Vanda Pharmaceuticals Announces Completion of Transfer of FDA Marketing Authorization for PONVORY®

May 30, 2024

WASHINGTON, May 30, 2024 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that ownership of the U.S. New Drug Application and Investigational New Drug Applications for PONVORY® (ponesimod) has been transferred to Vanda from a Johnson & Johnson Company, which now fully allows Vanda to commercialize PONVORY® in the U.S.

"This milestone completes the transfer of the FDA marketing authorization to Vanda and allows Vanda to commence full commercialization efforts and begin clinical development programs as we seek to maximize the potential of Ponvory in the treatment of a host of inflammatory disorders," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board.

Vanda acquired U.S. and Canadian rights to PONVORY® from a Johnson & Johnson Company on December 7, 2023. PONVORY® is approved by the U.S. Food and Drug Administration (FDA) 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 (RMS).

In anticipation of the commercial launch of PONVORY® for RMS in the third quarter of 2024, Vanda is initiating a host of commercial activities including the creation of a specialty sales force, a prescriber awareness program and a comprehensive marketing program.

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.

About PONVORY®

Vanda acquired U.S. and Canadian rights to PONVORY® from Actelion Pharmaceuticals Ltd., a Johnson & Johnson Company on December 7, 2023. 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.ponvoryus.com. The PONVORY® Orange Book listed patent with the latest expiry date is set to expire in October 2042.

CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

Various statements in this press release, including, but not limited to, statements regarding Vanda's commercial and clinical development plans for PONVORY® and the initiation of commercial activities 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 execute the commercial launch of PONVORY® in the U.S. in the third quarter of 2024 and initiate its clinical development program for PONVORY® in the treatment of inflammatory disorders other than RMS, the results of any clinical trials conducted for PONVORY® in the treatment of such disorders, and Vanda's ability to obtain regulatory approval of PONVORY® for any such disorders and Vanda's ability to successfully create a specialty sales force, a prescriber awareness program and a comprehensive marketing program for PONVORY®. 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 Kelleher / Dan Moore
Collected Strategies
VANDA-CS@collectedstrategies.com

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