BAUSCH Health

Biovail Receives Canadian Approval for Ralivia(TM) for the Treatment of Moderately Severe Pain

August 25, 2008

TORONTO--(BUSINESS WIRE)--Aug. 25, 2008--Biovail Corporation (NYSE:BVF)(TSX:BVF) today announced that it has received an expanded indication for once-daily Ralivia(TM) - to include the treatment of moderately severe pain in addition to moderate pain - from the Therapeutic Products Directorate (TPD) in Canada. Ralivia(TM) is now indicated for the management of moderate to moderately severe pain in adults who require continuous treatment for several days or more.

"This revised indication for moderately severe pain underscores the effectiveness of Ralivia(TM) in patients with moderate to moderately severe pain," said Biovail Chief Executive Officer Bill Wells. "Ralivia(TM) provides an analgesic option for patients with moderate to moderately severe pain without the risk of long-term cardiovascular and gastrointestinal risks that are associated with non-steroidal anti-inflammatory drugs and COX-2 inhibitors."

The new indication is based on the results of four 12-week, randomized, double-blind, parallel-group, placebo-controlled trials with Ralivia(TM) in more than 3,000 patients with persistent, moderate-to-severe pain due to osteoarthritis of the knee and/or hip, and low back pain. An additional study confirmed the safety and efficacy of Ralivia(TM) administered for up to 58 weeks.

Ralivia(TM) has been shown to produce significant reductions in pain intensity relative to placebo as early as the first day of treatment, with analgesic efficacy increasing throughout the first four weeks of treatment. Ralivia(TM) has also been shown to produce significant improvements in sleep, including improvements in sleep quality, trouble falling asleep, and awakening by pain at night and in the morning.

Ralivia(TM) is the only once-daily tramadol formulation that has also been approved by the United States Food and Drug Administration (FDA), and the only one with over 2.5 years of U.S. patient experience, during which time approximately 2.6 million prescriptions have been written.

Dosage Regimen

Ralivia(TM) should normally be started at a dose of 100mg once daily, and may gradually be increased in 100mg increments every five days, as necessary, and depending upon tolerability, to the relief of pain. The maximum dose of Ralivia(TM) is 300mg once daily.

Safety Precautions

Patients who are prescribed Ralivia(TM) may experience side effects, including dizziness, nausea, constipation and headache. These side effects are most likely to present shortly after the commencement of treatment. Patients in whom these side effects persist should contact their doctor.

Tramadol has a potential to cause psychic and physical dependence. Tramadol should not be used in opioid-dependent patients. In patients with a tendency to abuse drugs or a history of drug dependence, and in patients who are chronically abusing opioids, treatment with tramadol is not recommended. Withdrawal symptoms may occur following abrupt discontinuation of therapy.

Patients on prolonged therapy should be withdrawn gradually from tramadol if it is no longer required for pain control.

Patients and health-care professionals who wish to obtain more information about Ralivia(TM) are encouraged to visit the Products subdirectory on the Company's Web site at www.biovail.com or to call Biovail Medical Information at 1-866-825-8120.

Caution Regarding Forward-Looking Information and "Safe Harbor" Statement

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 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, strategies, intentions, plans, beliefs, estimates and outlook, including, without limitation, statements concerning Ralivia(TM), the expanded indication and the safety precautions associated therewith, 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: the results of continuing safety and efficacy studies by industry and government agencies; the patient's dosage regime; the particular attributes, traits and health of the patient; the regulatory environment; acceptance and demand for new pharmaceutical products and new indications for existing products; the impact of competitive products and pricing; regulatory matters including compliance with pharmaceutical regulations; and other risks detailed from time to time in the Company's filings with the U.S. 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.

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. 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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