Solvay Pharmaceuticals, Inc. and Wyeth Pharmaceuticals announce receipt of an FDA action letter for bifeprunox

14.08.2007 - Solvay Pharmaceuticals, Inc. and Wyeth Pharmaceuticals, a division of Wyeth, announced the receipt of an action letter from the U.S. Food and Drug Administration (FDA) in response to the New Drug Application (NDA) for bifeprunox, an atypical antipsychotic that was reviewed for the acute treatment of schizophrenia, as well as the maintenance of stable adult patients. The Agency stated that the drug was not approvable at this time.

The FDA stated in the letter that bifeprunox demonstrated effectiveness in the long-term maintenance study and indicated that a second positive maintenance study could be sufficient to support a maintenance claim for bifeprunox. The Companies believe that bifeprunox offers distinct benefits for the long-term maintenance of patients with schizophrenia. The Companies will meet with the FDA to discuss the study design and to assess how the additional study, combined with ongoing and planned studies can support a maintenance indication.

Although the FDA acknowledged that bifeprunox separated from placebo in two short-term studies in the acute setting, the Agency concluded that the efficacy data, when compared to reference drugs, were not sufficient for approval.

The Agency also requested further information regarding human metabolism of bifeprunox, and information regarding a complex case of a patient who died while participating in one of the trials.

"We believe that bifeprunox is a promising drug for the treatment of schizophrenia, and that there is a need for new treatment options to help people with schizophrenia manage their disease," says Laurence Downey, M.D., President and CEO of Solvay Pharmaceuticals, Inc. "We will work with the FDA to address its comments and pursue the approval of bifeprunox as soon as possible."

Bifeprunox, a partial dopamine agonist designed to normalize levels of chemical activity in the brain, has been studied in approximately 2,650 patients with schizophrenia at more than 200 Phase 2 and 3 clinical trial sites in the United States and throughout the world.