NEWS RELEASE

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NS-089/NCNP-02 Receives Orphan Drug Designation from the European Commission for the Treatment of Duchenne Muscular Dystrophy

PARAMUS, NJ: December 21, 2023 – NS Pharma, Inc. (NS Pharma), a subsidiary of Nippon Shinyaku Co., Ltd., announced that, on December 13, 2023, the European Commission (EC) has granted orphan drug designation for NS-089/NCNP-02, which is being developed for the treatment of Duchenne muscular dystrophy (Duchenne), a rare and deadly genetic disorder that occurs primarily in males. There are various genetic mutations that cause Duchenne, and NS-089/NCNP-02 targets a gene mutation that can be treated by exon 44 skipping.

The orphan drug designation by the EC is issued to drugs which are intended for diseases that affect fewer than five in 10,000 people in the European Union (EU) and are life-threatening or chronically debilitating. The designation provides NS Pharma with a ten-year marketing exclusivity period, supporting the company's continued development and evaluation of this therapy.

NS-089/NCNP-2 was previously granted rare pediatric disease designation in June 2023, designated as a breakthrough therapy in July 2023, and designated as an orphan drug in July 2023 by the U.S. Food and Drug Administration (FDA).

"We are one step closer to helping patients with Duchenne who are amenable to exon 44 skipping access life-changing treatment," said NS Pharma Vice President, Research & Development, Takeshi Seita. "Our team is ready and excited to continue our development of this innovative science."

NS-089/NCNP-02 is an antisense nucleic acid discovered through joint research between Nippon Shinyaku and the National Center of Neurology and Psychiatry (NCNP). It skips part of the genetic information of the dystrophin gene and produces a functional dystrophin protein with a slightly shorter chain length, which is expected to have the effect of suppressing muscle function deterioration.

NS Pharma has been actively working to develop agents for the treatment of intractable and rare diseases, with a goal of launching treatments for patients with Duchenne as soon as possible.

About Duchenne Muscular Dystrophy (Duchenne)
Duchenne is a progressive form of muscular dystrophy that occurs primarily in males. It 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. For more information about Duchenne, please visit wespeakduchenne.com.

About NS Pharma, Inc.
NS Pharma, Inc., is a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. NS Pharma is a registered trademark of the Nippon Shinyaku group of companies. For more information, please visit nspharma.com.

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