



UCB
News

UCB Interim Report for the first nine months of 2013:

UCB reports solid growth of Cimzia[®], Vimpat[®] and Neupro[®], positive pipeline developments and confirms financial outlook

- Stable total revenue of €2.5bn; 'CVN' combined net sales of €847 million; +27%
- Continued growth in emerging markets¹ and Japan
- New approved indications for Cimzia[®]
- Vimpat[®] monotherapy indication (partial onset seizures) filed in the U.S.
- Financial outlook confirmed

Brussels, Belgium – 25 October 2013 - 7:00am – regulated information: UCB today announced its interim report for the first nine months of 2013.

"The first nine months of 2013 confirm the solid growth trends of our core medicines, Cimzia[®], Vimpat[®] and Neupro[®] as well as in emerging markets, while we continue to absorb the remaining post exclusivity impacts on Keppra[®]," said Roch Doliveux, CEO of UCB. "At the same time we are pleased with the regulatory approvals for Cimzia[®] for new indications, further broadening patient access in the U.S. and the EU. Additionally, as planned, we have recently filed Vimpat[®] for monotherapy in the U.S."

Total revenue in the first nine months of 2013 reached €2 499 million (-3%; +1% at constant exchange rates) driven by the double digit growth of Cimzia[®], Vimpat[®] and Neupro[®] reaching combined net sales of €847 million, (+27%; +31% at constant exchange rates), which offset the Keppra[®] decline of 18% to €532 million, and due to the continuous decline of the mature products as well as exchange rate effects.

€ million	9m 2013	9m 2012	Actual	Constant
Revenue	2 499	2 565	-3%	+1%
Net sales CVN	847	665	27%	31%
Cimzia[®]	423	334	27%	31%
Vimpat[®]	294	237	24%	27%
Neupro[®]	130	93	40%	41%
Keppra[®]	532	652	-18%	-16%

UCB confirms its financial outlook 2013, with total revenue 2013 anticipated at approximately €3.4 billion. Recurring EBITDA is expected at approximately €680-710 million. Core earnings per share of €1.90-2.05 are expected based on 179.3 million weighted average shares outstanding.

Cimzia[®] (certolizumab pegol) for Crohn's disease (CD) and rheumatoid arthritis (RA), continued its growth trend in the U.S. and Europe with a strong launch in Japan. Patient access has also been broadened to U.S. adult patients suffering from active psoriatic arthritis (PsA) or active ankylosing spondylitis (AS) and adult patients in the EU with severe active axial spondyloarthritis (axSpA).

€ million	9m 2013	9m 2012	Actual	Constant
North America	271	231	17%	21%
Europe	120	95	27%	28%
Japan	14	-	>100%	>100%
BRICMT¹	4	1	>100%	>100%
Rest of the World	14	8	86%	95%
Total Cimzia®	423	334	27%	31%

Vimpat® (lacosamide) for adjunctive therapy for epilepsy, showed consistent double digit growth in all regions where the medicine is available. UCB has filed Vimpat® in the U.S. as monotherapy treatment in adult epilepsy patients with partial-onset seizures.

€ million	9m 2013	9m 2012	Actual	Constant
North America	224	177	27%	30%
Europe	64	56	14%	14%
BRICMT¹	2	1	70%	70%
Rest of the World	4	3	20%	26%
Total Vimpat®	294	237	24%	27%

Neupro® (rotigotine), the patch for Parkinson's disease (PD) and restless legs syndrome (RLS), grew by a strong 40% driven by the successful launch in the U.S. and supported by the launch in Japan.

€ million	9m 2013	9m 2012	Actual	Constant
North America	28	6	>100%	>100%
Europe	94	84	12%	12%
Japan	5	-	>100%	>100%
BRICMT¹	1	1	78%	76%
Rest of the World	2	1	27%	29%
Total Neupro®	130	93	40%	41%

Net sales of the anti-epileptic drug Keppra® (levetiracetam) decreased as expected. The post exclusivity erosion continues in both affected regions, with the U.S. declining at single-digit rates and the EU at double-digit rates. In the emerging markets and Japan (at constant exchange rates), Keppra® is growing at double-digit growth rates.

€ million	9m 2013	9m 2012	Actual	Constant
North America	165	176	-6%	-4%
Europe	237	356	-33%	-33%
Japan	42	41	4%	30%
BRICMT¹	57	46	23%	25%
Rest of the World	31	33	-6%	-4%
Total Keppra®	532	652	-18%	-16%

Clinical pipeline update: central nervous system (CNS)

In February, Neupro® (rotigotine) was launched in Japan by Otsuka Pharmaceutical for early and advanced Parkinson's disease (PD) as well as restless legs syndrome (RLS).

In March, Vimpat® (lacosamide) generated positive results in the Phase 3 U.S. monotherapy study in patients with partial onset seizures. The data have been submitted to the U.S. Food & Drug Administration (FDA) as part of its supplemental New Drug Application (sNDA) and were accepted for filing early October. Vimpat® for adjunctive epilepsy in children has started the phase 3 in September 2013, first results are expected in 2017.

In May, UCB and Otsuka Pharmaceutical, received regulatory approval in Japan for E Keppra® (levetiracetam) as adjunctive therapy in the treatment of partial-onset seizures in pediatric patients with epilepsy, aged four years and older.

Clinical pipeline update: immunology

In February, UCB filed with FDA and with the European Medicines Agency (EMA) applications to extend the marketing authorization for Cimzia® (certolizumab pegol) for the treatment of adult patients with active psoriatic arthritis (PsA) and for adult patients with active axial spondyloarthritis (axSpA). In March, UCB and Astellas, its immunology partner in Japan, launched Cimzia® in the treatment of rheumatoid arthritis (RA).

In September, the European CHMP adopted a positive opinion for Cimzia® in adult patients with severe active axial spondyloarthritis (axSpA) comprising ankylosing spondylitis (AS) and axSpA without radiographic evidence of AS (nr-axSpA). In October, the European Commission granted the amended marketing authorization.

In September and October respectively, the FDA approved Cimzia® for the treatment of adult patients with psoriatic arthritis (PsA) and for the treatment of adults with active ankylosing spondylitis (AS). The FDA also issued a Complete Response Letter for the supplemental Biologics License Application of Cimzia® for the treatment of adults with active axial spondyloarthritis (axSpA).

In July, UCB entered into a world-wide exclusive license grant to R-Pharm, a privately owned pharmaceutical company based in Moscow, Russia, to develop and commercialize olokizumab in all indications, including rheumatoid arthritis.

For CDP7657, a CD40 ligand antibody under development in partnership with Biogen Idec, UCB started a phase 1b study in SLE. First results are expected in H2 2014.

A new compound entered the clinical development pipeline in phase 1: UCB5857, a selective and potent small molecule for the potential treatment of multiple immunological indications. First results are expected in Q2 2014.

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 9 000 people in approximately 40 countries, the company generated revenue of EUR 3.4 billion in 2012. 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 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.