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**Neupro®** 

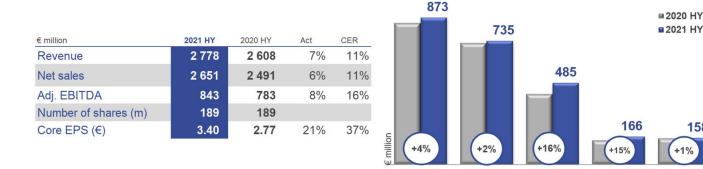
UCB Half Year Report 2021, Brussels (Belgium), 29 July 2021 - 7:00 (CEST) - regulated information -

# First half 2021 with sustainable performance – delivering on UCB's strategy and guidance

- Revenue increased to € 2.8 billion (+7%; +11% CER¹) net sales to € 2 651 million (+6%; +11% CER)
- Underlying profitability (adj. EBITDA<sup>2</sup>) was € 843 million (+8%; +16% CER) or 30% of revenue
- All clinical development programs on track with 6 phase 3 studies to read out as planned
- R&D update: bimekizumab with positive CHMP opinion for psoriasis and phase 3 read-out for hidradenitis suppurativa (HS) moved to 2022; two new study starts for rozanolixizumab and a phase 2 started with bepranemab in Alzheimer's Disease
- Financial guidance for 2021 unchanged: Revenue expected to reach € 5.45 5.65 billion. adjusted EBITDA<sup>2</sup> 27 - 28% of revenue, Core EPS<sup>3</sup> of € 5.60 - 6.10

Jean-Christophe Tellier, CEO UCB commented: "We are very satisfied with the ongoing performance of UCB – we are delivering on our ambitious targets and strategy. We are thankful to our employees and partners for their agility managing the new and changing environment. The coming months will be marked by the expected launch of bimekizumab for people living with psoriasis backed by three superiority studies as well as in total six phase 3 study read-outs from our late-stage pipeline. Our progress on sustainability, namely in quality and risk, is recognized by top rankings like ISS ESG, MSCI and Sustainalytics. We are very confident in our late stage pipeline, our ability to lead in five patient populations in 2025 and to deliver on our short- and long-term guidance."

## UCB's HY 2021 financial results & Core product net sales:



HY 2021 revenue reached € 2.8 billion (+7%; +11% CER). Net sales went up by 6% to € 2 651million (+11% CER), driven by the sustainable growth of UCB's key products.

Cimzia®

Vimpat®

**Keppra®** 

**Briviact®** 

Underlying profitability (adjusted EBITDA<sup>2</sup>) reached € 843 million (+8%; +16% CER) integrating high investments into the future of UCB, namely product launches and product development.

Driven by lower other expenses, profit increased to € 571 million (+47%; +60% CER) of which the full amount is attributable to UCB shareholders. Core EPS³ were € 3.40 after € 2.77 in HY 2020.

<sup>&</sup>lt;sup>1</sup> CER = constant exchange rates

<sup>&</sup>lt;sup>2</sup> adj. EBITDA = adjusted Earnings Before Interest, Taxes, Depreciation and Amortization charges.

<sup>&</sup>lt;sup>3</sup> Core EPS = core earnings per share



## Regulatory and R&D update

**Bimekizumab** - In June, the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion recommending granting a marketing authorization for *bimekizumab*, for the treatment of **moderate to severe plaque psoriasis** in adults. The European Commission is expected to deliver its decision on the marketing authorization of *bimekizumab*, under the trade name Bimzelx<sup>®</sup>, by end of summer 2021. Regulatory reviews are also underway in the U.S., the UK, Japan, Australia and Canada. Subject to respective approvals, UCB will bring *bimekizumab* to patients starting in the second half 2021.

**Bimekizumab** - The ongoing Phase 3 program in moderate to severe hidradenitis suppurativa (HS), a chronic, inflammatory, and debilitating follicular skin disease, showed accelerated patient recruitment, hence the first headline results are now expected before the end of 2022. First headline results from the phase 3 studies for the treatment of psoriatic arthritis, ankylosing spondylitis and non-radiographic axial spondyloarthritis are expected as planned in Q4 2021.

