BAUSCH Health

Biovail Comments on Proposed Generic Wellbutrin XL(R) Trial

January 22, 2010

TORONTO, Jan 22, 2010 (BUSINESS WIRE) -- Biovail Corporation (NYSE/TSX: BVF) today commented on a proposed clinical trial recently announced by Teva Pharmaceutical Industries Ltd. According to Teva, the trial is intended to address reports of inefficacy and adverse events by consumers who switched from Wellbutrin XL(R) 300 mg, Biovail's FDA-approved brand of the antidepressant, bupropion hydrochloride, to Budeprion XL, Teva's generic formulation of the drug. The trial was described in a Dow Jones Newswire article dated December 2, 2009.
Based on the limited information that has been made available about the clinical trial by Teva, Biovail believes the proposed study will not likely effectively address the complaints of consumers because it is too small in size and too brief in duration.

According to the December 2, 2009 article, the proposed study will enroll 138 patients who complained after switching from Wellbutrin XL$^{(R)}$ 300 mg to Budeprion XL. The study purportedly will employ a "double dummy" design in which patients will receive both placebo and active doses of each product over 16 days, alternating after eight days. Patients will be confined in a clinical setting for a total period of 24 days.

A statement in the article attributed to Teva's head of regulatory affairs suggests that the study will rely on blood-level data to verify bioequivalence of Wellbutrin XL$^{(R)}$ and Budeprion XL. The article indicates that bioequivalence will be based on the standard statistical criteria of the U.S. Food and Drug Administration (FDA). Adverse events are also to be recorded.

Budeprion XL is already deemed to be bioequivalent to Wellbutrin XL$^{(R)}$ by the FDA as defined by existing standard FDA criteria. Biovail believes this determination is likely to be confirmed by the proposed new trial.

However, based on available information, an independent expert retained by Biovail to consider the matter noted, "Even if Wellbutrin XL$^{(R)}$ and Budeprion XL were found (again) to be bioequivalent according to FDA bioequivalence criteria, the failure to find systematic differences in AUC and C_{max} in the study does not exclude the possibility of other between-product differences affecting clinical response."

Biovail believes the size of the proposed Teva study, while much larger than needed for bioequivalence testing, is likely too small to demonstrate that Wellbutrin XL$^{(R)}$ 300 mg and Budeprion XL have similar safety, tolerability, and/or efficacy profiles. In addition, the eight-day treatment periods in the proposed trial may be too brief for a clinically meaningful result, since most antidepressant clinical trials require treatment periods of at least 28 days.

To meaningfully address the reports of inefficacy and adverse events, Biovail's expert believes that a more extensive re-randomized trial should be conducted. In such a study, a larger number of subjects, both those who have and have not reported difficulties upon being switched from Wellbutrin XL$^{(R)}$ 300 mg to Budeprion XL in the past, would be assigned to Wellbutrin XL$^{(R)}$ and placebo Budeprion XL under double-dummy conditions. During the study, groups of subjects

would be re-randomized to Budeprion XL and placebo Wellbutrin XL(R), or continued on their original treatment.

Based on the views of its outside expert, Biovail believes a much larger and differently designed trial than has been proposed by Teva is required to demonstrate what, if any, clinical differences exist between Wellbutrin XL(R) 300 mg and Budeprion XL.

Biovail's primary concern is the safety and well-being of patients.

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, including, without limitation, the anticipated design of Teva's proposed clinical trial and the Company's beliefs and those of its experts regarding the anticipated results of Teva's proposed clinical trial and the design of possible alternative trials. Forward-looking statements can generally be identified by the use of words such as "believe," "anticipate," "expect," "intend," "plan," "will," "may", "potential", "proposed" 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: uncertainties associated with conducting clinical trials and the anticipated results therefrom, changes to the design of Teva's proposed clinical trial, 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 "Key Information - 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
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