotides

ENA® is an ethylene-bridged nucleic acid in which ethylene is bridged at the furanose sugar ring at 2'-O and 4'-C ends. Short-chain nucleic acids and ENA® oligonucleotides found in ENA® demonstrate high binding force with complementary DNA and RNA as well as superior thermal stability and nuclease resistance. ENA® is a registered trademark of Daiichi Sankyo.