

# NEWS RELEASE



April 14, 2023

## **NS Pharma Announces FDA Clearance to Initiate Phase II Study for NS-089/NCNP-02, an Exon 44 Skipping Candidate 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: April 14, 2023,** – NS Pharma, Inc. announced today the U.S. Food & Drug Administration (FDA) has agreed to the planned Phase II study of NS-089/NCNP-02 for Duchenne muscular dystrophy. NS-089/NCNP-02 is an investigational candidate for patients with Duchenne muscular dystrophy amenable to exon 44 skipping therapy.

“Progress has been made in the treatment of Duchenne, but patients and families need new and more treatment options,” said Vamshi Rao, MD, Ann & Robert H. Lurie Children’s Hospital of Chicago. “There are currently no available antisense treatments that target Duchenne patients amenable to exon 44 skipping therapy, which is why I am excited about this program and the potential advance of effective treatments for Duchenne muscular dystrophy.”

Study efficacy measures will include the expression of dystrophin protein and motor function. Trial details will be made available through [ClinicalTrials.gov](https://clinicaltrials.gov). Additional information will be provided once the trial is ready to begin enrolling.

“We are pleased to announce FDA’s clearance to proceed with our Phase II clinical trial in our endeavor to help patients with Duchenne amenable to exon 44 skipping therapy,” said Takeshi Seita, Vice President, R&D at NS Pharma, Inc. “We are confident in our exon skipping drug discovery platform and excited about the future potential of our development program.”

In addition to NS-089/NCNP-02, NS Pharma’s parent company, Nippon Shinyaku, has four 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 pulmonary 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.

Contact

U.S. Media Contact:

[media@nspharma.com](mailto:media@nspharma.com)