# Vanda Pharmaceuticals Settles Fanapt® Patent Litigation with Taro

October 24, 2016

**Vanda Grants Taro a license to sell generic Fanapt® beginning November 2027**

WASHINGTON, Oct. 24, 2016 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced it has entered into a License Agreement (the License Agreement) with Taro Pharmaceuticals U.S.A., Inc. and Taro Pharmaceutical Industries Ltd. (collectively, Taro) to resolve Vanda's patent litigation against Taro regarding Taro's Abbreviated New Drug Application seeking approval of its generic version of Vanda's Fanapt® (iloperidone).

Under the License Agreement, Vanda granted Taro a non-exclusive license to manufacture and commercialize Taro'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. Taro 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 Taro 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®**
Fanapt® is an atypical antipsychotic agent indicated for the treatment of schizophrenia in adults. In choosing among treatments, prescribers should consider the ability of Fanapt® to prolong the QT interval and the use of other drugs first. Prescribers should also consider the need to titrate Fanapt® slowly to avoid orthostatic hypotension, which may lead to delayed effectiveness compared to some other drugs that do not require similar titration.

IMPORTANT WARNINGS and PRECAUTIONS: increased mortality in elderly patients with dementia-related psychosis; QT prolongation; neuroleptic malignant syndrome; tardive dyskinesia; hyperglycemia and diabetes mellitus; weight gain; seizures; orthostatic hypotension and syncope; leukopenia, neutropenia and agranulocytosis; hyperprolactinemia; body temperature regulation; dysphagia; suicide; priapism; potential for cognitive and motor impairment.

COMMONLY OBSERVED ADVERSE REACTIONS of FANAPT® (>=5% and 2x placebo): dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight increased.

For full U.S. Prescribing Information, including 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, plans to submit the License Agreement for regulatory approval and the potential dismissal of the litigation. 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 the U.S. District Court will grant orders dismissing the litigation, 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 June 30, 2016, which are on file with the SEC and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Vanda's quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2016, to be filed with the SEC in the fourth quarter of 2016. 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.

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