NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

August 20, 2020

VILTEPSO™ (viltolarsen) injection

Now Commercially Available in the U.S.

KYOTO, Japan August 20th, 2020 – Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Kyoto: President, Shigenobu Maekawa) announced today that NS Pharma, Inc. (Paramus, NJ; President, Tsugio Tanaka), a wholly owned subsidiary of Nippon Shinyaku made VILTEPSO™ (viltolarsen) now available for commercial sales in the United States market as of August 19 (EST).

NS Pharma received marketing authorization for VILTEPSO under an accelerated approval pathway from the U.S. Food & Drug Administration (FDA) on August 12 (EST) for the treatment of Duchenne Muscular Dystrophy (DMD) amenable to exon 53 skipping therapy. To help navigate access to and reimbursement of VILTEPSO, NS Pharma is offering services and resources to patients, caregivers and their healthcare providers through the NS Support™ program.

Nippon Shinyaku and NS Pharma will contribute to the treatment of patients with DMD by assisting each patient in obtaining the access to VILTEPSO.

<VILTEPSO>

VILTEPSO is an antisense oligonucleotide 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. VILTEPSO received marketing authorization under an accelerated approval pathway in Japan in March 2020 and became commercially available in Japan in May this year. Currently, a phase 3 study (RACER53 study) is ongoing in approximately 30 centers worldwide as a confirmatory study.

< Duchenne Muscular Dystrophy (DMD)>

DMD is a progressive form of muscular dystrophy that occurs primarily in males. DMD causes progressive weakness and loss of skeletal, cardiac, and pulmonary muscles. Early signs of DMD may include delayed ability to sit, stand or walk. There is a progressive loss of mobility, and by adolescence, patients with DMD may require the use of a wheelchair. Cardiac and respiratory muscle problems begin in the teenage years and lead to serious, life-threatening complications. There are many types of genetic mutations that can cause DMD. VILTEPSO is indicated for patients with DMD mutations that are amenable to exon 53 skipping.

< About NS Pharma, Inc. >

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

< 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 more information about VILTEPSO, see Full Prescribing Information.

< Contact >

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