Columbia Laboratories' NDA for PROCHIEVEÃ,® Vaginal Progesterone Gel Accepted for Filing by FDA

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LIVINGSTON, N.J. and MORRISTOWN, N.J., June 27, 2011 /PRNewswire/ -- Columbia Laboratories, Inc. (Nasdaq: CBRX [1]) and Watson Pharmaceuticals, Inc. (NYSE: WPI [2]) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing Columbia's New Drug Application (NDA) for PROCHIEVE® (progesterone gel) for the reduction of risk of preterm birth in women with short uterine cervical length in the mid-trimester of pregnancy. The acceptance of the NDA for filing means FDA has determined that the application is sufficiently complete to permit a substantive review. The acceptance for filing does not provide any assurance that the FDA will ultimately approve the NDA.

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In addition, Columbia has voluntarily withdrawn its request for priority review. Following discussions with FDA, the companies determined that a standard review would afford the agency the appropriate timeframe necessary to complete its review of the application, including empaneling an agency advisory committee, if necessary. Under the Prescription Drug User Fee Act III (PDUFA), the FDA's goal under standard review is to review and act on the NDA by February 26, 2012.

Under the terms of the Purchase and Collaboration Agreement between Columbia and Watson, acceptance of the PROCHIEVE NDA will trigger a $5 million milestone payment to Columbia from Watson.

"We are pleased to achieve this important regulatory milestone and look forward to working with the FDA as they review the data package for the PROCHIEVE New Drug Application," said Frank Condella, President and Chief Executive Officer of Columbia Laboratories, Inc.

"Premature birth is a critical problem in this country and currently no therapeutic option exists
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