**Rozanolixizumab** - first headline results from the phase 3 study for the treatment of myasthenia gravis are expected as planned in Q1 2022.

Maintaining UCB's focus on autoantibody-mediated neuroinflammation, UCB is investigating two additional patient populations:

- (i) people living with autoimmune encephalitis (AIE) a rare and serious medical condition, in which the immune system attacks the brain leading to epileptic seizures, movement disorders as well as cognitive decline in some patients. There is no therapy approved for AIE. The phase 2a study in AIE starts in Q3 2021; first topline results are expected in H1 2024.
- (ii) people living with myelin oligodendrocyte glycoprotein (MOG)-antibody disease a rare autoimmune inflammatory demyelinating disorder of the central nervous system caused by autoantibodies that target the MOG protein leading to temporal functional blindness, muscle weakness, bladder dysfunction, sensory loss, and/or pain. There is no approved therapy for MOG-antibody disease. The Phase 3 study will start in Q4 2021.

UCB decided to prioritize these autoantibody mediated neuroinflammatory indications over chronic inflammatory demyelinating polyneuropathy (CIDP) representing a heterogenous and complex patient population, with approximately only 30% of patients having detectable autoantibodies. Following this strategic decision, results of the phase 2a study in CIDP will be presented during an upcoming scientific meeting.

**Zilucoplan** - first headline results from the phase 3 study for the treatment of myasthenia gravis are expected as planned in Q4 2021.

Zilucoplan was tested in a proof of concept (phase 2a) study in immune-mediated necrotizing myopathy (IMNM): The results of this study indicate that complement activation is not relevant in the disease biology of IMNM. UCB decided to not move forward with its IMNM development program. The results in IMNM do not affect UCB's confidence in zilucoplan for other indications with complement activation as a key disease mechanism.

**Bepranemab** (**UCB0107**) - in Q2 2021 a Phase 2 study started investigating the efficacy and safety of *bepranemab* in patients with early Alzheimer's disease in partnership with Roche/Genentech. First headline results are expected in H1 2025.





**UCB0599** - is a small molecule that prevents the pathological misfolding and accumulation of alphasynuclein, a protein which plays a key role in Parkinson's disease (PD) pathology. Inhibition of alphasynuclein misfolding has the potential to slow down the progression of PD. UCB0599 belongs to a series of molecules discovered by Neuropore, which were in-licensed by UCB in 2014. In April, a phase 2a study started with UCB0599 for study participants with early-stage PD. First headline results are expected in H2 2023.

**All other clinical development programs are continuing as planned.** In the first six months of 2021, 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 core product<sup>4</sup>

€ million	2021 HY	2020 HY	Act	CER
U.S.	553	533	4%	14%
Europe	208	210	-1%	-1%
International markets	112	99	13%	23%
Total Cimzia®	873	842	4%	11%

Cimzia® (certolizumab pegol) for people living with autoimmune and inflammatory TNF mediated diseases, outperformed the anti-TNF market and was driven by continued growth in the U.S. and strong growth in international markets, reaching more patients.

€ million	2021 HY	2020 HY	Act	CER
U.S.	534	534	0%	9%
Europe	141	127	11%	11%
International markets	60	61	-1%	6%
Total Vimpat <sup>®</sup>	735	722	2%	9%

Vimpat® (*lacosamide*), continues to reach more and more people living with epilepsy, reflected in strong growth at CER in all regions. International markets were impacted by order patterns for Japan.

€ million	2021 HY	2020 HY	Act	CER
U.S.	84	98	-15%	-7%
Europe	110	115	-4%	-4%
International markets	291	206	41%	53%
Total Keppra®	485	419	16%	23%

**Keppra®** (*levetiracetam*) for patients living with epilepsy. The continued generic erosion in the U.S. and Europe has been overcompensated by the performance in Japan. UCB took over distribution of E Keppra® from partner Otsuka in October 2020 and now books the in-market net sales. Generic entries to the Japanese market are expected in Q4 2021.

