BAUSCH Health

Biovail Enters into License and Collaboration Agreement with Alexza for AZ-004

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NDA Filed by Alexza in Dec. 2009;Undergoing FDA Review for Treatment of Agitation;Targets Unmet Medical Need;Further Builds Specialty CNS Pipeline

TORONTO, Feb 10, 2010 (BUSINESS WIRE) -- Biovail Corporation (NYSE:BVF) (TSX:BVF) today announced that its subsidiary, Biovail Laboratories International SRL (BLS), has entered into a collaboration and license agreement with Alexza Pharmaceuticals, Inc. BLS has acquired the U.S. and Canadian rights to commercialize AZ-004 - a novel formulation of loxapine administered via deep lung inhalation using Alexza's proprietary Staccato(R) device. AZ-004 is initially targeted for the rapid treatment of agitation in patients with schizophrenia or bipolar disorder. In December 2009, Alexza submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Staccato loxapine. A response from the FDA is anticipated in October 2010.

"This agreement provides Biovail with a promising late-stage specialty CNS product," said Bill Wells, Biovail's Chief Executive Officer. "In clinical studies conducted by Alexza, *Staccato* loxapine rapidly delivered drug into the blood stream through the deep lung in a unique, non-invasive manner. We are delighted to be partnering with Alexza to bring this important treatment to market."

The collaboration provides for the development and commercialization of AZ-004 for multiple indications, including the initial indication of treating agitation in schizophrenia and bipolar patients, combined with potential future clinical development for the treatment in additional psychiatric and/or neurological indications and the symptoms associated with these indications.

Biovail intends to deploy a sales force to commercialize AZ-004 in the U.S. Alexza will continue to manage the ongoing AZ-004 NDA review and approval process in connection with the initial indication, and has entered into a manufacturing and supply agreement to supply Biovail clinical and commercial product.

Under the terms of the agreement, Biovail has paid an upfront fee of $40 million, and could pay up to $90 million in potential milestones contingent on the successful approval of the first AZ-004 NDA, successful commercial manufacturing scale-up, and the successful completion of additional clinical trials, regulatory submission (if required) and approval of a supplemental NDA (if required) in the outpatient setting for patients with schizophrenia or bipolar disorder. Biovail will also make tiered, royalty payments of 10% to 25% on net commercial sales of *Staccato* loxapine. Alexza will supply AZ-004 to Biovail for commercialization, and will receive a per-unit transfer price, based upon annual product volume.

The AZ-004 NDA contains efficacy and safety data from more than 1,600 patients and subjects who have been studied in thirteen different clinical trials. In 2008, Alexza announced that it successfully initiated and completed two pivotal Phase 3 clinical trials. In connection with these studies, Alexza reported that both doses of AZ-004 (5mg and 10mg) met the primary and key secondary endpoints of the studies with statistically significant reductions in agitation, as compared to placebo. In these studies, the administration of AZ-004 was generally safe and well tolerated.

About Agitation

Episodes of agitation afflict many people suffering from major psychiatric disorders, including schizophrenia, which affects approximately 2.4 million adults in the U.S., and bipolar disorder, which affects approximately 5.7 million adults in the U.S. More than 90% of these patients will experience agitation in their lifetime.

Agitation generally escalates over time with patients initially feeling uncomfortable, tense and restless. As the agitation intensifies, their behavior appears more noticeable to others as they become threatening and potentially violent, especially if the agitation is not treated. While patients seek treatment at different points along this agitation continuum, those with the most severe symptoms generally require treatment with injectable drugs in emergency medical settings, and currently are thought to represent the agitation market. Alexza, however, believes the therapeutic market for agitation is broader than only this limited perspective of patients in severe crisis -- many more are in need of treatment for an agitation episode.

Market research indicates that approximately 50% of treated acute agitation episodes are treated in emergency settings, another approximately 35% of the treated agitation episodes suffered by schizophrenic and bipolar patients are treated in an inpatient setting (hospital and long-term residential settings), and approximately 15% are treated in a physician's office.

Market research studies with schizophrenia patient caregivers and bipolar patients indicate these patients currently experience an average of 11 to 12 episodes of acute agitation each year.

Agitation episodes are currently treated about 55% of the time with oral antipsychotics and about 45% of the time with intra-muscular, or IM, injections. Oral medications work relatively slowly but are easy to administer, painless and are less threatening to patients. IM injections have a faster onset of action and a higher predictability of drug effect, but because they are invasive, IM injections are usually the treatment option of last-resort. Currently, no non-invasive therapies are available that work faster than 30 minutes to help agitated patients in need of treatment.

About AZ-004 (*Staccato* loxapine*)*

AZ-004 is an anti-agitation therapeutic that combines Alexza's proprietary *Staccato* system with loxapine, a drug belonging to the class of compounds known generally as antipsychotics. Loxapine is currently available in an oral formulation in the U.S. for the management of the manifestations of schizophrenia. The *Staccato* system is a hand-held, single-dose inhaler that delivers a drug aerosol to the deep lung that results in IV-like pharmacokinetics and rapid systemic effects.

About Alexza Pharmaceuticals, Inc.

Alexza Pharmaceuticals is a pharmaceutical company focused on the research, development and commercialization of novel, proprietary products for the acute treatment of central nervous system conditions. Alexza's technology, the *Staccato* system, vaporizes unformulated drug to form a condensation aerosol that, when inhaled, allows for rapid systemic drug delivery through deep lung inhalation. The drug is quickly absorbed through the lungs into the bloodstream, providing speed of therapeutic onset that is comparable to intravenous administration, but with greater ease, patient comfort and convenience.

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 .

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, our ability to establish or acquire a U.S. sales force, uncertainties associated with the successful integration of AZ-004 into our business and operations, uncertainties with respect to the development path that will be required by regulatory authorities, uncertainties with respect to the results of future clinical trials, the ability of Alexza to manufacture and supply AZ-004 and the ability of its suppliers to supply Alexza with the components and active pharmaceutical ingredient necessary to manufacture AZ-004, reliance on key strategic alliances, contractual disagreements with third parties, 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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