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Biovail Provides Update on Pimavanserin Collaborative Development Program

October 06, 2009

TORONTO--(BUSINESS WIRE)--Oct. 6, 2009-- Biovail Corporation (NYSE/TSX: BVF) today provided an update on its Phase III program with pimavanserin for Parkinson's disease psychosis (PDP), which is being pursued in collaboration with ACADIA Pharmaceuticals Inc. Following the announcement on September 1st of disappointing top-line results from the first Phase III PDP trial, Biovail and ACADIA remain committed to the successful development of pimavanserin and have established a development strategy that they believe will strengthen the PDP program. The parties also intend to pursue adjunctive therapy with pimavanserin for schizophrenia as a third indication in the collaboration.

"We remain enthusiastic about pimavanserin's prospects in a number of specialty CNS indications, including schizophrenia where existing data for the molecule as co-therapy are compelling," said Bill Wells, Biovail's Chief Executive Officer. "The steps we're taking today are designed to fully exploit pimavanserin's potential and to bring this novel therapeutic to market as quickly as possible."

ACADIA has conducted a substantial portion of the analysis of the data from its first Phase III PDP trial with pimavanserin (-012 Study). While the -012 Study did not meet its primary endpoint of antipsychotic efficacy and had a larger than expected placebo response, signals of antipsychotic efficacy were observed in the pimavanserin 40 mg study arm. These signals were most prominent in the United States portion of the study, which comprised nearly one-half of the patients in the trial. The efficacy signals also were supported by additional secondary and exploratory measures, including efficacy measures and favorable outcomes in assessments of sleep and caregiver burden. Several findings from the -012 Study will be used in the design of future PDP studies to help mitigate the placebo response and to increase the chances of success. These findings relate to dose selection, the method and application of ratings, and other study design elements.

ACADIA and Biovail have agreed on a development strategy for PDP that involves using the findings from the -012 Study together with those from the second, ongoing Phase III trial (-014 Study), which is testing 10 mg and 20 mg doses of pimavanserin, to arrive at an enhanced study design that may be used in new Phase III trials. Accordingly, the ongoing -014 Study will be concluded at its current enrollment level (about 120 patients) to allow for the analysis of data as soon as practicable. Meanwhile, the parties will begin planning for a new Phase III PDP trial using a 40 mg dose of pimavanserin. Consistent with the terms of the original collaboration agreement, Biovail will be responsible for the cost of this third Phase III trial. This study is expected to start in the first half of 2010. ACADIA will continue its ongoing open-label safety extension studies in patients with PDP.

In addition, Biovail intends to pursue adjunctive therapy with pimavanserin for schizophrenia as a third indication in the collaboration. Alzheimer's disease psychosis (ADP) remains the second indication provided for in the collaboration. The parties currently intend to focus their efforts on the PDP and schizophrenia programs, but also are moving forward with planning for an initial study in ADP.

About Pimavanserin

Pimavanserin is a 5-HT_{2A} receptor inverse agonist in Phase III development as a treatment for Parkinson's disease psychosis. This new chemical entity, which was discovered by ACADIA, is a small molecule that can be taken orally as a tablet once-a-day. ACADIA and Biovail have formed a collaboration to co-develop and commercialize pimavanserin for neurological and psychiatric indications in the United States and Canada. ACADIA retains rights to pimavanserin in the rest of the world.

About Parkinson's Disease Psychosis

According to the National Parkinson Foundation, over 1.5 million people in the United States suffer from Parkinson's disease. Up to 40 percent of patients with Parkinson's disease may develop psychotic symptoms, commonly consisting of visual hallucinations and delusions. Currently there is no therapy in the United States approved to treat PDP. The development of psychosis in patients with Parkinson's disease is associated with increased caregiver burden, nursing home placement, and increased mortality.

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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About ACADIA Pharmaceuticals

ACADIA is a biopharmaceutical company utilizing innovative technology to fuel drug discovery and clinical development of novel treatments for central nervous system disorders. ACADIA's product candidates include pimavanserin in Phase III for Parkinson's disease psychosis in collaboration with Biovail, a product candidate in Phase II for chronic pain and a product candidate in Phase I for glaucoma, both in collaboration with Allergan, as well as additional compounds in IND-track development. All of the product candidates in ACADIA's pipeline emanate from discoveries made using its proprietary drug discovery platform. ACADIA maintains a website at
www.acadia-pharm.com
to which ACADIA regularly posts copies of its press releases as well as additional information and through which interested parties can subscribe to receive email alerts.

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", "potential" 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, uncertainties with respect to the results of further clinical trials, uncertainties with respect to the development path that will be required by regulatory authorities, reliance on key strategic alliances, contractual disagreements with third parties, availability of raw materials and finished products, the regulatory environment and associated filings and approvals, 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.

Source: Biovail Corporation

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