BAUSCH Health

Biovail Announces Supply Agreement for Commercialization of Extended-Release Tramadol

January 02, 2008

TORONTO, Jan 02, 2008 (BUSINESS WIRE) -- Biovail Corporation (NYSE:BVF)(TSX:BVF) today announced that a subsidiary, Biovail Laboratories International SRL, has entered into an exclusive supply agreement with Janssen Pharmaceutica NV (Janssen), a division of Johnson & Johnson, for the marketing and distribution of Biovail's once-daily, extended-release formulation of tramadol hydrochloride in 86 countries in two regions - Central and Eastern Europe/Middle East and Latin America.

Under the terms of this agreement, which has a 10-year term, Biovail will manufacture and supply once-daily extended-release tramadol hydrochloride tablets in dosage strengths of 100mg, 200mg and 300mg to Janssen at contractually determined prices. Janssen affiliates will be responsible for all related promotional costs, as well as all regulatory filings and the management of the regulatory approvals process.

"The culmination of this commercialization agreement between Biovail and Janssen is the latest endorsement of Biovail's proven formulation of once-daily tramadol, and further validates the Company's strategy to engage strategic partners to commercialize its products outside Canada," said Biovail Interim Chairman and Chief Executive Officer Dr. Douglas Squires. "This agreement furthers our existing relationship with Ortho-McNeil, Inc., an affiliate of Janssen which markets our once-daily tramadol in the United States."

Proven Track Record

In February 2006, Ortho-McNeil, Inc. launched Biovail's extended-release version of tramadol for the treatment of moderate to moderately severe chronic pain under the brand name Ultram(R) ER in the United States and Puerto Rico. Ultram(R) ER extended-release tablets, which are available in 100mg, 200mg and 300mg dosage strengths, is the only once-daily tramadol formulation that has been approved by the U.S. Food and Drug Administration (FDA). Since its launch, approximately 1.8 million prescriptions have been written for Ultram(R) ER.

On November 1, 2007, Biovail Pharmaceuticals Canada, Biovail's sales and marketing division, launched the product in Canada under the brand name Ralivia(TM). Ralivia(TM) is indicated for the management of pain of moderate severity in patients who require continuous treatment for several days or more.

With respect to other regions, Biovail is evaluating potential commercialization options in Western Europe.

Caution Regarding Forward-Looking Information and "Safe Harbor" Statement Under the Private Securities Litigation Reform Act of 1995

To the extent any statements made in this press 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 within the meaning of the "safe harbor" provisions of applicable Canadian securities legislation. These forward-looking statements relate to, among other things, our

objectives, goals, strategies, intentions, plans 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, 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: acceptance and demand for once-daily tramadol in particular regions, the impact of competitive products and pricing, regulatory matters including compliance with pharmaceutical regulations, availability of raw materials and finished products, the regulatory environment, the outcome of legal proceedings and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission and the Canadian Securities Administrators, as well as the Company'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/A. Biovail cautions that the foregoing list of important factors that may affect future results is not exhaustive. When relying on our 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. We undertake no obligation to update or revise any forward-looking statement.

About Biovail Corporation

Biovail Corporation is a specialty pharmaceutical company, engaged in the formulation, clinical testing, registration, manufacture, and commercialization of pharmaceutical products utilizing advanced drug-delivery technologies. For more information about Biovail, visit the Company's Web site at
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