UCB News

UCB HY-Year Report 2022, Brussels (Belgium), 28 July 2022 – 7:00 (CEST) – regulated information

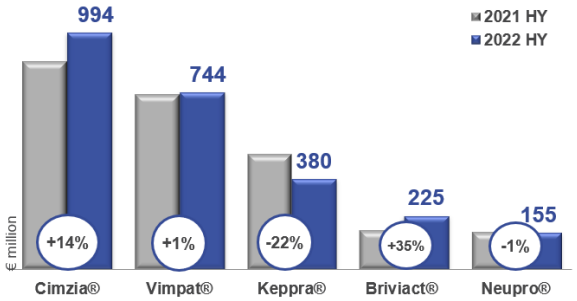
Strong first six months – UCB with continued delivery and strong resilience

- Revenue increased to € 2.93 billion (+5%; +3% CER[1]), net sales to € 2.70 billion (+2%; 0% CER) – impacted by generic erosion to Vimpat/U.S. and E Keppra/Japan
- Underlying profitability (adj. EBITDA[2]) was € 814 million (-3%; -2% CER), 28% of revenue – impacted by Zogenix inclusion since March
- Strong clinical pipeline: two additional phase 3 projects, development of rozanolixizumab in ITP de-prioritized
- Financial guidance for 2022* confirmed: Revenue expected in the range of € 5.3 - 5.4 billion, adjusted EBITDA[2] in the range 21 - 22 % of revenue, Core EPS[3] in the range of € 3.70 - 4.00

Jean-Christophe Tellier, CEO UCB says: "*We had a strong first half 2022, delivered good product growth and strong regional launches of BIMZELX®, which received great feedback from people living with psoriasis. As expected, we're seeing the impacts from the loss of exclusivity for E KEPPRA® in Japan and VIMPAT® in the U.S. We are confident to bring BIMZELX® to people living with psoriasis in the U.S. following our submission of the response to the complete response letter by the end of 2022. We are looking forward to our strong long-term growth ahead and our ability in creating value for all stakeholders, now and into the future - also driven by the new product launches currently under preparation serving people living with psoriasis, psoriatic arthritis, across the full spectrum of axial spondyloarthritis and generalized myasthenia gravis.*"

UCB's HY 2022 financial results & core product net sales

€ million	2022 HY	2021 HY	Act	CER
Revenue	2 925	2 778	5%	3%
Net sales	2 705	2 651	2%	0%
Adj. EBITDA	814	843	-3%	-2%
Number of shares (m)	190	189	0%	
Core EPS (€)	3.15	3.40	-7%	-4%



[1] CER = constant exchange rates
[2] adj. EBITDA = adjusted Earnings Before Interest, Taxes, Depreciation and Amortization charges
[3] Core EPS = core earnings per share
*As communicated on 24 June 2022

Inspired by **patients.**
Driven by **science.**

In the first six months 2022, **revenue** reached € 2 925 million (+5%; +3% CER[1]). **Net sales** went up by 2% to € 2 705 million (0% CER[1]), driven by the continued growth of UCB's product portfolio, namely CIMZIA® and BRIVIACT®, and by the addition of FINTEPLA®. Royalty income and fees increased from € 40 million to € 45 million. Other revenue benefitted from continued payments from R&D and licensing partners, including a one-time amount of € 70 million from sale of intellectual property rights, reaching € 175 million after € 87 million.

Underlying profitability (adjusted EBITDA[2]) reached € 814 million (-3%; -2% CER[1]) reflecting higher revenue and higher operating expenses driven by the Zogenix acquisition and the ongoing and coming launches – partly compensated by a strong increase in other operating income in connection with EVENITY® (romosozumab).

Profit decreased to € 399 million (-30%; -25% CER[1]) also due to the higher amortization charges and fees in connection with the Zogenix acquisition. **Core EPS[3]** were € 3.15 after € 3.40 in the first six months 2021.

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[3] Core EPS = core earnings per share

Regulatory and R&D update

BIMZELX® (bimekizumab) - In January and February 2022, BIMZELX® was approved in Japan and Canada respectively. In March 2022, BIMZELX® was approved in Australia.

