Press Release

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Daiichi Sankyo Announces the Results Summary of Phase 1/2 Clinical Trial in Japan for DS-5141

Tokyo, Japan (January 13, 2021) - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) today announced the results summary of the Phase 1/2 clinical trial in Japan (hereafter, the study) of DS-5141 (hereafter, the drug) [*1] in patients with Duchenne muscular dystrophy(DMD) [*2], which Daiichi Sankyo is jointly developing with the Orphan Disease Treatment Institute Co., Ltd. (ODTI)[*3].

The study is a clinical trial to examine the safety and efficacy of the drug, which was administered subcutaneously once weekly for 12 weeks followed by once weekly subcutaneously administration for 48 weeks to patients with DMD.

No safety concerns, such as discontinuation or clinically significant adverse events, were observed in the study. Efficacy in terms of the production of messenger RNA with exon 45 skipping of the dystrophin gene (the trial's secondary endpoint) was found in all patients, and the expression of dystrophin protein (the trial's primary endpoint) showed a clear increase in several patients. Analysis of the trial result is currently ongoing.

Daiichi Sankyo will continue to investigate this study's result in detail as part of its efforts to provide new treatment options for patients with DMD.

*1 DS-5141

DS-5141, a nucleic acid drug expected to treat muscular dystrophy, skips exon 45 splicing, producing an incomplete but functional dystrophin protein during messenger RNA processing from the dystrophin gene in patient's myocytes. In addition, it contains ENA® oligonucleotide, Daiichi Sankyo's proprietary modified nucleic acid, as an active ingredient, and received the SAKIGAKE designation in April 2017.

*2 Duchenne muscular dystrophy (DMD)

Duchenne muscular dystrophy is a severe rare hereditary disease with an incidence of about one in 3,500 male newborns regardless of ethnicity. It is caused by the deficiency of dystrophin protein production in the patient's muscle cells, significantly limiting possible treatments and their effects.

*3 Orphan Disease Treatment Institute Co., Ltd. (ODTI)

ODTI was founded in 2013 through joint investment with a fund run by the Innovation Network Corporation of Japan and Mitsubishi UFJ Capital Company Limited.

About Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centered around rare diseases and immune disorders. For more information, please visit: www.daiichisankyo.com/.