Vanda Pharmaceuticals Announces a U.S. Patent Allowance for PONVORY® (ponesimod) in the U.S.

January 26, 2024

WASHINGTON, Jan. 25, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that the U.S. Patent and Trademark Office has issued a notice of allowance for its PONVORY® (ponesimod) patent application, number 17/962,968, covering methods for reducing clinical management events before or during the treatment of multiple sclerosis and methods for reinitiating treatment after missed doses. When issued, this patent is anticipated to expire on October 10, 2042. Upon issuance, Vanda intends to list this patent in the U.S. Food and Drug Administration publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

Vanda acquired rights to U.S. and Canadian rights to PONVORY® from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company. PONVORY® is approved by the U.S. Food and Drug Administration and Health Canada to treat adults with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease.

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.

About PONVORY®

PONVORY® (ponesimod) is a daily oral selective sphingosine-1-phosphate receptor 1 (S1P1R) modulator, indicated to treat adults with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. PONVORY® blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. PONVORY® does not require genetic testing or first-dose cardiac monitoring for most patients. Because initiation of PONVORY® treatment results in a decrease in heart rate, first-dose monitoring is recommended in patients with certain preexisting cardiac conditions. For full U.S. Prescribing Information for PONVORY®, including Important Safety Information, visit www.ponvory.com. The PONVORY® Orange Book listed patent with the latest expiry date is set to expire in December 2035.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic autoimmune inflammatory disease of the central nervous system (CNS) in which immune cells attack myelin (the protective casing that insulates nerve cells), damaging or destroying it and causing inflammation. This affects how the CNS processes information and communicates with the rest of the body, causing the neurologic signs and symptoms of MS. Symptoms vary by person, but common symptoms include fatigue, balance and walking problems, numbness or tingling, dizziness and vertigo, vision problems, bladder and bowel problems and weakness.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Various statements in this press release, including, but not limited to statements regarding the USPTO's plans to issue the new PONVORY® patent, the anticipated life of the patent and Vanda's intentions to list the patent in the Orange Book, 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, the payment by Vanda to the USPTO of all fees required prior to the issuance of the patent, the ultimate issuance of the patent by the USPTO and Vanda's ability to protect its intellectual property rights and defend the new PONVORY® patent against any attempt to invalidate it. Therefore, no assurance can be given 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. 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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