In May 2022, UCB announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the Biologics License Application (BLA) for bimekizumab for the treatment of adults with moderate to severe plaque psoriasis. The letter indicates that the FDA could not approve the application in its current form and that certain pre-approval inspection observations of UCB's manufacturing site in Belgium must be resolved before approval of the application. The CRL is not related to efficacy nor to safety of bimekizumab. UCB is working with the U.S. FDA to address and resolve the pre-approval inspection observations and bring this potential treatment option for moderate to severe plaque psoriasis to patients in the U.S. UCB aims to submit the response to the bimekizumab CRL to the U.S. FDA by the end of 2022.

In March 2022, **FINTEPLA® (fenfluramine)** oral solution was approved in the U.S. for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients two years of age and older. Additionally, the U.S. FDA has granted pediatric exclusivity for the product. It is already approved for the treatment of seizures associated with Dravet syndrome in patients two years of age and older in the U.S., Europe and the UK.
Following the acquisition of Zogenix UCB decided to continue with the development of the Phase 3 with fenfluramine in CDKL5 deficiency disorder (CDD). The Phase 3 program evaluates efficacy and safety as an adjunctive therapy in patients 1 to 35 years of age with CDD and uncontrolled seizures. First topline results are expected in H2 2024. CDD is a rare developmental epileptic encephalopathy caused by mutations in the CDKL5 gene. In June 2022, the FDA granted orphan drug designation to FINTEPLA® to treat CDD.

Following the acquisition of Zogenix, UCB sees a high unmet medical need to continue with the development of **MT1621** (nucleoside therapy) in Thymidine Kinase 2 deficiency (TK2d). TK2d is an ultra-rare debilitating

and life-threatening (often fatal) genetic mitochondrial disorder and causes progressive and severe muscle weakness. Given the high unmet need, no approved therapies, and MT1621 considered to change the disease trajectory, UCB has an opportunity to create pivotal patient value. The clinical development program is complete. UCB is currently engaged in discussions with regulatory agencies to validate the global submission strategy. The target submission projections are aimed for 2023.

Rozanolixizumab - UCB decided to de-prioritize the development of rozanolixizumab in immune thrombocytopenia (ITP). Since UCB took the decision to progress the rozanolixizumab ITP development program to Phase 3 in 2019, the treatment landscape for people living with ITP has significantly evolved. New targeted therapies, offering multiple opportunities to transform the care and management of ITP, are now available or in late-stage development. This evolution looks set to address many of the significant unmet needs faced by the ITP patient community. Taking these factors into account, UCB will not progress with the rozanolixizumab ITP development program. This allows UCB to reallocate resources to areas with higher unmet medical needs. All other rozanolixizumab programs continue as planned.

All other clinical development programs are continuing as planned. In 2022, the timelines for UCB's clinical development program have not experienced any material delays due to COVID-19. UCB continues to monitor the impact of COVID-19 on all ongoing clinical trials and will implement changes as necessary.

Net sales break-down by product

Due to rounding, some financial data may not add up in the tables.

€ million	2022 HY	2021 HY	Act	CER
U.S.	644	553	16%	5%
Europe	209	208	1%	0%
International markets	141	112	26%	24%
Total Cimzia®	994	873	14%	7%

CIMZIA® (certolizumab pegol), for people living with inflammatory TNF-mediated diseases, went up by 14% (+7% CER), outperforming the anti-TNF market based on strong differentiation and driven by continued growth in all markets, namely in the U.S. and strong growth in international markets, reaching more patients.

€ million	2022 HY	2021 HY	Act	CER
U.S.	520	534	-3%	-12%
Europe	155	141	10%	10%
International markets	68	60	14%	11%
Total Vimpat®	744	735	1%	-6%

VIMPAT® (lacosamide) for people living with epilepsy showed net sales of € 744 million. After strong growth in the U.S. in the beginning of the year, the expected generic erosion in the U.S. since end of March impacted the performance in the U.S., compensated by continued good growth in Europe and international markets.

€ million	2022 HY	2021 HY	Act	CER
U.S.	71	84	-15%	-23%
Europe	105	110	-4%	-5%
International markets	204	291	-30%	-30%
Total Keppra®	380	485	-22%	-23%

KEPPRA® (levetiracetam) available for people living with epilepsy reported 22% lower net sales. The generic erosion in Japan started early January this year and was stronger than expected due to multiple generics and governmental support for generic levetiracetam.

