

NEWS RELEASE



September 17, 2021

VILTEPSO® (viltolarsen) injection Interim Long-Term Clinical Trial Data Scheduled for Presentation at the World Muscle Society 2021 Virtual Conference

PARAMUS, NJ: September 17, 2021 – NS Pharma, Inc. (NS Pharma; President, Tsugio Tanaka), a wholly owned subsidiary of Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; President, Toru Nakai), announced today an electronic poster presentation on long-term efficacy and safety data (interim analysis at 109 weeks) from the open-label extension (up to 192 weeks) of a Phase 2 study of VILTEPSO® (viltolarsen) injection at the World Muscle Society 2021 Virtual Conference being held September 20–24.

The electronic poster presentation will be given by Paula Clemens, MD from the University of Pittsburgh School of Medicine on Thursday, September 23rd from 16:30 to 18:30 BST. For more information, please visit the World Muscle Society Virtual Conference website to view the full program: <https://www.wms2021.com/page/programme>.

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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