NEWS RELEASE

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

The FDA's Rare Pediatric Disease Designation is granted for treatments intended for serious or life-threatening diseases that affect children under the age of 18 and less than 200,000 patients in the U.S.

NS-089/NCNP-02 is an antisense nucleotide discovered through joint research between NS Pharma's parent company, Nippon Shinyaku, and the National Center for Psychiatry and Neurological Medicine (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.

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Contact
U.S. Media Contact:
media@nspharma.com