Biovail Announces U.S. Availability of Xenazine(R) Tablets

November 24, 2008

TORONTO, Nov 24, 2008 (BUSINESS WIRE) -- Biovail Corporation today announced that Xenazine(R) tablets, an orphan drug recently approved by the U.S. Food and Drug Administration (FDA) for the treatment of chorea associated with Huntington's disease (HD), is now available throughout the United States. Xenazine(R) is the first and only FDA-approved treatment for any HD-related symptom.
"We are delighted to be involved in bringing this important product to market," said Biovail Chief Executive Officer Bill Wells. "Xenazine(R) is the first commercial product stemming from our New Strategic Focus - one that targets unmet medical needs in specialty central nervous system, or CNS markets."

Xenazine(R) will be distributed throughout the United States via a specialty pharmacy network. This approach to distributing the medication is designed to both help streamline prescription fulfillment, as well as to provide specialized assistance to healthcare professionals, patients and caregivers, including addressing questions about the appropriate use of Xenazine(R). Upon approval of Xenazine(R), the FDA determined that a Risk Evaluation and Mitigation Strategy (REMS) was necessary to ensure that the benefits of the drug outweigh the risks of depression and suicidality, to promote the informed prescribing and proper titration and dosing of Xenazine(R), and to minimize the risk of drug-drug interactions. Also as part of the program associated with the REMS, Biovail's marketing partner, Ovation Pharmaceuticals, Inc. has begun the process of educating physicians, pharmacists, patients and their caregivers about the safe and effective use of the drug.

About Chorea

Chorea is the most common symptom of Huntington's disease, which affects approximately 25,000 people in the U.S. It is characterized by jerky, involuntary movements throughout the body, often appearing as writhing, twisting and turning in a constant, uncontrollable dance-like motion. As chorea progresses, the involuntary, jerk-like movements worsen, making it difficult for individuals to carry out voluntary movements associated with daily living, such as speaking, eating and dressing. Over time, chorea presents an increasing safety risk to HD patients, often resulting in the need for assistance and supervision, and even institutionalization. Currently, there is no known cure for HD and the disease is ultimately fatal.

About Xenazine(R)

The precise mechanism by which Xenazine(R) exerts its anti-chorea effects is unknown, but it is believed to be related to its effects as a reversible depletor of monoamines by inhibiting a molecule known as vesicular monoamine transporter 2 (VMAT2). Xenazine(R) has received Orphan Drug status from the FDA.

The efficacy of Xenazine(R) as a treatment for chorea associated with Huntington's disease was demonstrated in a randomized, double-blind, placebo-controlled multi-center trial with a treatment duration of 12 weeks. The primary efficacy endpoint was the Total Chorea Score, an item of the Unified Huntington's Disease Rating Scale (UHDRS). The treatment effect of 3.5 units

was highly statistically significant. At one week after discontinuation of the study medication, the Total Chorea Scores of subjects receiving Xenazine(R) returned to baseline.

Important Safety Information and Boxed Warning

Xenazine(R) can increase the risk of depression and suicidal thoughts and behavior (suicidality) in patients with Huntington's disease. Anyone considering the use of Xenazine(R) must balance the risks of depression and suicidality with the clinical need for control of choreiform movements. Close observation of patients for the emergence or worsening of depression, suicidality, or unusual changes in behavior should accompany therapy. Patients, their caregivers, and families should be informed of the risk of depression and suicidality and should be instructed to report behaviors of concern promptly to the treating physician.

Particular caution should be exercised in treating patients with a history of depression or prior suicide attempts or ideation, which are increased in frequency in Huntington's disease. Xenazine(R) is contraindicated in patients who are actively suicidal, and in patients with untreated or inadequately treated depression.

Xenazine(R) is also contraindicated in patients with impaired hepatic function, and in patients taking monoamine oxidase inhibitors or reserpine. At least 20 days should elapse after stopping reserpine before starting Xenazine(R). Although Xenazine(R) has been shown to decrease the chorea associated with HD, it was also shown to cause slight worsening in mood, cognition, rigidity and functional capacity and prescribers should periodically re-evaluate the need for therapy. Some adverse effects such as depression, fatigue, insomnia, sedation/somnolence, parkinsonism, akathisia, QTc prolongation and interactions with CYP2D6 inhibitors may be dose dependent, and resolve or lessen with dose adjustment. The most frequent adverse events reported with Xenazine(R) compared to placebo in a randomized, 12-week, placebo controlled clinical trial of HD subjects include sedation/somnolence (31% vs. 3%), fatigue (22% vs. 13%), insomnia (22% vs. 0%), depression (19% vs. 0%), akathisia (19% vs. 0%), anxiety (15% vs. 3%) and nausea (13% vs. 7%). For more information, please see full prescribing information including Boxed Warning or go to
www.xenazineusa.com
.

About Biovail Corporation

Biovail Corporation is a specialty pharmaceutical company engaged in the formulation, clinical testing, registration, manufacture, and commercialization of pharmaceutical products. The Company is focused on the development and commercialization of medicines that address unmet medical needs in niche specialty central nervous system (CNS) markets. For more information about Biovail, visit the Company's Web site at
www.biovail.com
.

For further information, please contact Nelson F. Isabel at 905-286-3000 or send inquiries to
ir@biovail.com
.

SOURCE: Biovail Corporation

Biovail Corporation
Nelson F. Isabel, 905-286-3000
Vice President, Investor Relations &
Corporate Communications

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
908-569-3692