



Vanda Announces FDA Has Accepted for Review the Fanapt® Supplemental New Drug Application for Maintenance Treatment of Schizophrenia in Adults

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WASHINGTON, Sept. 15, 2015 /PRNewswire/ -- Vanda Pharmaceuticals Inc. (Vanda) (NASDAQ: VNDA) today announced that the U.S. Food and Drug Administration (FDA) has accepted for review Vanda's filing of a supplemental New Drug Application (sNDA) for Fanapt® seeking approval as a maintenance treatment of schizophrenia in adults.

Vanda is seeking approval based on the results of the REPRIEVE clinical study, which evaluated the long-term maintenance of efficacy and safety of Fanapt®.

The FDA has set a user fee goal date under the Prescription Drug User Fee Act of May 27, 2016, which is the target date for the FDA to complete its review of the sNDA.

About Vanda Pharmaceuticals Inc.

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, 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

Various statements in this release, including, without limitation, statements regarding the target completion date of the FDA's review of the sNDA, are "forward-looking statements" under the securities laws. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties, including, without limitation, risks that the FDA will not complete its review of the sNDA by the user fee goal date or that the FDA may not ultimately approve the sNDA. Important factors that could cause actual results to differ materially from those reflected in Vanda's forward-looking statements are set forth 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, 2014 and quarterly report on Form 10-Q for the quarter ended June 30, 2015, 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.

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.

Corporate Contact:

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

Media Contact:

Laney Landsman
Vice President
Makovsky
(212) 508-9643
llandsman@makovsky.com

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