NEWS RELEASE

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NS Pharma Announces Change in Commercial Leadership

The company is developing innovative therapies for rare diseases like the exon-skipping therapy VILTEPSO®.

PARAMUS, NJ: November 26, 2024 – NS Pharma, Inc. (NS Pharma) announced a change of leadership within its Commercial division. Effective September 9, 2024, Donald Foy – who had previously served as national sales director – was appointed to the role of vice president, Commercial. Jennifer Tamberino – who had been Regional Business Director, East, National Sales – was promoted to backfill Foy's former position as national sales director.

"It is with incredible excitement that we announce Don's promotion to lead our sales, marketing, market access, operations and patient services departments as our new head of Commercial at NS Pharma," said NS Pharma President Yukiteru Sugiyama, Ph.D. "With Don and Jennifer at the helm, we are well-positioned to execute our plans for growth in the rare disease space in the United States. Our new leadership structure is designed to foster industry collaboration and company innovation from the top down."

Foy replaces outgoing executive Gardner Gendron, who held the position for five years and oversaw the launch and commercialization of viltolarsen (VILTEPSO) for the treatment of Duchenne muscular dystrophy (Duchenne), a rare muscle-wasting neurological disorder.

Prior to joining NS Pharma, Foy served in leadership roles for 17 years in the pharmaceutical industry, with more than 24 years of experience both in sales and in cross-functional positions supporting a diverse set of stakeholders. Tamberino has a four-year tenure with NS Pharma demonstrating effective leadership and business acumen.

NS Pharma currently has one commercial product, VILTEPSO, with several others in its pipeline for the treatment of Duchenne and, separately, the treatment of eosinophilic granulomatosis with polyangiitis (EGPA), a form of vasculitis. It is also slated to market deramiocel (CAP-1002), which is being developed by Capricor Therapeutics for the treatment of Duchenne cardiomyopathy.

About VILTEPSO® (Viltolarsen) Injection

Prior to its approval in the U.S. in August 2020, 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 Duchenne who are amenable to exon 53 skipping therapy. Prior to its approval in Japan, VILTEPSO was granted the SAKIGAKE designation, orphan drug designation, and designation of Conditional Early Approval System.

Indication

VILTEPSO is indicated for the treatment of Duchenne in patients who have a confirmed mutation of the Duchenne 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

Warnings and Precautions: Kidney toxicity was observed in animals who received viltolarsen. Although kidney toxicity was not observed in the clinical studies with VILTEPSO, the clinical experience with VILTEPSO is limited, and kidney toxicity, including potentially fatal glomerulonephritis, has been observed after administration of some antisense oligonucleotides. Kidney function should be monitored in patients taking VILTEPSO. Serum creatinine may not be a reliable measure of kidney function in patients with Duchenne.

Serum cystatin C, urine dipstick, and urine protein-to-creatinine ratio should be

measured before starting VILTEPSO. Consider also measuring glomerular filtration rate before starting VILTEPSO. During treatment, monitor urine dipstick every month, and serum cystatin C and urine protein-to-creatinine ratio every three months.

Urine should be free of excreted VILTEPSO for monitoring of urine protein. Obtain urine either prior to VILTEPSO infusion, or at least 48 hours after the most recent infusion. Alternatively, use a laboratory test that does not use the reagent pyrogallol red, which has the potential to generate a false positive result due to cross reaction with any VILTEPSO in the urine. If a persistent increase in serum cystatin C or proteinuria is detected, refer to a pediatric nephrologist for further evaluation.

Adverse Reactions: The most common adverse reactions include upper respiratory tract infection, injection site reaction, cough, and pyrexia.

To report an adverse event, or for general inquiries, please call NS Pharma Medical Information at 1-866-NSPHARM (1-866-677-4276)

For more information about VILTEPSO, see full Prescribing Information.

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

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