Vanda Pharmaceuticals Announces the Submission of an NDA to the FDA for Bysanti™ for the Treatments of Acute Bipolar I Disorder and Schizophrenia

March 31, 2025

WASHINGTON, March 31, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced that a New Drug Application (NDA) was submitted to the U.S. Food and Drug Administration (FDA) requesting marketing approval of Bysanti™ (milsaperidone) for the treatments of acute bipolar I disorder and schizophrenia. The NDA is supported by several clinical studies assessing the efficacy and safety of Bysanti™.

Bysanti™ is a new chemical entity that belongs in the class of atypical antipsychotic drugs. Bysanti™ is believed to achieve its therapeutic effect by interacting with a host of neurotransmitter receptors in the brain, including the alpha-adrenergic receptor, serotonin receptors and dopamine receptors.

If approved, Bysanti™ could be available for sale in the US in 2026. Exclusivity, including pending patent applications, could extend into the 2040s. Additionally, Vanda initiated a Phase III clinical study for Bysanti™ as a once-daily adjunctive treatment for major depressive disorder (MDD) in the fourth quarter of 2024. Results are expected in 2026.

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 X @vandapharma.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this press release, including, but not limited to, statements regarding Bysanti™'s mechanism of action, the potential commercial availability of Bysanti™, the potential to extend patent exclusivity for Bysanti™ into the 2040s, and the anticipated timing of the availability of results from the Phase III clinical study of Bysanti™ for the treatment of MDD are "forward-looking statements" under the securities laws. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Forward-looking statements are based upon current expectations and assumptions that involve risks, changes in circumstances 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 assumptions regarding how Bysanti™ achieves its therapeutic effect, Vanda's ability to complete the clinical development of and obtain regulatory approval for Bysanti™ for the treatments of acute bipolar I disorder and schizophrenia by 2026, Vanda's ability to satisfy the conditions necessary to extend Bysanti™'s patent exclusivity into the 2040s and Vanda's ability to complete the Phase III clinical study of Bysanti™ for the treatment of MDD and receive results in 2026. 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 most recent Annual Report on Form 10-K, 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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