Warner Chilcott Announces 3-Month Extension of PDUFA Date on Next Generation Actonel Product

ARDEE, Ireland, July 16, 2010 /PRNewswire via COMTEX News Network/ -- Warner Chilcott plc (Nasdaq: WCRX) announced today that it has received a communication from the U.S. Food & Drug Administration (FDA) related to its next generation Actonel(R) product (risedronate sodium) delayed-release tablets extending the Prescription Drug User Fee Act (PDUFA) date by three months to allow sufficient time to review additional information solicited by the FDA and previously provided by the Company. The new PDUFA date is October 24, 2010.

The Company

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

Forward Looking Statements

This press release contains forward-looking statements, including statements concerning our operations, our 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 facilities that 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; our ability to realize the anticipated opportunities from the PGP Acquisition; the other risks identified in our periodic filings including our Annual Report on Form 10-K for the year ended December 31, 2009, and from time-to-time in our 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.

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