FDA grants authorization for Individual Patient Expanded Access Protocol for the use of tradipitant for gastroparesis

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WASHINGTON, July 13, 2020 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) announced today that the U.S. Food and Drug Administration (FDA) has authorized a single patient in an Individual Patient Expanded Access protocol (VP-VLY-686-3303). This patient had previously participated in a randomized study of tradipitant in gastroparesis for 12 weeks. The patient and treating physician requested expanded access to continue treatment beyond 12 weeks, as the treating physician had judged that tradipitant was the only treatment that effectively managed the patient's gastroparesis symptoms.

The FDA's Division of Gastroenterology has authorized expanded access to tradipitant for this patient for an additional 6 months under this protocol with the potential to renew upon written request containing additional safety information collected during those 6 months.

The 12-week randomized placebo-controlled Phase III study of tradipitant in patients with gastroparesis that this patient originally participated in is ongoing. In December 2018, Vanda reported results of a Phase II study of tradipitant in gastroparesis where tradipitant was shown to be effective at reducing nausea and other cardinal symptoms of gastroparesis and well tolerated.

About Tradipitant

Tradipitant is an NK-1R antagonist licensed by Vanda from Eli Lilly and Company. Tradipitant is currently in clinical development for gastroparesis, motion sickness and atopic dermatitis. The FDA has imposed a partial clinical hold on tradipitant clinical protocols of longer than 12 weeks duration. The partial clinical hold does not apply to the individual-patient protocol described above.

About Vanda Pharmaceuticals Inc.

Vanda is a leading global biopharmaceutical company focused on the development and commercialization of innovative therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com and follow us on Twitter @vandapharma.

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