Vanda Pharmaceuticals Acquires Rights to NK-1 Receptor Antagonist from Eli Lilly and Company

April 16, 2012

WASHINGTON, April 16, 2012 /PRNewswire via COMTEX/ --Vanda Pharmaceuticals Inc. (NASDAQ: VNDA), a biopharmaceutical company focused on the development and commercialization of products for central nervous system disorders, announced today that it has acquired an exclusive world-wide license from Eli Lilly and Company (Lilly) to develop and commercialize a small molecule neurokinin 1 receptor (NK-1R) antagonist for all human indications.

NK-1R antagonists have been evaluated in a number of indications including chemotherapy-induced nausea and vomiting (CINV), post-operative nausea and vomiting (PONV), alcohol dependence, anxiety, depression, and pruritus. VLY-686 (formerly known at Lilly as LY686017) has demonstrated proof-of-concept in alcohol dependence in a study published by the NIH (1). In that study VLY-686 was shown to reduce alcohol cravings and voluntary alcohol consumption among patients with alcohol dependence. Merck's Emend® (aprepitant) is the only marketed NK-1R antagonist in the United States and is approved for the treatment of CINV and the prevention of PONV.

"The licensing of VLY-686 is an important milestone for Vanda, as we continue to realize our vision of developing treatments to address unmet medical needs," said Mihael H. Polymeropoulos, M.D., President and CEO of Vanda.

Under the terms of the agreement with Lilly, Vanda will pay an initial license fee of $1.0 million and will be responsible for all development costs. Lilly is also eligible to receive additional payments based upon achievement of specified development and commercialization milestones as well as tiered-royalties on net sales at percentage rates up to the low double digits. These milestones include $4.0 million for pre-NDA approval milestones and up to $95.0 million for future regulatory approval and sales milestones.

In 2012, Vanda intends to initiate and complete the technology transfer activities and further examine the clinical and commercial profile of VLY-686. This strategic evaluation will further inform potential indications for an early development clinical program.

About VLY-686
VLY-686 (formerly known at Lilly as LY686017) is an NK-1R antagonist currently at the clinical stage of development, with previous research focusing on the potential as a novel therapeutic in alcohol dependence (1). The patent describing VLY-686 as a new chemical entity expires worldwide in April 2023, except in the United States, where it expires in June 2024, absent any applicable patent term adjustments.

About the Neurokinin-1 Receptor and Substance P
The NK-1R is expressed throughout different tissues of the body, with major activity found in neuronal tissue. Substance P (SP) and NK-1R interactions in neuronal tissue regulate neurogenic inflammation locally and the pain perception pathway through the central nervous system. Other tissues, including endothelial cells and immune cells, have also exhibited SP and NK-1R activity (2). The activation of NK-1R by the natural ligand SP is involved in numerous physiological processes, including the perception of pain, behavioral stressors, cravings, and the processes of nausea and vomiting (1,2,3). An inappropriate over-expression of SP either in nervous tissue or peripherally could result in pathological conditions such as substance dependence, anxiety, nausea/vomiting, and pruritus (1,2,3,4). An NK-1R antagonist may possess the ability to reduce this over-stimulation of the NK-1R, and as a result address the underlying pathophysiology of the symptoms in these conditions.

About Vanda:
Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of products for the treatment of central nervous system disorders. For more on Vanda Pharmaceuticals Inc., please visit http://www.vandapharma.com.

References

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS
Various statements in this release are "forward-looking statements" under the securities laws. Words such as, but not limited to, "believe," "expect," "anticipate," "estimate," "intend," "plan," "project," "target," "likely," "will," "would," and "could," or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Important factors that could cause actual results to differ materially from those reflected in the company's forward-looking statements include, among others: the extent and effectiveness of the development, sales and marketing and distribution support Fanapt® receives; Vanda's ability to successfully commercialize Fanapt® outside of the U.S. and Canada; delays in the completion of Vanda's clinical trials; a failure of Vanda's products, product candidates or partnered products to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products, product candidates or partnered products or to comply with ongoing regulatory requirements; a lack of acceptance of Vanda's products, product candidates or partnered products in the marketplace, or a failure to become or remain profitable; Vanda's expectations regarding trends with respect to its costs and expenses; Vanda's inability to obtain the capital necessary to fund additional research and development activities; Vanda's failure to identify or obtain rights to new products or product candidates; Vanda's failure to develop or obtain sales, marketing and

distribution resources and expertise or to otherwise manage its growth; limitations on Vanda's ability to utilize some or all of its prior net operating losses and research and development credits; a loss of any of Vanda's key scientists or management personnel; losses incurred from product liability claims made against Vanda; a loss of rights to develop and commercialize Vanda's products or product candidates under its license and sublicense agreements and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Vanda's annual report on Form 10-K for the fiscal year ended December 31, 2011 which is on file with the SEC and available on the SEC's website at www.sec.gov. In addition to the risks described above and in Vanda's annual report on Form 10-K and quarterly reports on Form 10-Q, other unknown or unpredictable factors also could affect Vanda's results. There can be no assurance 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. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

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 release is provided only as of the date of this 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.

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