€ million	2022 HY	2021 HY	Act	CER
U.S.	174	124	40%	27%
Europe	43	38	14%	13%
International markets	8	5	53%	42%
Total Briviact®	225	166	35%	25%

BRIVIACT® (brivaracetam), used by people living with epilepsy showed continued, significant growth in all regions Briviact® is available to patients. Briviact® has a different mode of action from Vimpat® and differentiates from Keppra®.

€ million	2022 HY	2021 HY	Act	CER
U.S.	46	48	-4%	-13%
Europe	83	82	0%	0%
International markets	27	28	-2%	-4%
Total Neupro®	155	158	-1%	-5%

NEUPRO® (rotigotine), the patch for Parkinson's disease and restless legs syndrome, recorded declining net sales in the U.S. and international markets, namely Japan, and stable net sales in Europe – in a competitive market environment.

NAYZILAM® (midazolam) Nasal SprayCIV, a nasal rescue treatment for epilepsy seizure clusters in the U.S. (launched since December 2019) reached net sales of € 36 million after € 21 million.

FINTEPLA® (fenfluramine) is now part of the UCB epilepsy portfolio thanks to the completed acquisition of Zogenix, Inc. in early March. FINTEPLA® is approved for seizures associated with rare epileptic syndromes, Dravet (since mid-2020) and Lennox-Gastaut syndrome (since late March 2022), providing new treatment options for patients and families living with these rare syndromes that are particularly challenging to treat. Net sales (March - June) were € 35 million. The integration of Zogenix is ongoing and expected to be completed as planned by the end of 2022.

BIMZELX® (bimekizumab) for people living with psoriasis is being launched in Europe and the UK since autumn last year and in Japan and Canada most recently this year. Reported net sales were € 10 million after € 4 million in the second half 2021.

For the U.S., UCB received a complete response letter (CRL) from the U.S. Food and Drug Administration (FDA). The letter indicates that the FDA cannot approve the application in its current form. The CRL states that certain pre-approval inspection observations must be resolved before approval of the application. UCB will

address all observations and questions noted in the CRL and is fully confident in the quality of its manufacturing process. UCB aims to submit the response to the CRL to the FDA by the end of 2022.

EVENITY® (romosozumab) for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture is being successfully launched in Europe since March 2020 and reported net sales of € 9 million. EVENITY® is being launched successfully globally by Amgen, Astellas and UCB since 2019, with net sales outside Europe reported by the partners.

2022 HY financial highlights

Due to rounding, some financial data may not add up in the tables.
For the net financial debt, the reporting date for comparative period is 31 December 2021

For the six months ended 30 June	ACTUAL		VARIANCE	
€ million	2022	2021	ACTUAL RATES	CER
Revenue	**2 925**	**2 778**	**5%**	**3%**
Net sales	2 705	2 651	2%	0%
Royalty income and fees	45	40	12%	1%
Other revenue	175	87	>100%	97%
Gross Profit	**2 080**	**2 089**	**0%**	**-2%**
Adjusted Gross Profit	**2 250**	**2 167**	**4%**	**2%**
Marketing and selling expenses	- 730	- 606	21%	14%
Research and development expenses	- 798	- 753	6%	3%
General and administrative expenses	- 115	- 98	18%	15%
Other operating income/expenses (-)	114	50	>100%	>100%
Adjusted EBIT	**551**	**682**	**-19%**	**-16%**
Restructuring, Impairment and Other income/expenses (-)	- 61	- 4	>100%	>100%
EBIT (operating profit)	**490**	**678**	**-28%**	**-24%**
Net financial expenses (-)	- 9	- 35	-74%	-75%
Share of profit/ loss (-) of associates	0	0	N/A	N/A
Profit before income taxes	**481**	**643**	**-25%**	**-21%**
Income tax expense (-)	- 82	- 76	7%	3%
Profit from continuing operations	**399**	**567**	**-30%**	**-25%**
Profit/loss (-) from discontinued operations	0	4	-99%	-99%
Profit	**399**	**571**	**-30%**	**-25%**
Attributable to UCB shareholders	399	571	-30%	-25%
Attributable to non-controlling interests	0	0	N/A	N/A
Adjusted EBITDA	**814**	**843**	**-3%**	**-2%**
Capital expenditure (including intangible assets)	174	187	-7%	N/A
Net financial cash / debt (-)	-2 502	- 860	>100%	N/A
Operating cash flow from continuing operations	393	484	-19%	N/A
Weighted average number of shares – non diluted (million)	**190**	**189**	**0%**	**N/A**
EPS (€ per weighted average number of shares – non diluted)	**2.10**	**3.02**	**-30%**	**-32%**
Core EPS (€ per weighted average number of shares – non diluted)	**3.15**	**3.40**	**-7%**	**-4%**

