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News
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UCB's Kremers Urban Pharmaceuticals Inc. receives FDA approval for extended release methylphenidate hydrochloride

- Extended release methylphenidate hydrochloride product is bioequivalent to Concerta QD®
- 18mg and 27mg extended release methylphenidate hydrochloride product approved
- Tentative approval for the 36mg and 54 mg

Brussels and Princeton, NJ 10 July 2013 - regulated information– UCB announced today that Kremers Urban Pharmaceuticals Inc. (KU), its U.S. subsidiary focused on specialty generics, received approval from the U.S. Food and Drug Administration (FDA) for 18mg and 27mg extended release methylphenidate hydrochloride product, for which Concerta® is the reference listed drug product. KU has begun launch operations and supplying the US-market with the product. KU also received tentative approval for the 36mg and 54 mg. KU will be eligible for final approval after exclusivity expiration in September 2013.

KU's extended release methylphenidate hydrochloride product is bioequivalent to Concerta QD® marketed by ALZA Corporation (a unit of Johnson & Johnson). Each tablet is designed to be effective for 12-hours.

In September 2011, KU announced that it has reached a settlement dismissing all pending litigation arising from its Abbreviated New Drug Application (ANDA) to market an extended release methylphenidate hydrochloride product. The settlement allows Kremers Urban to commercially launch its methylphenidate ANDA product under the existing Alza Corporation patents.

The launch of KU's new generic product was already considered in UCB's 2013 financial guidance.

For further information

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Notes to the editor

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 8 500 people in about 40 countries, the company generated revenue of EUR 3.4 billion in 2012. UCB is listed on Euronext Brussels (symbol: UCB).

About Kremers UrbanPharmacuticals Inc. (KU)

KU is the generic subsidiary of UCB in the US. It is a specialty generic pharmaceutical company focused on difficult, "high barrier" to entry generic products. To learn more visit www.kremersurban.com.

UCB Forward-Looking Statement

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. UCB is providing this information as of the date of this press release and expressly disclaims any duty to update any information contained in this press release, either to confirm the actual results or to report a change in its expectations.

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.