



Vanda Pharmaceuticals, Northwell Health Conduct ODYSSEY Trial In Patients With Severe COVID-19 Pneumonia

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WASHINGTON, April 15, 2020 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) and Northwell Health's research arm, [The Feinstein Institutes for Medical Research](#), today announced enrollment of the first patient in Vanda's clinical trial, [ODYSSEY VLY-686-3501](#) (NCT04326426), yesterday at Lenox Hill Hospital in New York City.

ODYSSEY is a Phase III double-blind placebo-controlled trial investigating the efficacy and safety of tradipitant, a neurokinin-1 receptor antagonist, in the treatment of neurogenic inflammation of the lung secondary to SARS-CoV-2 (COVID-19) infection. This novel coronavirus is associated with a lower respiratory tract inflammation that often progresses to Acute Respiratory Distress Syndrome (ARDS) requiring mechanical ventilation.

"With the strong leadership and health expertise of Northwell Health, we expect to be able to accelerate enrollment in this study and provide results in the coming months," said Mihael H. Polymeropoulos, M.D., President and Chief Executive Officer of Vanda. "As the mortality rate from COVID-19 continues to rise in New York from ARDS, it is critical for clinical research to be fully embraced by the public, scientific community, health professionals and the government. We could not think of a better partner to leverage all of these constituencies than Northwell Health as we strive to complete this study as soon as possible and bring potential relief to patients suffering from COVID-19."

The study, led by Dr. Bushra Mina, M.D., is expected to randomize approximately 300 patients with confirmed COVID-19 pneumonia who receive either tradipitant or placebo. Vanda, alongside investigators at Lenox Hill Hospital, will evaluate clinical and laboratory outcomes to determine the efficacy of tradipitant in treating patients with COVID-19 pneumonia.

"Our primary focus is to quickly evaluate the impact of tradipitant in the treatment of patients with neurogenic inflammation of the lung as a result of COVID-19," said Dr. Mina, Section Chief of Pulmonary Medicine, Director of Pulmonary & Critical Care Fellowship at Lenox Hill Hospital, and lead ODYSSEY study investigator. "The initiation of this clinical trial represents a significant milestone in our efforts to combat this health crisis and support our ultimate goal of patient recovery."

"We are pleased to team up with Vanda," said Kevin J. Tracey, M.D., President and CEO of the Feinstein Institutes. "Carefully designed clinical trials are an essential early step to assess risk and benefit of experimental approaches for COVID-19."

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 as well as atopic dermatitis.

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 Vanda's [Twitter](#) and [LinkedIn](#).

About the Feinstein Institutes

[The Feinstein Institutes for Medical Research](#) is the research arm of Northwell Health, the largest health care provider and private employer in New York State. Home to 50 research labs, 2,500 clinical research studies and 5,000 researchers and staff, the Feinstein Institutes raises the standard of medical innovation through its five institutes of behavioral science, bioelectronic medicine, cancer, health innovations and outcomes, and molecular medicine. The Feinstein Institutes make breakthroughs in genetics, oncology, brain research, mental health, autoimmunity, and are the global scientific leader in bioelectronic medicine – a new field of science that has the potential to revolutionize medicine. For more information about how The Feinstein Institutes produce knowledge to cure disease, visit feinstein.northwell.edu.

About Northwell Health

Northwell Health is New York State's largest health care provider and private employer, with 23 hospitals, about 750 outpatient facilities and more than 13,600 affiliated physicians. Northwell cares for over two million people annually in the New York metro area and beyond, thanks to philanthropic support from its communities. Northwell's 70,000 employees – 16,000-plus nurses and 4,000 employed doctors, including members of Northwell Health Physician Partners – are working to change health care for the better. Northwell is making breakthroughs in medicine at the Feinstein Institutes for Medical Research, and training the next generation of medical professionals at the visionary Donald and Barbara Zucker School of Medicine at Hofstra/Northwell and the Hofstra Northwell School of Graduate Nursing and Physician Assistant Studies. For information on Northwell's more than 100 medical specialties, visit Northwell.edu and follow them @NorthwellHealth on [Facebook](#), [Twitter](#), [Instagram](#) and [LinkedIn](#).

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this release are "forward-looking statements" under the securities laws. These forward-looking statements include, without limitation, statements regarding the design, enrollment and completion of Vanda's ODYSSEY VLY-686-3501 study, the potential for tradipitant to be a safe and effective treatment for certain patients with COVID-19 and Vanda's ability to make tradipitant available to patients for the treatment of COVID-19. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements include, among others: Vanda's ability to enroll patients for its ODYSSEY VLY-686-3501 study; a failure of tradipitant to be demonstrably safe and effective in the treatment of COVID-19; Vanda's ability to obtain FDA approval of tradipitant for the treatment of COVID-19; and other factors that are set forth in

the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2019, which is on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be set forth in those sections of Vanda's annual report on Form 10-Q for the fiscal quarter ended March 31, 2020, to be filed with the SEC in the second quarter of 2020. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, other unknown or unpredictable factors also could affect Vanda's results. There can be no assurance that the actual results or developments anticipated by Vanda will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, Vanda. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved. All written and verbal forward-looking statements attributable to Vanda or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. Vanda cautions investors not to rely too heavily on the forward-looking statements Vanda makes or that are made on its behalf. The information in this release is provided only as of the date of this release, and Vanda undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Media Contact

Feinstein Institutes:

Matthew Libassi

516-465-8325

milibassi@northwell.edu

Vanda Pharmaceuticals:

AJ Jones II

202-734-3400

aj.jones@vandapharma.com

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