The statutory auditor has issued an unqualified review report dated 27 July 2022 on the company's condensed consolidated interim financial statements as of and for the six-month period ended 30 June 2022, and has confirmed that the accounting data reported in the press release is consistent, in all material respects, with the accounts from which it has been derived.

Revenue in the first six months 2022 went up by 5% (+3% CER[1]) to € 2 925 million and **net sales** reached € 2 705 million (+2%; 0% CER[1]). This was driven by the continued growth of UCB's product portfolio, namely CIMZIA® and BRIVIACT®, BIMZELX® being launched now in Europe, the UK, Japan and Canada and by the addition of FINTEPLA® following the acquisition of Zogenix.

Royalty income and fees were € 45 million (+12%; 1% CER[1]). Other revenue reached € 175 million (+> 100%; +97% CER[1]) due to milestones and other payments from R&D partners and include a one-time amount of € 70 million from sale of intellectual property rights (olokizumab).

Gross profit was stable with € 2 080 million (0%; -2% CER[1]). The cost of sales for products and services increased by the write-off of some commercial bimekizumab inventory after not being able to launch in the U.S. market. The gross margin was 71% after 75% - impacted by the addition of FINTEPLA® amortization. If adjusted for "amortization of intangible assets linked to sales", the adjusted gross margin is 77% after 78% in the first six months of 2021.

Operating expenses increased to € 1 529 million (+9%; +5% CER[1]) reflecting:

- 21% higher marketing and selling expenses of € 730 million – driven by launches and pre-launch activities: FINTEPLA® launch activities, BIMZELX® global launch activities and preparations, EVENITY® ongoing launch activities and global launch preparations for generalized myasthenia gravis.
- 6% higher research and development expenses of € 798 million reflecting the investments in UCB's progressing pipeline encompassing six late-stage assets and ongoing earlier stage research. The strategic decision to terminate the development in ITP lead to termination costs of € 29 million. The R&D ratio remained stable at 27% in the first six months of 2022,
- 18% higher general and administrative expenses of € 115 million, due to implementation expenses for improved value-focused allocation of resources and the integration of Zogenix,
- significantly higher other operating income of € 114 million after € 50 million in the first half 2021 - driven by an income of € 108 million (+96%) reflecting the net contribution from Amgen in connection with the commercialization of EVENITY®.

Underlying operational profitability – adjusted EBITDA[2] – reached € 814 million (-3%; -2% CER[1]) reflecting higher revenue and higher operating expenses driven by the impacts from the Zogenix acquisition and the ongoing and coming launches. Partly compensated by the strong increase in other operating income in connection with EVENITY®. The adjusted EBITDA ratio (in % of revenue) reached 28%, after 30% in the first six months of 2021.

Total impairment, restructuring and other income/expenses were expenses of € 61 million. This was mainly due to fees related to the acquisition of Zogenix, Inc. and restructuring expenses. In the first six months 2021, the pre-tax expenses were € 4 million and included mainly restructuring expenses offset with the unwinding of cumulative currency translation adjustments.

Net financial expenses went down to € 9 million from € 35 million, mainly due to a one-time positive currency impact of € 25 million

Income tax expenses were € 82 million, after € 76 million. The average effective tax rate was 17% compared to 12% in the first six months 2021. This is driven by the continued and sustainable use of R&D incentives in line with UCB's business activities overcompensated by the inability to launch bimekizumab in the U.S. in 2022.

Profit amounted to € 399 million (-30%; -25% CER[1]) also due to the higher amortization charges and fees in connection with the Zogenix acquisition. The full amount is attributable to UCB shareholders as the contributions to non-controlling interests have expired at the end of 2020. **Core EPS[3]** were € 3.15 after € 3.40 in the first six months 2021.

