Vanda Pharmaceuticals Closes Enrollment In The ODYSSEY Study Comparing Tradipitant And Placebo In Hospitalized COVID-19 Pneumonia Patients

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WASHINGTON, Aug. 3, 2021 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that enrollment has closed in the ODYSSEY study comparing tradipitant and placebo in hospitalized COVID-19 pneumonia patients.

Enrollment was closed because the study met the pre-defined futility criteria, indicating that the study was unlikely to succeed in its pre-specified primary endpoint. The study was designed to determine whether tradipitant plus standard of care is superior to placebo plus standard of care in treating hospitalized patients with COVID-19 pneumonia who required supplemental oxygen support. The primary endpoint of the study is the difference between treatment and placebo on time to 2-point improvement on a 7-point ordinal scale. Treatment duration was 14 days and evaluation for the primary endpoint was at Day 28. Additional secondary endpoints include other changes in clinical and laboratory status.

An independent data and safety monitoring board (DSMB) met to assess the planned interim analysis results. The DSMB determined that the study is unlikely to show a significant difference between treatment arms at the pre-specified primary endpoint and recommended termination of the study for futility. The DSMB also determined that there are no safety concerns that contributed to its recommendation. The ODYSSEY study was initiated in April 2020 with an enrollment goal of 324 patients of which 153 have enrolled to date.

Separately, Vanda will continue the genetics component of the study with the goal of identifying genetic susceptibility factors contributing to the incidence of severe pneumonia among patients infected with the SARS-CoV-2 virus. In pursuit of that goal, Vanda has recently reported in the *Journal of Global Antimicrobial Resistance* on loss of function mutations in the IFNAR2 gene associated with COVID-19 severe infection susceptibility.[1]

For more information on the trial visit clinicaltrials.gov and search NCT04326426.

References

1. Smieszek, S.P., Polymeropoulos, V.M., Xiao, C., Polymeropoulos, C.M., Polymeropoulos, M.H. (2021). Loss-of-function mutations in *IFNAR2* in COVID-19 severe infection susceptibility. *Journal of Global Antimicrobial Resistance*, S2213-7165(21)00156-9. Advance online publication. https://doi.org/10.1016/j.jgar.2021.06.005

About Tradipitant

Tradipitant is a neurokinin-1 receptor antagonist licensed by Vanda from Eli Lilly and Company. Tradipitant is currently in clinical development for gastroparesis, COVID-19 pneumonia, motion sickness and atopic dermatitis. The FDA has imposed a partial clinical hold on tradipitant clinical protocols of longer than 12 weeks duration.

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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding Vanda's genetic analysis of SARS-CoV-2 virus patients, are "forward-looking statements" under the securities laws. 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, new information learned in in further analysis of ODYSSEY study data, and Vanda's ability to complete the genetics component of the study. Therefore, no assurance can be given that the 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. Forward-looking statements in this press release should be evaluated together with the various risks and uncertainties that affect Vanda's business and market, particularly those identified in the "Cautionary Note Regarding Forward-Looking Statements", "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, 2020, as updated by Vanda's subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the U.S. Securities and Exchange Commission, which are available at www.sec.gov.

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 press release is provided only as of the date of this press 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, except as required by law.

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