Vanda Pharmaceuticals Settles Fanapt® Patent Litigation with Apotex

December 7, 2016

WASHINGTON, Dec. 7, 2016 /PRNewswire/ -- Vanda Grants Apotex a license to sell generic Fanapt® beginning November 2027

Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced it has entered into a License Agreement (the License Agreement) with Apotex Inc. and Apotex Corp. (collectively, Apotex) to resolve Vanda's patent litigation against Apotex regarding Apotex's Abbreviated New Drug Application seeking approval of its generic version of Vanda's Fanapt® (iloperidone).

Under the License Agreement, Vanda granted Apotex a non-exclusive license to manufacture and commercialize Apotex's version of Fanapt® in the U.S. effective November 2, 2027, unless prior to that date Vanda obtains pediatric exclusivity for Fanapt®, in which case, the license will be effective May 2, 2028. Apotex may enter the market earlier under certain limited circumstances.

The License Agreement is subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice. The License Agreement provides for a full settlement and release by Vanda and Apotex of all claims that are the subject of the litigation.

About Vanda Pharmaceuticals Inc.
Vanda is a specialty pharmaceutical company focused on the development and commercialization of novel therapies to address high unmet medical needs and improve the lives of patients. For more on Vanda Pharmaceuticals Inc., please visit www.vandapharma.com.

About Fanapt®
For full U.S. Prescribing Information for Fanapt®, including indication, Boxed Warnings and Important Safety Information, visit our Web site at www.fanapt.com.

CAUTIONARY NOTE REGARDING Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding the anticipated results and actions to be taken under the License Agreement and plans to submit the License Agreement for regulatory approval. These 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 Vanda's forward-looking statements include, but are not limited to, risks regarding whether regulatory authorities challenge the enforceability of or seek to enjoin the entry into the License Agreement, whether additional third parties may seek to market generic versions of Fanapt® and the results of any litigation that Vanda files to defend and/or assert its patents against such third parties 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, 2015 and quarterly report on Form 10-Q for the quarter ended September 30, 2016, which are 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.

Investor Contact:
Jim Kelly
Senior Vice President & Chief Financial Officer
Vanda Pharmaceuticals Inc.
(202) 734-3428
jim.kelly@vandapharma.com

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/vanda-pharmaceuticals-settles-fanapt-patent-litigation-with-apotex-300374937.html

SOURCE Vanda Pharmaceuticals Inc.