NEWS RELEASE

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VILTEPSO® (viltolarsen) injection Long-Term Clinical Trial Data to be Presented at the PPMD 2021 Virtual Annual Conference

PARAMUS, NJ: May 12, 2021 – NS Pharma, Inc. (NS Pharma; President, Tsugio Tanaka), a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; President, Shigenobu Maekawa), announced today that new, long-term efficacy and safety data (interim analysis at 109 weeks) from the open-label extension of a Phase 2 study of VILTEPSO® (viltolarsen) injection will be presented at the PPMD 2021 Annual Conference being held virtually from June 23-26.

"This VILTEPSO data we are presenting at the PPMD Annual Conference represents some of the longest treatment times with exon-skipping therapy reported to date," said Leslie Magnus, MD, Vice President, Medical Affairs. "This data, compared to a matched historical control group, provides information on the potential long-term effectiveness and safety of VILTEPSO that is critical for healthcare professionals and Duchenne patients and their caregivers."

In addition to this Phase 2 open-label extension study, NS Pharma continues to investigate the efficacy and safety of VILTEPSO in the confirmatory Phase 3 RACER53 trial. This study was initiated in October 2019 and is currently enrolling patients. The purpose of this Phase 3 trial is to confirm the clinical findings that were submitted under the Accelerated Approval pathway.

About VILTEPSO® (viltolarsen) injection

Prior to its approval in the U.S., VILTEPSO was granted Priority Review as well as Rare Pediatric Disease, Orphan Drug and Fast Track Designations. In March 2020,

VILTEPSO was approved in Japan for the treatment of patients with DMD who are amenable to exon 53 skipping therapy. Prior to its approval in Japan, VILTEPSO was granted with the SAKIGAKE designation, Orphan Drug designation, and designation of Conditional Early Approval System.

Indication

VILTEPSO is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with VILTEPSO. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Important Safety Information

In clinical studies, no patients experienced kidney toxicity during treatment with VILTEPSO. However, kidney toxicity from drugs like VILTEPSO may be possible. Your doctor may monitor the health of your kidneys before starting and during treatment with VILTEPSO.

Common side effects include upper respiratory tract infection, injection site reaction, cough, and fever.

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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