

Prestwick Pharmaceuticals Receives FDA Approvable Letter for XENAZINE(R) (Tetrabenazine) for Treatment of Chorea Associated with Huntington's Disease

WASHINGTON--(BUSINESS WIRE)--March 31, 2006--Prestwick Pharmaceuticals announced that the company has received an approvable letter from the U.S. Food and Drug Administration (FDA) for XENAZINE(R) (tetrabenazine), which is under review for the treatment of chorea associated with Huntington's disease (HD). The approvable letter specifies conditions that the company must meet prior to obtaining approval to market XENAZINE in the U.S. In this letter, the FDA also indicated its intent to discuss the company's New Drug Application (NDA) at a public meeting of the Peripheral and Central Nervous System Advisory Committee. The date for this Advisory Committee review has not been set.

"Prestwick is committed to making XENAZINE available in the U.S. as a treatment option for patients with chorea associated with Huntington's disease. We plan to work closely with the FDA to satisfy the conditions specified in the approvable letter and to present the safety and effectiveness of XENAZINE to the Advisory Committee," said Kathleen Clarence-Smith, M.D., Ph.D., Chief Executive Officer of Prestwick Pharmaceuticals.

XENAZINE is a highly selective and reversible dopamine depletor that works by inhibiting vesicular monoamine transporter 2 (VMAT2). XENAZINE is the first product for which an NDA has been filed in the U.S. for treatment of chorea associated with Huntington's disease. Chorea, a debilitating feature of a number of neurological diseases, is characterized by excessive, involuntary, and repetitive movements, which may involve the face, limbs, or the entire body. In HD, it is the result of overactivity of the neurotransmitter dopamine. The FDA designated tetrabenazine an orphan product for Huntington's disease because it affects only an estimated 30,000 patients in the U.S. The FDA also designated tetrabenazine a fast track product because there are no other drugs available in the U.S. to treat chorea. XENAZINE is approved in 8 markets outside of the U.S. and is currently marketed by Prestwick Pharmaceuticals Canada as NITOMAN(R).

About Prestwick

Prestwick Pharmaceuticals, Inc. is a product-based specialty pharmaceutical company engaged in the development and marketing of small molecule drugs for chronic diseases of the central nervous system (CNS). Based in Washington, DC, the company was formed in November 2002, and is privately held.

Prestwick Pharmaceuticals has rights to a portfolio of five product candidates obtained under licenses from third parties that are being studied for a range of CNS conditions with significant unmet needs, including Huntington's disease, Parkinson's disease, restless legs syndrome, schizophrenia, autism, Alzheimer's disease, and sleep apnea. Tetrabenazine, the company's lead product candidate, was licensed for marketing in the U.S. and Canada by Cambridge Laboratories (Ireland), Limited ("Cambridge"), which has worldwide rights to the product. Cambridge markets the product itself in the UK and Eire (Ireland), and through marketing partners in European and other markets.

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