

NEWS RELEASE



August 19, 2020

VILTEPSO™ (viltolarsen) injection Now Commercially Available in the U.S.

PARAMUS, NJ: August 19, 2020 – 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 VILTEPSO™ (viltolarsen) injection is now commercially available in the U.S. On August 12, 2020, the U.S. Food & Drug Administration (FDA) approved VILTEPSO for patients with Duchenne muscular dystrophy (DMD) who are amenable to exon 53 skipping therapy.

To help navigate access and reimbursement with VILTEPSO, NS Pharma is offering services and resources to patients, caregivers and their healthcare providers through the NS Support™ program.

“The response by the DMD community to the FDA approval of VILTEPSO has been incredibly uplifting, and underscores NS Pharma’s responsibility that goes beyond the development of new and exciting treatment options,” said Tsugio Tanaka, President, NS Pharma, Inc. “Through our NS Support program, we will assist each patient and family obtain access to VILTEPSO, and help navigate obstacles related to location in the U.S. or financial circumstances.”

VILTEPSO is commercially available through a network of specialty distributors and specialty pharmacy providers. The distribution partners in this limited network were selected for their experience providing responsive, reliable service to healthcare providers and families with DMD.

Patients receiving treatment with VILTEPSO have the option and flexibility to receive

infusions at their home or at a hospital or treatment center. VILTEPSO is administered by a trained healthcare professional as an 80 mg per kg of body weight 60-minute weekly intravenous infusion.

VILTEPSO received an Accelerated Approval by the FDA based on an increase in dystrophin, a key protein for supporting muscle health. The continued approval of VILTEPSO may be contingent on confirmation of a clinical benefit in a Phase 3 confirmatory trial.

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.
- The most common side effects of VILTEPSO included upper respiratory tract infection, injection site reaction, cough and fever.

For additional safety information, please see the full [Prescribing Information](#).

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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