NEWS RELEASE

NIPPON SHINYAKU CO., LTD.

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Submission of New Drug Application for NS-065/NCNP-01 (viltolarsen) in China

Kyoto, Japan, June 25, 2021 – Nippon Shinyaku Co., Ltd. (Nippon Shinyaku; Headquarters, Kyoto; President, Shigenobu Maekawa) announced that it submitted the New Drug Application (NDA) for NS-065/NCNP-01 (generic name: viltolarsen) to the National Medical Products Administration (NMPA) in China.

Viltolarsen 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. It was approved by the Ministry of Health, Labour and Welfare (MHLW) in March 2020 in Japan and the US Food and Drug Administration (FDA) in August of the same year, and information on this drug is provided through Nippon Shinyaku in Japan and our subsidiary NS Pharma, Inc., in the United States.

DMD is an inherited muscle disorder that male children develop. It causes a loss of muscle power due to a deficiency of normal dystrophin, a protein involved in constructing the framework of muscle cells.

In China, if a treatment for a life-threatening disease with no effective treatment has been marketed outside China, its NDA can be submitted based on foreign clinical data. We submitted the NDA for viltolarsen as a treatment for progressive muscular dystrophy, which is included in the list of rare diseases by the Chinese government. The NDA in China is based on the NDA dossier filed in Japan and the United States. We hope for an early approval because viltolarsen will be reviewed under the priority review system.

Nippon Shinyaku has been working actively having a sense of mission to develop agents for the treatment of intractable and rare diseases, and aiming at providing medicine for DMD patients in China as soon as possible.

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