

NEWS RELEASE



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NS Pharma Announces FDA Clearance to Initiate a Phase I/II Study for NS-050/NCNP-03, an Exon 50 Skipping Candidate for the Treatment of Duchenne Muscular Dystrophy

NS-050/NCNP-03 is NS Pharma's second exon skipping investigational therapy to receive FDA clinical study initiation clearance in 2023. Their exon 44 skipping treatment, NS-089/NCNP-02 was cleared on March 31, 2023.

NS Pharma, Inc. (NS Pharma; President, Tsugio Tanaka) is a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; President, Toru Nakai)

PARAMUS, NJ: June 15, 2023 – NS Pharma, Inc. announced today the U.S. Food & Drug Administration (FDA) has agreed to the planned Phase I/II study of NS-050/NCNP-03, an investigational candidate for patients with Duchenne muscular dystrophy amenable to exon 50 skipping therapy. Study assessments will include dystrophin production, muscle strength, mobility and functional exercise capacity.

“This is the second trial clearance from the FDA that NS Pharma has received this year and marks the third candidate from our R&D pipeline to begin clinical trials in Duchenne,” said Tsugio Tanaka, President, NS Pharma, Inc. “Our rapid development plans reflect the urgent needs of the Duchenne community and our commitment to extending the impact of our exon skipping technology.”

NS Pharma's parent company, Nippon Shinyaku, plans to begin clinical trial enrollment for NS-050/NCNP-03 in the US during the second half of 2023. Additional details will be provided once the trial is ready to begin enrolling participants.

“Exon skipping therapies have the potential to treat a wide range of patients with Duchenne, but more than half of Duchenne patients potentially amenable to exon skipping therapy have no approved treatment options that target their specific mutation,” said Vamshi Rao, MD, Ann & Robert H. Lurie Children’s Hospital of Chicago. “That is why it is exciting that this year we are beginning studies of two treatments that have the potential to reach even more Duchenne patients with targeted exon skipping therapies.”

In addition to NS-050/NCNP-03, NS Pharma’s parent company, Nippon Shinyaku, has three investigational exon skipping candidates in various stages of preclinical development.

About Duchenne Muscular Dystrophy (Duchenne)

Duchenne is a progressive form of muscular dystrophy that occurs primarily in males. Duchenne causes progressive weakness and loss of skeletal, cardiac, and respiratory muscles. Early signs of Duchenne may include delayed ability to sit, stand or walk. There is a progressive loss of mobility, and by adolescence, patients with Duchenne may require the use of a wheelchair. Cardiac and respiratory muscle problems begin in the teenage years and lead to serious, life-threatening complications.

About NS Pharma, Inc.

NS Pharma, Inc., is a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. For more information, please visit <http://www.nspharma.com>. NS Pharma is a registered trademark of the Nippon Shinyaku group of companies.

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