Vanda Announces Bysanti™ NDA Filing; FDA Decision Expected in Early 2026

May 5, 2025

WASHINGTON, May 5, 2025 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the U.S. Food and Drug Administration (FDA) informed Vanda that the New Drug Application (NDA) for Bysanti™ (milsaperidone) has been filed, and that at this time no potential review issues have been identified. The FDA has set February 21, 2026 as the target date for decision on this application.

Bysanti™ is a new chemical entity, which was initially identified as an active metabolite of iloperidone. Vanda has discovered that milsaperidone, when administered orally, quickly interconverts to iloperidone. In clinical studies, milsaperidone and iloperidone have been shown to be bioequivalent at both low and high doses, administered both in single and multiple dose studies.

The results of these clinical studies will be presented in late May, at the 2025 American Society of Clinical Psychopharmacology annual meeting in Scottsdale, Arizona.

The efficacy and safety of Bysanti™ for the indications of bipolar I manic and mixed episodes and schizophrenia are supported by the clinical studies described on the iloperidone prescribing information. These include two studies in acute episodes of schizophrenia, one study in bipolar I disorder with manic or mixed episodes, and one relapse prevention study in schizophrenia. The safety of Bysanti™ is further supported by data in several thousand patients exposed to iloperidone in clinical studies, as well as the post marketing iloperidone experience, with more than 80,000 patient year exposures. The unique physical and chemical properties of milsaperidone make it amenable to the development of lipid esters that could allow the future development of long acting injectable formulations.

Bysanti™ is currently under development in a clinical study as a once-a-day adjunctive treatment of major depressive disorder (MDD) for patients with inadequate response on their current treatment. Results are expected in 2026.

Bysanti™ is eligible for 5 year regulatory data exclusivity if approved by the FDA. Current Bysanti™ related patent applications, if issued, would extend into the 2040's.

Bysanti™ belongs to the class of atypical antipsychotics showing strong affinity to the alpha 1 adrenergic receptor, in addition to certain serotonin and dopamine receptors that are believed to explain its therapeutic effects.

"The extraordinary discovery of bioequivalence to iloperidone, of this novel chemical entity, allows for the efficient development of Bysanti™ and opens new opportunities to further explore additional therapeutic applications of this molecule," said Dr. Mihael Polymeropoulos, Vanda's President, CEO and Chairman of the Board.

About Bysanti™

Bysanti™ is a new chemical entity that belongs in the class of atypical antipsychotic drugs. If approved, Bysanti™ could be available for sale in the US in 2026. 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. Exclusivity, including pending patent applications, could extend into the 2040s.

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 the potential to develop long acting injectable formulations of Bysanti™, the expected timing of the clinical study results for Bysanti™ in MDD, Bysanti™'s mechanism of action, the potential commerci availability of Bysanti™, the potential to extend patent exclusivity for Bysanti™ into the 2040s, the potential to develop additional therapeutic applications for Bysanti™, and the anticipated timing of the completion of the FDA's review of the Bysanti™ NDA 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 ability to complete its clinical study in MDD and report results in 2026, Vanda's assumptions regarding how Bysanti™ achieves its therapeutic effect, Vanda's ability to obtain regulatory approval for Bysanti™ for the acute treatment of bipolar I disorder and schizophrenia and initiate its commercial launch in 2026, Vanda's ability to satisfy the conditions necessary to extend Bysanti™'s patent exclusivity into the 2040s, Vanda's ability to identify additional indications for Bysanti™ and the FDA's ability to complete its review of, and reach a decision with respect to, the Bysanti™ NDA by February 21, 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.

Corporate Contact:

Kevin Moran
Senior Vice President, Chief Financial Officer and Treasurer
Vanda Pharmaceuticals Inc.
202-734-3400
pr@vandapharma.com

Jim Golden/Jack Keleher/Dan Moore
Collected Strategies
VANDA-CS@colectedstrategies.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/vanda-announces-bysanti-nda-filing-fda-decision-expected-in-early-2026-302445753.html

SOURCE Vanda Pharmaceuticals Inc.