€ million	2021 HY	2020 HY	Act	CER
U.S.	124	111	11%	22%
Europe	38	29	29%	29%
International markets	5	4	32%	35%
Total Briviact®	166	144	15%	24%

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

€ million	2021 HY	2020 HY	Act	CER
U.S.	48	48	0%	9%
Europe	82	84	-2%	-2%
International markets	28	24	15%	23%
Total Neupro®	158	156	1%	5%

**Neupro®** (*rotigotine*), the patch for Parkinson's disease, with good growth in the U.S. at CER in a competitive market environment and strong growth in international markets including Japan.

**Nayzilam**® (*midazolam*) **Nasal Spray**<sup>CIV</sup>, a nasal rescue treatment for epilepsy seizure clusters in the U.S. was successfully launched during 2020, despite the pandemic, and reached net sales of € 21 million in the first six months 2021 after € 11 million in HY 2020.

**Evenity**<sup>®</sup> (*romosozumab*) for the treatment of severe osteoporosis in postmenopausal women at high risk of fracture, had its first European launch in March 2020, and reported net sales of € 4 million in the first six months 2021 (after € 1 million in HY 2020) - impacted by the pandemic which significantly impedes outreach to new patient populations. Evenity<sup>®</sup> is being launched successfully globally by Amgen, Astellas and UCB since 2019, with net sales outside Europe reported by the partners.

<sup>&</sup>lt;sup>4</sup> Due to rounding, some financial data may not add up in the tables.





# 2021 HY financial highlights<sup>5</sup>

For the six months ended 30 June <sup>1</sup>	Actual 2020		Variance	
€ million			Actual rates	CER
Revenue	2 778	2 608	7%	11%
Net sales	2 651	2 491	6%	11%
Royalty income and fees	40	38	7%	17%
Other revenue	87	79	9%	12%
Gross profit	2 089	1 925	9%	14%
Marketing and selling expenses	-606	-569	7%	13%
Research and development expenses	-753	-689	9%	12%
General and administrative expenses	-98	-94	4%	5%
Other operating income / expenses (-)	50	41	21%	33%
Adjusted EBIT	682	614	11%	21%
Restructuring, impairment and other income / expenses (-)	-4	-95	n.a.	n.a.
EBIT (operating profit)	678	519	31%	42%
Net financial expenses (-)	-35	-61	-44%	-43%
Profit before income taxes	643	458	41%	54%
Income tax expense (-)	-76	-70	10%	22%
Profit from continuing operations	567	388	46%	59%
Profit/loss (-) from discontinued operations	4	0	n.a.	n.a.
Profit	571	388	47%	60%
Attributable to UCB shareholders	571	363	58%	71%
Attributable to non-controlling interests	-	25	n.a.	n.a.
Adjusted EBITDA	843	783	8%	16%
Capital expenditure (including intangible assets)	187	102	83%	n.a.
Net financial debt <sup>6</sup>	-1 515	-1411	7%	n.a.
Operating cash flow from continuing operations	484	377	28%	n.a.
Weighted average number of shares - non-diluted (million)	189	189	0%	n.a.
EPS (€ per weighted average number of shares - non diluted)	3.02	1.92	58%	+76%
Core EPS (€ per weighted average number of shares - non diluted)	3.40	2.77	21%	37%

"The statutory auditor has issued an unqualified review report dated 28 July 2021 on the company's condensed consolidated interim financial statements as of and for the six month period ended 30 June 2021, 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 2021 increased by 7% (+11% CER) to € 2 778 million and net sales increased by 6% (+11% CER) to € 2 651 million. Net sales before "designated hedging reclassified to net sales" were € 2 611 million with a plus of 4% (+11% CER). This growth was driven by the resilient UCB product portfolio – despite the pandemic. The change of distribution model for E-Keppra<sup>®</sup> in Japan supported the net sales growth. Adjusted for this impact, net sales would have increased by +7% CER.

<sup>&</sup>lt;sup>6</sup> For the net financial debt, the reporting date for comparative period is 31 December 2020.



<sup>&</sup>lt;sup>5</sup> Due to rounding, some financial data may not add up in the tables.



Royalty income and fees were € 40 million, plus 7% and other revenue went up by 9% to € 87 million due to milestones and other payments from R&D partners.

**Gross profit** reached € 2 089 million, with a plus of 9% (+14% CER) and reflecting an improved gross margin of 75% compared to the first six months 2020 with 74%.

