

UCB Interim Report - first three months 2012

# Strong growth of core medicines and significant pipeline performance

- Core medicines Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup> reaching combined sales of EUR 200 million in the first three months of 2012, up 50%
- First three months financial performance in-line with company expectations with total revenue at EUR 877 million
- Strong pipeline performance: Neupro® approved in the U.S.; Cimzia® filed in Japan, juvenile RA started, positive results for PsA and axSpA/AS, CDP7851 phase 3 initiated
- Financial outlook 2012 confirmed

Brussels (Belgium), 26 April 2012 – 07:00 (CEST) – regulated information - UCB announced today its interim report for the first three months of 2012.

"UCB is now particularly well-positioned for the future. For the first three months of 2012, we are enjoying strong growth of our core medicines, Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup>, which off-set generic erosion of Keppra<sup>®</sup>", said Roch Doliveux, CEO of UCB. We are pleased with our pipeline performance, which includes the Neupro<sup>®</sup> approval in the U.S., Cimzia<sup>®</sup> positive clinical results in phase 3 studies leading hopefully to regulatory approval of new indications to broaden patient access, and a new medicine having started phase 3 – the sclerostin antibody in postmenopausal osteoporosis."

Total revenue in the first three months of 2012 reached EUR 877 million (-2%) driven by the growth of Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup> which compensated, as expected, generic erosion of mature products, especially Keppra<sup>®</sup>.

Underlying profitability (recurring EBITDA) and net profit performance meet the company's expectations.

## Continued growth of core medicines

In the first three months of 2012, UCB's core medicines Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup> delivered growth reaching combined sales of EUR 200 million, +50% at actual exchange rates; +46% at constant rates compared with the first three months in 2011. Cimzia<sup>®</sup> (*certolizumab pegol*) for Crohn's disease (CD) and rheumatoid arthritis (RA), reached net sales of EUR 97 million (+45% at actual exchange rates; +41% at constant rates). Vimpat<sup>®</sup> (*lacosamide*) for adjunctive therapy of epilepsy grew by 67% (+62% at constant rates), with net sales of EUR 76 million. Neupro<sup>®</sup> (*rotigotine*), the patch for Parkinson's disease (PD) and restless legs syndrome (RLS) grew by 26% (+25% at constant rates) also driven by the study results showing results for the



multi-dimensions of PD. Net sales reached EUR 27 million. UCB brings Neupro® to patients in the U.S. in July 2012.

Net sales of the anti-epileptic drug Keppra<sup>®</sup> (*levetiracetam*) decreased by 17% (-19% at constant rates) during the first three months of 2012 to EUR 222 million. The generic erosion continues both in the U.S., especially due to generic versions to Keppra<sup>®</sup> XR since September 2011, and in Europe where it is accelerating. In other regions and in Japan especially, E Keppra<sup>®</sup> is showing double digit growth.

# Central nervous system (CNS) R&D update:

In April, Neupro<sup>®</sup> received U.S. regulatory approval. The room temperature stable patch is now approved for early and advanced Parkinson's disease (PD) as well as restless legs syndrome (RLS). Neupro<sup>®</sup> will be available for patients in the U.S. in July 2012.

In January, the Vimpat<sup>®</sup> open-label pilot Phase 2 study for adjunctive therapy in primary generalised tonic-clonic seizures (PGTCS) showed positive results. The compound will now move into Phase 3 development for PGTCS.

All other clinical development projects in epilepsy are also on track: brivaracetam for adjunctive therapy, Vimpat<sup>®</sup> for monotherapy in U.S. and Europe as well as paediatric adjunctive therapy and UCB0942.

## Immunology R&D update:

In January, UCB has filed certolizumab pegol for marketing authorisation with the Japanese Ministry of Health, Labour and Welfare (MHLW). UCB and Astellas Pharma Inc. have agreed to co-develop and co-promote certolizumab pegol in Japan. In February and April respectively, the Phase 3 trials for Cimzia<sup>®</sup> in psoriatic arthritis (PsA) and axial spondyloarthritis (AxSpA) including ankylosing spondylitis (AS) reported first positive results. Submission to regulatory authorities for these indications is planned by the end of 2012.

In March, for Cimzia<sup>®</sup> the Phase 3 program in juvenile rheumatoid arthritis has started as scheduled. First results are expected in the second half of 2014.

In April, the sclerostin antibody (CDP7851/AMG 785) Phase 3 clinical trial program started for the treatment of postmenopausal osteoporosis (PMO). The Phase 3 program includes a two-year study in more than 5,000 postmenopausal women with osteoporosis where the primary endpoint will evaluate the incidence of new vertebral fractures at 12 months. Initial results from the phase 3 program are expected by the end of 2015.

The other clinical development projects in immunology, namely Cimzia<sup>®</sup> "Exxelerate<sup>TM</sup>" and "C-Early<sup>TM</sup>", *epratuzumab* in systemic lupus erythematosus (SLE), CDP7851 in fracture healing, *olokizumab* in RA and CDP7657 in SLE are advancing as planned.

UCB News 2/3



### **Outlook 2012 confirmed**

UCB expects its financial results in 2012 to be driven by the continued growth of Cimzia<sup>®</sup>, Vimpat<sup>®</sup> and Neupro<sup>®</sup> as well as by post-exclusivity expiry erosion for Keppra<sup>®</sup>in the U.S. and Europe. Total revenue 2012 is anticipated at approximately EUR 3.1 billion. Recurring EBITDA is expected at approximately EUR 630-660 million. Core earnings per share of EUR 1.60-1.70 are expected– based on 176.4 million weighted average shares outstanding.

#### 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 8 500 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. UCB is listed on Euronext Brussels (symbol: UCB).

## 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 quarantees 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.

UCB News 3/3