



FDA Approves Vanda Pharmaceuticals' Fanapt(TM) for the Treatment of Schizophrenia

May 6, 2009

ROCKVILLE, Md., May 6 /PRNewswire-FirstCall/ -- Vanda Pharmaceuticals Inc. (Nasdaq: VNDA) announced today that the US Food and Drug Administration (FDA) has granted marketing approval of Fanapt™ (iloperidone) for the acute treatment of adult patients with schizophrenia. The approval was supported by two placebo-controlled Phase III clinical studies comparing Fanapt™ to placebo and active control in patients with schizophrenia, as well as safety data from more than 3,000 patients.

Fanapt™ is a mixed dopamine D2 / serotonin 5HT2A receptor antagonist, and belongs to the class of atypical antipsychotics.

"The approval of Fanapt™ marks a new opportunity for many patients with schizophrenia, who experience only partial responses to current therapies, to achieve better control of their symptoms," remarked Dr. Peter J. Weiden, Professor of Psychiatry and Director of the Psychotic Disorders Program at the University of Illinois at Chicago. "Having Fanapt™ available is a major help for our patients in offering an effective antipsychotic with an excellent side effect profile across a wide range of major tolerability problems associated with other antipsychotic therapies."

The efficacy of Fanapt™ for the treatment of schizophrenia was supported by two placebo-controlled short-term (4- and 6-week) trials. Both trials enrolled patients who met the DSM-III/IV criteria for schizophrenia, and Fanapt™ was shown to be superior to placebo in controlling symptoms of schizophrenia across doses of 12mg to 24mg per day. The recommended target dose range of Fanapt™ is 12mg to 24 mg per day. Titration to the target dose of 12mg per day can be achieved in 4 days.

Vanda plans to make Fanapt™ available in pharmacies later this year.

"Fanapt™ is an important option for psychiatrists in treating patients with schizophrenia. It is an effective antipsychotic with excellent tolerability," added Dr. Steven G. Potkin Professor of Psychiatry and Human Behavior at the University of California at Irvine. "We also look forward to Vanda's continuing development of long-acting formulations of Fanapt™, to further address the significant unmet medical issues in this population of patients."

"The approval of Fanapt™ by the FDA represents many years of tireless efforts by current and former colleagues, many investigators and thousands of patients who participated in the development of this new treatment for schizophrenia. I would like to extend my gratitude to all those who contributed and reaffirm the commitment of Vanda Pharmaceuticals to the discovery and development of medicines for those in need," said Mihael H. Polymeropoulos, MD, Vanda's Chief Executive Officer.

In a 4-week placebo-controlled trial (n=604) involving one fixed dose of Fanapt™ (24 mg/day) compared to placebo and an active control (Geodon(R)), the 24 mg/day Fanapt™ dose was superior to placebo in the Positive and Negative Syndrome Scale (PANSS) total score.

In a 6-week placebo-controlled trial (n=706) involving two dose ranges of Fanapt™ (12-16 mg/day and 20-24 mg/day) compared to placebo and an active control (Risperdal(R)), both doses of Fanapt™ were superior to placebo on the Brief Psychiatric Rating Scale (BPRS) total score.

While it is not known how long patients treated with Fanapt™ should be maintained on treatment, it is generally recommended that responding patients be continued beyond the acute response. Patients should be periodically reassessed to determine the need for maintenance treatment.

Fanapt™ was generally well-tolerated and the most commonly observed adverse reactions (incidence \geq 5% and two-fold greater than placebo) were dizziness, dry mouth, fatigue, nasal congestion, orthostatic hypotension, somnolence, tachycardia, and weight increased.

Weight gain was mild, and the overall mean weight increase across all short- and long-term studies was 2.1 kg. Fanapt™ was not associated with any medically important elevations in glucose, triglycerides or cholesterol. Fanapt™ was also associated with only modest elevations of prolactin as compared to larger elevations seen with some other drugs in this class.

Fanapt™ has a low incidence of extrapyramidal symptoms (movement disorders and tremors) and a placebo-like rate of akathisia (restlessness, inability to sit still), which are adverse events that are often associated with some other drugs in the class of atypical antipsychotics.

