

Vanda Pharmaceuticals Submits Iloperidone New Drug Application

Vanda Pharmaceuticals

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Vanda Pharmaceuticals Inc. (NASDAQ:VNDA) announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for iloperidone, an investigational atypical antipsychotic for the treatment of schizophrenia. The application includes data from 35 clinical trials and more than 3,000 patients treated with iloperidone (see also).

Iloperidone has demonstrated efficacy in treating the symptoms of schizophrenia both in the acute and the chronic setting. Iloperidone's binding to a number of dopamine and serotonin receptors provides a favorable safety profile on adverse symptoms, such as weight gain, extrapyramidal symptoms, akathisia and prolactin elevation. The NDA submission also contains pharmacogenetic data aimed to further improve the benefit/risk profile of iloperidone in the treatment of patients with schizophrenia.

"The submission of the iloperidone NDA marks a significant milestone for Vanda. Iloperidone may become an important instrument in the treatment of patients with schizophrenia and may help to usher the field of psychiatry into an era of personalized medicine," said Mihael H. Polymeropoulos, M.D., President and CEO, Vanda Pharmaceuticals Inc.

"For a serious brain disorder like schizophrenia, which affects about three million Americans in the prime of life, it is vital that new pharmacotherapeutic agents be developed in light of the fact that existing antipsychotic treatments work partially in some patients and not others, leaving many patients continuously disabled. The NIMH-funded CATIE effectiveness study revealed the efficacy or safety limitations of current agents. Iloperidone is a new antipsychotic that could offer an important new option for many patients suffering from schizophrenia," said Dr. Henry Nasrallah, Professor of Psychiatry, Neurology, and Neuroscience, University of Cincinnati College of Medicine.

First Step Towards Personalized Medicine

"The application of personalized medicine in schizophrenia is significant because response to drugs varies considerably and discontinuation of treatment is high among patients," said Dr. Anil Malholtra, Director, Psychiatry Research, Zucker Hillside Hospital.

"Advancements in personalized medicine could change the treatment paradigm for schizophrenia, and possibly other mental illnesses," said Michael Fitzpatrick, Executive Director, NAMI (National Alliance on Mental Illness).