Core earnings per share, which reflect profit attributable to UCB shareholders, adjusted for the after-tax impact of to be adjusted items and the net amortization of intangibles linked to sales, reached € 3.15 based on 190 million weighted average shares outstanding after € 3.40 based on 189 million in the first six months 2021. In the first six months of 2022, mainly amortization of intangible assets linked to sales and expenses in connection with the acquisition of Zogenix, Inc. needed to be adjusted.

UCB updated its **financial guidance 2022** on 24 June 2022, which is confirmed:
UCB is aiming for revenues in the range of €5.30 - 5.40 billion based on continued core product growth and taking into account impacts from the loss of exclusivity for VIMPAT® in the U.S. (since March) and Europe (from September) and the strong generic competition to E KEPPRA® in Japan since January.

UCB continues to invest in research and development to advance its late-stage development pipeline and prepare for upcoming launches to offer potential new solutions for patients. Underlying profitability, adjusted EBITDA, is now expected in the range of 21 - 22% of revenue, also reflecting the continued research and development and marketing & selling investment levels. Core earnings per share are therefore expected in the range of €3.70 - 4.00 per share – based on an average of 189 million shares outstanding.

The figures for the updated financial guidance 2022 as mentioned above are calculated on the same basis as the actual figures for 2021; they have been extended by the consolidation of the acquisition of Zogenix, Inc.

Supported by solid multiple scenario planning and sustainable efficiency generating initiatives in all areas of UCB - being introduced since Q4 2021 - **UCB maintains its financial guidance for 2025.** Revenue in 2025 is expected to reach at least € 6 billion and the underlying profitability (adjusted EBITDA) should reach the low to mid-thirties in percent of revenue.

Based on UCB's current assessment of the Covid-19 pandemic and other macroeconomic factors, UCB remains confident in the fundamental underlying demand for its products in the short-term and its prospects for long-term growth. UCB will continue to closely follow the evolving COVID-19 pandemic and other macroeconomic factors and its consequences to the business environment diligently to assess potential near- and mid-term challenges.

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Find the financial reports on UCB website: http://www.ucb.com/investors/Download-center

Today, UCB will host a conference call/video webcast at 08.00 (EDT) / 13.00 (BST) / 14.00 (CEST)

Details are available on https://www.ucb.com/investors/UCB-financials/Half-year-financial-results

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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 approximately 8 600 people in approximately 40 countries, the company generated revenue of € 5.8 billion in 2021. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements
This press release contains forward-looking statements including, without limitation, statements containing the words "believes", "anticipates", "expects", "intends", "plans", "seeks", "estimates", "may", "will", "continue" and similar expressions. These forward-looking statements are based on current plans, estimates and beliefs of management. All statements, other than statements of historical facts, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, arbitration, political, regulatory or clinical results or practices and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions which might cause the actual results, financial condition, performance or achievements of UCB, or industry results, to differ materially from those that may be expressed or implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: the global spread and impact of COVID-19, changes in general economic, business and competitive conditions, the inability to obtain necessary regulatory approvals or to obtain them on acceptable terms or within expected timing, 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, safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars, 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. There is no guarantee that new product candidates will be discovered or identified in the pipeline, or that new indications for existing products will be developed and approved. Movement from concept to commercial product is uncertain; preclinical results do not guarantee safety and efficacy of product candidates in humans. So far, the complexity of the human body cannot be reproduced in computer models, cell culture systems or animal models. The length of the timing to complete clinical trials and to get regulatory approval for product marketing has varied in the past and UCB expects similar unpredictability going forward. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to disputes between the partners or may prove to be not as safe, effective or commercially successful as UCB may have believed at the start of such partnership. UCB' efforts to acquire other products or companies and to integrate the operations of such acquired companies may not be as successful as UCB may have believed at the moment of acquisition. Also, UCB or others could discover safety, side effects or manufacturing problems with its products and/or devices after they are marketed. The discovery of significant problems with a product similar to one of UCB's products that implicate an entire class of products may have a material adverse effect on sales of the entire class of affected products. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment, including pricing pressure, political and public scrutiny, customer and prescriber patterns or practices, and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement activities and outcomes. Finally, a breakdown, cyberattack or information security breach could compromise the confidentiality, integrity and availability of UCB's data and systems.
Given these uncertainties, you should not place undue reliance on any of such forward-looking statements. There can be no guarantee that the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labelling in

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