NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

November 25, 2021

Addition of Viltepso® to the List of Injection Drugs
That Physicians Providing Health Insurance Treatment Can Administer

KYOTO, Japan, November 25, 2021 – Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Toru Nakai) announced that Viltepso® Injection (Viltolarsen), a treatment for Duchenne muscular dystrophy (DMD), has been added to the list of injection drugs that the Ministry of Health, Labour and Welfare permits physicians providing health insurance treatment to administer. The addition of this drug to the list is valid from today, November 25, 2021.

This means that, if a medical specialist recognizes that it is difficult for a patient to visit a medical institution regularly, the patient can be injected with the drug at home by a physician who collaborates with the medical specialist. Treatment with the drug usually requires patients to visit a medical institution once a week. However, the possibility of the drug being administered at home will enable the patients to decrease the frequency of their visits to the medical institution. We expect that the patients' reduced burden of visiting a medical institution will help lessen the impact of medical treatment on their daily lives and consequently increase their quality of life (QOL).

Nippon Shinyaku has been seriously committed to fulfilling its mission to develop treatments for intractable and rare diseases. We will continue our efforts to provide DMD patients with treatments that can help them lead happier lives.

<About Viltepso®>
Viltepso® is a treatment for Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. In Japan, this indication for the drug was approved by the Ministry of Health, Labour and Welfare under a conditional early approval system in March 2020. Nippon Shinyaku has sold it and conducted detailing activities for it since May the same year. In the United States, the drug received accelerated approval from the Food and Drug Administration (FDA) in August 2020 and has been marketed through NS Pharma, Inc.

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