



Warner Chilcott Announces Receipt of FDA Response to Citizen Petition

HAMILTON, Bermuda, March 17, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Warner Chilcott Limited (Nasdaq: WCRX) announced today that it has received the FDA's response to its citizen petition requesting that the FDA impose a 30-month stay of approval on Abbreviated New Drug Applications ("ANDAs") referencing DORYX 100 and 75 mg delayed release tablets that were filed prior to the listing of the DORYX patent under the transition rules of the QI Program Supplemental Funding Act of 2008. In its joint-response to the citizen petitions of the Company and several other petitioners, the FDA took the position that a 30-month stay would not apply to approvals for such ANDAs.

In its response, the FDA noted that "under current law, a 30-month stay will apply to an ANDA referencing an old antibiotic if that ANDA contains a paragraph IV certification to a patent submitted to the [FDA] before the ANDA was submitted, and the NDA holder or patent owner sues the ANDA applicant for patent infringement as a result of notice of the paragraph IV certification." Based upon the FDA's statement, the Company believes that following the commencement of its anticipated infringement suit against Impax Laboratories, Inc. ("Impax") it will be entitled to a 30-month stay of approval with respect to the Impax ANDA for a generic version of DORYX 150 mg delayed-release tablets.

DORYX, which Warner Chilcott markets and sells in 150, 100 and 75 mg strengths in the United States under a license agreement with Mayne Pharma International Pty. Ltd., is a tetracycline-class oral antibiotic protected by Mayne's Patent No. 6,958,161 (the "161 Patent") which expires in 2022. The Company and Mayne intend to vigorously defend the 161 patent and pursue their legal rights.

About Warner Chilcott

Warner Chilcott is a leading specialty pharmaceutical company currently focused on the women's healthcare and dermatology segments of the U.S. pharmaceuticals market. The Company is a fully integrated company with internal resources dedicated to the development, manufacturing and promotion of its products. WCRX-G

Read more on <http://www.warnerchilcott.com>.

Warner Chilcott's Forward Looking Statements:

This press release contains forward-looking statements, including statements concerning our operations, our anticipated economic performance and financial condition, and our business plans and growth strategy and product development efforts. These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. The words "may," "might," "will," "should," "estimate," "project," "plan," "anticipate," "expect," "intend," "outlook," "believe" and other similar expressions are intended to identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of their dates. These forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain and subject to a number of risks and uncertainties.

The following represent some, but not necessarily all, of the factors that could cause actual results to differ from historical results or those anticipated or predicted by our forward-looking statements: our substantial indebtedness; competitive factors in the industry in which we operate (including the approval and introduction of generic or branded products that compete with our products); our ability to protect our intellectual property; a delay in qualifying our manufacturing facility to produce our products or production or regulatory problems with either third party manufacturers upon whom we may rely for some of our products or our own manufacturing facilities; pricing pressures from reimbursement policies of private managed care organizations and other third party payors, government sponsored health systems, the continued consolidation of the distribution network through which we sell our products, including wholesale drug distributors and the growth of large retail drug store chains; the loss of key senior management or scientific staff; adverse outcomes in our outstanding litigation or an increase in the number of litigation matters to which we are subject; government regulation affecting the development, manufacture, marketing and sale of pharmaceutical products, including our ability and the ability of companies with whom we do business to obtain necessary regulatory approvals; our ability to manage the growth of our business by successfully identifying, developing, acquiring or licensing new products at favorable prices and marketing such new products; our ability to obtain regulatory approval and customer acceptance of new products, and continued customer acceptance of our existing products; changes in tax laws or interpretations that could increase our consolidated tax liabilities; the other risks identified in our Annual Report on Form 10-K for the year ended December 31, 2008; and other risks detailed from time-to-time in our public filings, financial statements and other investor communications.

We caution you that the foregoing list of important factors is not exclusive. In addition, in light of these risks and uncertainties, the matters referred to in our forward-looking statements may not occur. We undertake no obligation to publicly update or revise any forward-looking statement as a result of new information, future events or otherwise, except as may be required by law.

SOURCE Warner Chilcott Limited

<http://www.warnerchilcott.com>

Copyright (C) 2009 PR Newswire. All rights reserved