BAUSCH Health

Biovail Announces Results from ACADIA's Phase III Trial of Pimavanserin in Parkinson's Disease Psychosis

September 01, 2009

Pimavanserin Misses Primary Endpoint of Antipsychotic Efficacy; Meets Key Secondary Endpoint of Motoric Tolerability

ACADIA Hosting a Conference Call Today, September 1 at 8:00 am ET

TORONTO--(BUSINESS WIRE)--Sep. 1, 2009-- Biovail Corporation (NYSE/TSX:BVF) today announced top-line results from ACADIA Pharmaceutical Inc.'s first pivotal Phase III trial with pimavanserin in patients with Parkinson's disease psychosis, or PDP. The study did not meet its primary endpoint of antipsychotic efficacy as measured using the Scale for the Assessment of Positive Symptoms, or SAPS. Pimavanserin met the key secondary endpoint of motoric tolerability as measured using the Unified Parkinson's Disease Rating Scale, or UPDRS. Pimavanserin was safe and well tolerated, with the frequency of adverse events generally similar between the pimavanserin and placebo arms.

The primary endpoint of the study was the mean change in SAPS scores at day 42 compared to baseline for each of the two pimavanserin treatment arms versus placebo. Patients showed marked improvements in the SAPS scores across all study arms (mean reductions in SAPS scores were 5.9 points in the placebo arm, 5.8 points in the 10 mg pimavanserin arm, and 6.7 points in the 40 mg pimavanserin arm); however, statistical significance was not achieved in either pimavanserin arm primarily due to the larger than expected improvement in placebo-treated patients.

"We're clearly disappointed with the results, but such setbacks are not uncommon in the industry and are a reminder that we need to continue to build our pipeline with promising compounds," said Biovail CEO Bill Wells. "We will analyze the data in conjunction with ACADIA over the next several weeks before deciding on next steps."

Trial Design

The Phase III trial was a multi-center, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of pimavanserin in patients with PDP. A total of 298 patients were enrolled in the trial and randomized to one of three study arms, including two different doses of pimavanserin (10 mg or 40 mg) and placebo. Patients received oral doses of either pimavanserin or placebo once daily for six weeks. Patients remained on stable doses of their existing anti-Parkinson's therapy throughout the study. The primary endpoint was antipsychotic efficacy as measured using the hallucinations and delusions domains of the SAPS. The key secondary endpoint was motoric tolerability as measured using Parts II and III of the UPDRS.

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, including Parkinson's disease psychosis (PDP) and Alzheimer's disease psychosis (ADP), 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.

Conference Call and Webcast Information

ACADIA will host a conference call and webcast today, September 1, 2009, at 8:00 a.m. EDT to discuss the top-line results from the pivotal Phase III trial with pimavanserin in patients with PDP. The conference call can be accessed by dialing 866-713-8564 for participants in the U.S. or Canada and 617-597-5312 for international callers (reference passcode 15968327). A telephone replay of the conference call may be accessed through September 15, 2009 by dialing 888-286-8010 for callers in the U.S. or Canada and 617-801-6888 for international callers (reference passcode 88296469). The conference call also will be webcast live on ACADIA's website, www.acadia-pharm.com
, under the investors section and will be archived there until September 15, 2009.

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 with respect to the result of future clinical trials, the development path that will be required by regulatory authorities, 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 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.

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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