Similarly to some other drugs in this class, Fanapt™ may affect heart rhythm parameters and specifically the QTc interval, which may lead physicians to consider prescribing Fanapt™ after other antipsychotics are tried first.

About Schizophrenia

Schizophrenia is a chronic debilitating disorder which affects more than two million Americans, and millions more worldwide. While significant progress has been made in understanding the disease and developing treatments, there remains a significant unmet medical need. More than 50% of patients switch their medication in a given year due to either poor response or the experience of adverse events. Worldwide sales from the class of atypical antipsychotics exceeded US \$20 billion in 2007.

About Vanda

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

CONFERENCE CALL

The company has scheduled a conference call for tomorrow, Thursday, May 7, 2009 at 10:30 AM ET. During the call, Mihael H. Polymeropoulos, M.D., President and CEO and Stephanie R. Irish, Acting Chief Financial Officer, will discuss the FDA's approval of Fanapt™. Investors can call 1-866-314-4865 (domestic) and 1-617-213-8050 (international) prior to the 10:30 AM start time and ask for the Vanda Pharmaceuticals conference call hosted by Dr. Polymeropoulos. A replay of the call will be available Thursday, May 7, 2009, at 1:30 PM ET and will be accessible until Thursday, May 14, 2009, at 5:00 PM ET. The replay call-in number is 1-888-286-8010 for domestic callers and 1-617-801-6888 for international callers. The access number is 55054292.

The conference call will be broadcast simultaneously on the company's Web site, <http://www.vandapharma.com>. Investors should click on the Investor Relations tab and are advised to go to the Web site at least 15 minutes early to register, download, and install any necessary software. The call will also be archived on the Vanda Web site for a period of 30 days, through June 6, 2009.

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," "targets," "likely," "will," "would," and "could," 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. Vanda Pharmaceuticals Inc. is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in the company's forward-looking statements include, among others: delays in the completion of Vanda's clinical trials; a failure of Vanda's products to be demonstrably safe and effective; Vanda's failure to obtain regulatory approval for its products or to comply with ongoing regulatory requirements for its products; a lack of acceptance of Vanda's 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 its commercial and research and development activities; Vanda's failure to identify or obtain rights to new products; Vanda's failure to develop or obtain sales, marketing and distribution resources and expertise or to otherwise manage its growth; 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 under its license and sublicense agreements and other factors that are described in the "Risk Factors" section (Part I, Item 1A) of Vanda's annual report on Form 10-K/A for the fiscal year ended December 31, 2008 (File No. 001-34186). In addition to the risks described above and in Part I, Item 1A of Vanda's annual report on Form 10-K/A, 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.

IMPORTANT INFORMATION/SOLICITATION PARTICIPANTS LEGEND

Vanda Pharmaceuticals Inc. and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Vanda in connection with the upcoming annual meeting of stockholders. Stockholders may obtain information regarding the names, affiliations and interests of such individuals in Vanda's proxy statement filed with the Securities and Exchange Commission (the "SEC") on April 2, 2008, for the 2008 annual meeting. To the extent holdings of Vanda's securities have changed since the information set forth in that proxy statement, such changes have been reflected on Initial Statements of Beneficial Ownership of Securities on Form 3 and Statements of Change in Ownership of Securities on Form 4 filed with the SEC. Updated information regarding the names, affiliations and interests of these directors and executive officers in connection with the matters to be voted on at the annual meeting will be included in the proxy statement filed by Vanda in connection with the annual meeting. In addition, Vanda files annual, quarterly and special reports, proxy and information statements, and other information with the SEC. These documents are available free of charge at the SEC's web site at www.sec.gov or from Vanda at www.vandapharma.com. STOCKHOLDERS ARE URGED TO READ THE PROXY STATEMENT CAREFULLY WHEN IT IS AVAILABLE, AS IT WILL CONTAIN IMPORTANT INFORMATION THAT STOCKHOLDERS SHOULD CONSIDER BEFORE MAKING ANY VOTING OR INVESTMENT DECISION.

SOURCE: Vanda Pharmaceuticals Inc.

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