UCB announces submission of Kremers Urban's methylphenidate HCl ER bioequivalence study results to FDA

- Kremers Urban has submitted to FDA final results of new bioequivalence studies
- At this time, Kremers Urban plans to continue making its product available to patients
- UCB's intention to divest Kremers Urban is unchanged

Brussels (Belgium), June 8, 2015 – 19:00 CET – UCB announced today that its US specialty generics subsidiary, Kremers Urban Pharmaceuticals Inc. ("KU"), has submitted to the U.S. Food and Drug Administration (FDA) the final results of new bioequivalence studies designed to assess whether KU's methylphenidate hydrochloride extended-release tablets meet the criteria for establishing bioequivalence to the reference drug (Concerta®, registered trademark of ALZA Corporation) that are recommended in a revised draft guidance issued by FDA in November 2014.

KU has requested a meeting with FDA to discuss the results and will continue to work with FDA in the best interests of patients. At this time, KU plans to continue making its BX-rated product available to patients.

KU announced in November 2014 that FDA had requested additional bioequivalence testing based on the agency's revised draft guidance.

UCB's intention to divest its US specialty generic business remains unchanged.

For further information

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About UCB

UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development of innovative medicines and solutions to transform the lives of people living with severe diseases of the immune system or of the central nervous system. With more than 8500 people in approximately 40 countries, the company generated revenue of € 3.3 billion in 2014. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

About Kremers Urban Pharmaceuticals Inc. (KU)
KU is the generic subsidiary of UCB in the US. It is a specialty generic pharmaceutical company focused on generic products. To learn more visit www.kremersurban.com.

CONCERTA® is a registered trademark of ALZA Corporation.

Forward looking statements
This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms, costs associated with research and development, changes in the prospects for products in the pipeline or under development by UCB, effects of future judicial decisions or governmental investigations, product liability claims, challenges to patent protection for products or product candidates, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in tax laws or the administration of such laws and hiring and retention of its employees.

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There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.