

NEWS RELEASE



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FDA Grants Orphan Drug Designation to NS-089/NCNP-02 for the Treatment of Duchenne Muscular Dystrophy

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: August 7, 2023 – NS Pharma, Inc. announced today the U.S. Food & Drug Administration (FDA) has granted Orphan Drug Designation to NS-089/NCNP-02, an investigational candidate for patients with Duchenne muscular dystrophy amenable to exon 44 skipping therapy.

The FDA issues Orphan Drug Designations to support the development and evaluation of new treatments to prevent, diagnose, or treat a rare disease or condition.

NS-089/NCNP-02 previously received Rare Pediatric Disease Designation from the FDA in June 2023 and Breakthrough Therapy Designation in July 2023.

NS-089/NCNP-02 is an antisense nucleotide discovered through joint research between NS Pharma's parent company, Nippon Shinyaku, and the National Center of Neurology and Psychiatry (Kodaira City; President, Kazuyuki Nakagome).

Clinical development of NS-089/NCNP-02 includes a planned Phase 2 study in the United States conducted by NS Pharma and a Phase 2 study conducted in Japan by Nippon Shinyaku. Additional details will be provided once the trials are ready to begin enrolling participants.

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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