



Vanda Pharmaceuticals Confirms Iloperidone Efficacy With Positive Phase III Clinical Trial Results in Schizophrenia

December 7, 2006

Demonstrates Statistically Significant Efficacy vs. Placebo
Achieves Significant Efficacy on Positive and Negative Symptoms
Validates Pharmacogenetic Markers of Efficacy and Safety
New Drug Application (NDA) Filing Expected in Late 2007

ROCKVILLE, Md., Dec. 7 /PRNewswire-FirstCall/ -- Vanda Pharmaceuticals Inc. (Nasdaq: VNDA), a biopharmaceutical company focused on the development and commercialization of clinical-stage product candidates, today announced positive top-line results from the company's Phase III clinical trial evaluating iloperidone, an atypical antipsychotic, in patients with schizophrenia. Iloperidone demonstrated statistically significant improvement compared to placebo on the Positive and Negative Symptom Scale (PANSS), the trial's primary endpoint. Additionally, iloperidone achieved significant efficacy on the positive and negative symptom subscales of PANSS. The safety profile was consistent with what has been observed in previous iloperidone Phase III trials.

Vanda also evaluated iloperidone's efficacy and safety in patients with specific genetic profiles using its expertise in pharmacogenetics (PG), as part of its commitment to give physicians and patients information to help personalize their antipsychotic therapy. Vanda had previously identified a polymorphism in a gene, occurring in approximately 70% of patients, hypothesized to be associated with the pathogenesis of schizophrenia which appeared to correlate with iloperidone response. Iloperidone achieved statistical significance vs. placebo on the PANSS scale in these patients, with a magnitude of response greater than that seen in the overall iloperidone population.

The Phase III trial was a randomized, double-blind, placebo-controlled, multi-center, 4 week inpatient study that enrolled 604 patients with schizophrenia. The trial examined iloperidone 12 mg dosed twice-daily, or 24 mg per day. The primary endpoint was efficacy vs. placebo in PANSS (total) using the Mixed Method Repeated Measures (MMRM) methodology. The secondary endpoint was efficacy in the genetic subpopulation.

The specific findings of efficacy vs. placebo include:
Efficacy (intent to treat population):

- PANSS (total): $p=0.006$
- PANSS (positive symptoms only): $p=0.0009$
- PANSS (negative symptoms only): $p=0.027$
- Brief Psychiatric Rating Scale (BPRS): $p=0.0128$

Efficacy (genetic subpopulation):

- PANSS (total): $p=0.002$

Under Last Observation Carried Forward (LOCF) methodology, iloperidone met the primary and secondary endpoints with statistical significance. Iloperidone efficacy was also equal to the active arm.

Vanda also measured the effect of iloperidone on the QT interval, a well understood atypical antipsychotic class side effect. The mean QT prolongation was consistent with previous experience. No patients experienced QT intervals in excess of 500 milliseconds, a threshold of concern to the FDA. Vanda also confirmed with an additional genetic marker that the QT prolongation was shorter in the majority of patients who are good iloperidone metabolizers.

The specific findings include:

- QTc change from baseline:
- All patients: 11.4 milliseconds (msec)
- Good metabolizers: 10.4 msec
- Poor metabolizers: 15.0 msec ($p=0.008$, good vs. poor)

"We are extremely pleased to have achieved this outcome with iloperidone. The success of this trial moves us one step closer to our NDA filing, expected in late 2007, and one step closer to making iloperidone available to patients and providers dealing with schizophrenia," stated Paolo Baroldi, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Vanda.

"We are especially pleased to have achieved our pharmacogenetic results," stated Mihael Polymeropoulos, M.D., President and CEO of Vanda. "For the first time in the treatment of a psychiatric disease, we have applied pharmacogenetic tools to identify patients best suited for a specific drug therapy. Our market research indicates that physicians treating schizophrenia patients would enthusiastically welcome such information in making prescribing decisions. We are committed to further exploration, after iloperidone approval, to identify the genetic basis of many aspects of iloperidone response."

About Schizophrenia

Schizophrenia is a chronic, debilitating mental disorder characterized by hallucinations, delusions, racing thoughts and other psychotic symptoms (collectively referred to as "positive symptoms"), as well as moodiness, anhedonia (inability to feel pleasure), loss of interest, eating and sleep

disturbances, and difficulty concentrating (collectively referred to as "negative symptoms"). Schizophrenia develops in late adolescence or early adulthood in approximately 1% of the world's population. Genetic and environmental factors are believed to be responsible for the disease.

CONFERENCE CALL

The company has scheduled a conference call for today, Thursday, December 7, 2006 at 9:00 AM ET. During the call, Mihael Polymeropoulos, M.D., President and CEO will discuss the results of this Phase III trial. Investors can call 1-800-638-5495 (domestic) and 1-617-614-3946 (international) prior to the 9:00 AM start time and ask for the Vanda Pharmaceuticals conference call hosted by Dr. Polymeropoulos. A replay of the call will be available on Thursday, December 7, 2006, beginning at 11:00 AM ET and will be accessible until Thursday, December 14, 2006, 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 49811320.

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 audio software. The call will also be archived on the Vanda Web site for a period of 30 days, through January 6, 2007.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Vanda's plans for its product candidates. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "targets," "likely," "will," "would," "should," and "could," and similar expressions or words, identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Vanda 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 Vanda's forward-looking statements include, among others, a failure of Vanda's product candidates to be demonstrably safe and effective, a failure to obtain regulatory approval for the company's products or to comply with ongoing regulatory requirements, a lack of acceptance of Vanda's product candidates in the marketplace, a failure of the company to become or remain profitable, Vanda's inability to obtain the capital necessary to fund its research and development activities, a loss of any of the company's key scientists or management personnel, and other factors that are described in the "Risk Factors" section of Vanda's report on Form 10-Q for its third quarter ended September 30, 2006. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Vanda undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

ABOUT VANDA PHARMACEUTICALS INC.:

Vanda Pharmaceuticals Inc. is a biopharmaceutical company focused on the development and commercialization of clinical-stage product candidates for central nervous system disorders. The company has three product candidates in clinical development. Vanda's lead product candidate, iloperidone, is a compound for the treatment of schizophrenia and bipolar disorder and is in Phase III for schizophrenia. Vanda's second product candidate, VEC-162, is a compound for the treatment of sleep and mood disorders which is currently in Phase III for insomnia. Vanda's third product candidate, VSF-173, is a compound for the treatment of excessive sleepiness and is ready for a Phase II clinical trial. For more on Vanda Pharmaceuticals Inc., please visit <http://www.vandapharma.com>.

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