Biovail Announces U.S. Availability of Aplenzin(TM) Tablets

April 07, 2009

TORONTO, Apr 07, 2009 (BUSINESS WIRE) -- Biovail Corporation today announced that Aplenzin(TM) (bupropion hydrobromide) extended-release tablets are now available by prescription in the United States for adults ages 18 and older. Aplenzin(TM), which was developed by Biovail, offers prescribers and their patients the benefit of convenience with simple one-tablet, once-daily dosing of bupropion at all doses.
Aplenzin(TM) was approved by the U.S. Food and Drug Administration (FDA) in April 2008 at dosage strengths of 174mg, 348mg and 522mg for the treatment of major depressive disorder (MDD). The 522mg dosage strength of Aplenzin(TM) represents the only FDA-approved single-tablet, once-daily treatment option equivalent to 450mg of bupropion hydrochloride therapy, which requires two or three tablets daily.

In December 2008, Biovail entered into a supply-and-distribution agreement with sanofi-aventis U.S., which is now marketing the product in the U.S. and Puerto Rico. Under the terms of the agreement, Biovail will manufacture, supply and sell Aplenzin(TM) to sanofi-aventis U.S. at contractually determined prices, which will be based on sanofi-aventis U.S.' net selling price. Biovail's supply price will range from 25% to 35% of net sales, depending on the level of net sales of Aplenzin(TM).

Important Safety Information

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Aplenzin(TM) or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Aplenzin(TM) is not approved for use in pediatric patients.

The full prescribing information, including the black box warning, is available on the Investor Relations section of
www.biovail.com
, under Resources or
www.aplenzin.com
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Caution Regarding Forward-Looking Information and "Safe Harbor" Statement

To the extent any statements made in this release contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities

Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and may be forward-looking information under applicable Canadian provincial securities legislation (collectively, "forward-looking statements"). These forward-looking statements relate to, among other things, our objectives, goals, targets, strategies, intentions, plans, beliefs, estimates and outlook, and can generally be identified by the use of words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements.

Although Biovail believes that the expectations reflected in such forward-looking statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Certain material factors or assumptions are applied in making forward-looking statements, including, but not limited to, factors and assumptions regarding the reliability of research findings, and actual results may differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from these expectations include, among other things: uncertainties associated with the launch of a new product and the accuracy of associated research, reliance on key strategic alliances, contractual disagreements with third parties, availability of raw materials and finished products, the regulatory environment, and other risks detailed from time to time in Biovail's filings with the Securities and Exchange Commission and the Canadian Securities Administrators, as well as Biovail's ability to anticipate and manage the risks associated with the foregoing. Additional information about these factors and about the material factors or assumptions underlying such forward-looking statements may be found in the body of this news release, as well as under the heading "Risk Factors" contained in Item 3(D) of Biovail's most recent Annual Report on Form 20-F.

The Company cautions that the foregoing list of important factors that may affect future results is not exhaustive. When relying on Biovail's forward-looking statements to make decisions with respect to the Company, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. Biovail undertakes no obligation to update or revise any forward-looking statement, except as required by law.

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
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SOURCE: Biovail Corporation

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