Vanda Pharmaceuticals Acquires U.S. and Canadian Rights to PONVORY® (ponesimod), a Selective S1P1R Modulator Approved for Patients with Relapsing Multiple Sclerosis

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WASHINGTON, Dec. 7, 2023 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (Nasdaq: VNDA) today announced that it has acquired U.S. and Canadian rights to PONVORY® (ponesimod) from Actelion Pharmaceuticals Ltd. (Janssen), a Johnson & Johnson Company. PONVORY® is approved by the U.S. Food and Drug Administration (FDA) and Health Canada to treat adults with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease and active secondary progressive disease. PONVORY® has a proven safety profile with over 10 years of data.

"The acquisition of Ponvory is a significant milestone for Vanda, as it expands our commercial portfolio and gives us access to a versatile immune response modifier that can potentially have broad application in treating a number of autoimmune-based disorders," said Mihael H. Polymeropoulos, M.D., Vanda's President, CEO and Chairman of the Board.

In a clinical study, PONVORY® was shown to be superior to Aubagio®, another approved drug for multiple sclerosis (MS), in the annual rate of relapse and it was also associated with fewer T2 and T1 MRI lesions versus the comparator. Approximately 9 out of 10 people taking PONVORY® did not experience disability progression over 2 years (as measured by the time to 3-month Confirmed Disability Progression).[1]

The effect of PONVORY® on the decrease of circulating lymphocytes is reversible so lymphocytes quickly return to baseline levels after discontinuation of PONVORY®. This rapid reversible effect is important for people needing to pause therapy for a vaccine. For women of childbearing age who want to become pregnant, PONVORY® is eliminated from the body in about 7 days after stopping treatment.

The mechanism of action of PONVORY® makes it also a potential therapeutic candidate for the treatment of a diverse group of inflammatory/autoimmune disorders ranging from psoriasis to ulcerative colitis. In a randomized placebo controlled clinical study, PONVORY® has also been shown to reduce the symptoms and signs of psoriasis.[2]

Under the terms of the agreement, Vanda paid $100 million to acquire the U.S. and Canadian rights to PONVORY®. Janssen will continue to operate the business pursuant to a Transitional Business License Agreement, during which time, Vanda and Janssen will transition regulatory and supply responsibility for PONVORY® to Vanda.

Stifel acted as exclusive financial advisor to Vanda with respect to this acquisition.

About PONVORY®

PONVORY® (ponesimod) is a daily oral selective sphingosine-1-phosphate receptor 1 (S1P1R) modulator, indicated to treat adults with relapsing forms of MS, 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 https://www.ponvory.com/.

The PONVORY® Orange Book listed patent with the latest expiry date is set to expire in December 2035.

About 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.

About Sphingosine-1-Phosphate Receptor 1 Modulators

PONVORY® (ponesimod) belongs in the molecular class of sphingosine-1-phosphate (S1P) analogs that act as modulators of the S1P receptor (S1PR). There are five S1PR (1-5) subtypes with different tissue distribution and functional specificity. PONVORY® is a selective ligand for the S1P1R subtype. It has been speculated that selectivity for S1P1R, rapid onset and reversibility of pharmacological effects, and an optimized titration regimen may differentiate ponesimod from fingolimod, the first of the oral S1PR modulators in the treatment of multiple sclerosis, and may lead to better safety and tolerability.[3] Besides fingolimod (FDA approved in 2010), there are four additional FDA-approved members in the S1P modulator class that include siponimod (2019), ozanimod (2020), ponesimod (2021) and etrasimod (2023). With the exception of etrasimod, all other drugs are currently approved for the treatment of MS. Ozanimod and etrasimod are approved for the treatment of ulcerative colitis.

The S1PR modulators act by preventing the egress of lymphocytes from the lymph nodes and as such reduce the number of circulating lymphocytes leading to a decrease of the autoimmune response at the target site.

Based on the latest Datamonitor market forecasts for multiple sclerosis and ulcerative colitis, the S1P market in the U.S. is expected to be approximately $2 billion in 2024 and to grow to approximately $3.5 billion in 2028.[4]

References

1. Kappos L., Fox RJ., Burcklen M. (2021). Ponesimod Compared With Teriflunomide in Patients With Relapsing Multiple Sclerosis in the Active-Comparator Phase 3 OPTIMUM Study: A Randomized Clinical Trial. JAMA neurology, 78(5), 558–567. https://doi.org/10.1001/jamaneurol.2021.0405
2. Vaclavkova, A., Chimenti, S., Arenberger, P., Holló, P., Sator, P. G., Burcklen, M., Stefani, M., & D'Ambrosio, D. (2014). Oral ponesimod in patients with chronic plaque psoriasis: a randomised, double-blind, placebo-controlled phase 2 trial. *Lancet (London, England)*, *384*(9959), 2036–2045. https://doi.org/10.1016/S0140-6736(14)60803-5
3. D'Ambrosio, D., Freedman, M. S., & Prinz, J. (2016). Ponesimod, a selective S1P1 receptor modulator: a potential treatment for multiple sclerosis and other immune-mediated diseases. *Therapeutic advances in chronic disease*, *7*(1), 18–33. https://doi.org/10.1177/2040622315617354
4. Datamonitor Healthcare – Multiple Sclerosis (MS) Patient-Based Market Forecast published October 2023 and Datamonitor Healthcare – Ulcerative Colitis Patient-Based Market Forecast published March 2023.

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 impact that the acquisition of PONVORY® will have on Vanda's commercial portfolio, the potential of PONVORY® to treat a diverse group of inflammatory/autoimmune disorders, the post-closing transitional plans to operate the U.S. and Canadian PONVORY® business during the transition period, the parties' plans to transition regulatory and supply responsibility for PONVORY® to Vanda, the duration of the patent protection for PONVORY®, the potential differentiation of PONVORY® from other drugs in its class, the safety and tolerability of PONVORY®, and the size and growth of the potential U.S. market for the class of S1P1R modulators 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 successfully commercialize PONVORY®, the results of any clinical trials conducted for PONVORY® in the treatment of other inflammatory/autoimmune disorders and Vanda's ability to obtain regulatory approval of PONVORY® for any such additional indications, the seller's ability to effectively operate the U.S. and Canadian PONVORY® business during the transition period, the parties' ability to transition regulatory and supply responsibility for PONVORY® to Vanda, the ability of the parties to successfully defend any challenge to the PONVORY® patents, the ability of the identified characteristics of PONVORY® and an optimized titration regimen to differentiate it from other drugs in its class and result in better safety and tolerability, and the market acceptance and commercial success of S1P1R modulators. 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 Current Report on Form 8-K 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.

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

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