BioSpectrum the business of Bio & Health Sciences ASIA EDITION

FDA to review Vanda blindness drug Tasimelteon

31 July 2013 | Regulatory | By BioSpectrum Bureau

Singapore: The US FDA has granted priority review classification to Vanda's New Drug Application (NDA) for tasimelteon, a circadian regulator for the treatment of Non-24-Hour Disorder (Non-24) in the totally blind.

FDA grants priority review status for a drug that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness" over current therapies. Currently, there is no approved treatment for Non-24 and tasimelteon has the potential to address this unmet medical need.

"We are extremely pleased that the FDA has granted tasimelteon priority review for the treatment of Non-24 in the totally blind," said Dr Mihael H Polymeropoulos, Vanda's president and CEO. "The agency's acceptance of the NDA and decision to place tasimelteon in a category of expedited review are important milestones for Vanda as we take another step toward our goal of providing patients with a treatment for Non-24."

The FDA determined the action target date under Prescription Drug User Fee Act (PDUFA-V), to be January 31, 2014. The FDA has also tentatively scheduled an advisory committee meeting to discuss the tasimelteon application on November 14, 2013.