Vanda Pharmaceuticals Announces the Initiation of ODYSSEY, an FDA Approved Clinical Study of Tradipitant in Hospitalized Patients with Severe COVID-19 Pneumonia

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WASHINGTON, April 2, 2020 /PRNewswire/ -- Vanda Pharmaceuticals Inc. ("Vanda") (Nasdaq: VNDA) today announced the initiation of clinical study, ODYSSEY VLY-686-3501, in hospitalized patients with COVID-19. The novel SARS-CoV-2 coronavirus is associated with a lower respiratory tract inflammation that often progresses to Acute Respiratory Distress Syndrome ("ARDS") requiring mechanical ventilation.

Vanda has received FDA permission to proceed with the study for the treatment and prevention of pneumonia associated with COVID-19. ODYSSEY, which will begin enrolling patients this month, is a Phase III double-blind placebo-controlled trial to investigate the efficacy and safety of tradipitant, a neurokinin-1 receptor antagonist, given orally twice daily to treat inflammatory lung injury associated with severe COVID-19 infection. The study will randomize approximately 300 patients aged 18-90 with severe COVID-19 infection who are suffering from pneumonia. The study will begin at New York area hospitals and will enroll hospitalized patients with COVID-19 ARDS.

"We greatly appreciate Vanda's efforts to develop innovative therapeutic treatments for COVID-19," said Dr. Bushra Mina, Pulmonary, and Critical Care physician at Lenox Hill Hospital, Northwell Health. "We share in their urgent and unrelenting efforts to bring immediate and effective treatments to the patients we are serving in this time of crisis."

A recent study in Wuhan, China found that 41.8% of 201 COVID-19 hospitalized patients developed ARDS, and, among these patients, 52.4% died[1], underscoring the high rate of mortality in this population.

"Given this critical and urgent unmet medical need, Vanda has immediately initiated activities aimed at a number of therapeutic approaches against COVID-19," said Mihael H. Polymeropoulos, M.D., President and Chief Executive Officer of Vanda. "Our approach will investigate therapeutics aimed at host processes that facilitate viral entry and replication, as well as therapeutics targeting the neuroinflammatory process that results in ARDS."

Tradipitant is currently in clinical trials for the treatment of a variety of indications, including atopic dermatitis, gastroparesis and motion sickness. In the ODYSSEY study, tradipitant will be administered in addition to the standard of care, at dosing levels previously tested and generally shown to be well tolerated.

Tradipitant targets the neurokinin-1 receptor, which is coded by the TACR1 gene and is the main receptor for substance P, an 11 amino acid neuropeptide with a diverse set of functions. It has been shown that the substance P neurokinin-1 receptor system is involved in the neuroinflammatory processes that leads to significant lung injury following a number of insults, including viral challenges.[2-6]

If the ODYSSEY study demonstrates significant tradipitant effectiveness in treating COVID-19 patients with ARDS, Vanda will work with the FDA in an effort to ensure that this therapy is made available to patients in an expedited manner.

"Someone immortal who cares for you will make a fair wind blow." (Athena speaking to Odysseus, Odyssey 15:51-52).

References:

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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.

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. We care for over two million people annually in the New York metro area and beyond, thanks to philanthropic support from our communities. Our 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. We're making breakthroughs in medicine at the Feinstein Institutes for Medical Research.

We're 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 our more than 100 medical specialties, visit Northwell.edu and follow us @NorthwellHealth on Facebook, Twitter, Instagram and LinkedIn.

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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 of Vanda's ODYSSEY 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 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 ending 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.

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