Operating expenses increased to € 1 407 million (+7%; +11% CER) reflecting

- 7% higher marketing and selling expenses of € 606 million driven by the ongoing launches of Cimzia<sup>®</sup> (new indication and regional expansion), Nayzilam<sup>®</sup>, and Evenity<sup>®</sup> and especially launch preparations for *bimekizumab* for people living with psoriasis, *zilucoplan* and *rozanolixizumab* in myasthenia gravis
- 9% higher research and development expenses of € 753 million reflecting the investments in UCB's progressing pipeline encompassing five late-stage assets which all are on track. This includes activities to ensure patient safety and recruitment managing the effects of the pandemic. The R&D ratio reached 27% in the first six months of 2020 after 26% in the first six months 2020.
- 4% higher general and administrative expenses of € 98 million, reflecting a similarly low-cost level like in the first six months 2020 due to the COVID-19 pandemic.
- operating income of € 50 million after € 41 million in 2020 driven by an income of € 55 million in connection with the commercialization of Evenity® in collaboration with Amgen, partly compensated by other operating expenses.

Underlying operational profitability – adjusted EBITDA<sup>7</sup> – went up to € 843 million (+8%; +16% CER) driven by continued revenue growth and higher operating expenses, reflecting the investments into the future of UCB, namely into product launches and clinical development. The adjusted EBITDA ratio for the first six months 2021 (in % of revenue) was stable at 30% compared to the first six months of 2020.

**Total impairment, restructuring and other income/expenses** were expenses of € 4 million. In the first six months 2020, the expenses were € 95 million and included fees related to the acquisitions of Ra Pharma and Engage Therapeutics as well as restructuring expenses, partially offset with income resulting from gain on the divestiture of non-core products.

**Net financial expenses** went down to € 35 million from € 61 million, mainly due to lower hedging costs and lower interest expenses.

**Income tax expenses** were € 76 million compared to € 70 million in June 2020. The average effective tax rate was 12% compared to 15% in June 2020, supported by R&D related incentives in key jurisdictions.

**Profit** amounted to € 571 million, of which the full amount is attributable to UCB shareholders as the contributions to non-controlling interests have expired end 2020. Driven by strong revenue and EBITDA growth as well as significantly lower restructuring expenses, lower financial expenses and taxes. For the first six months of 2020, profit was € 388 million of which € 363 million were attributable to UCB shareholders and € 25 million to non-controlling interests.

<sup>7</sup> adj. EBITDA = adjusted Earnings Before Interest, Taxes, Depreciation and Amortization charges.



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**Core earnings per share**, which reflect profit attributable to UCB shareholders, adjusted for the after-tax impact of to be adjusted items, the financial one-offs, the after-tax contribution from discontinued operations and the net amortization of intangibles linked to sales, reached € 3.40 after € 2.77 based on stable 189 million weighted average shares outstanding.

**Guidance 2021 unchanged:** For 2021, UCB is aiming for revenues in the range of € 5.45 - 5.65 billion thanks to the current core product growth and new patient populations being served, based on current assessment of the ongoing pandemic. UCB will continue to advance its late-stage development pipeline and prepare upcoming launches to offer potential novel solutions for patients.

Underlying profitability, adjusted EBITDA, is expected in the range of 27 - 28% of revenue, reflecting high R&D and marketing & sales investment levels. Core earnings per share are therefore expected in the range of € 5.60 - 6.10 based on an average of 189 million shares outstanding. The figures for the guidance 2021 as mentioned are calculated on the same basis as the actual figures for 2020.

**Guidance for 2025 unchanged:** UCB shares its growth ambition for 2025 - despite upcoming patent expirations: Based on the strong product portfolio and the promising late-stage pipeline assets, UCB aims to lead in specific populations by 2025, creating value for patients now and into the future. Revenue in 2025 are expected to reach at least € 6 billion and the underlying profitability (adjusted EBITDA) should reach the low to mid-thirties in percent of revenue.

Guidance 2021 & 2025: Based on UCB's current assessment of the Covid-19 pandemic, 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 evolving COVID-19 pandemic and its consequences to the business environment diligently to assess potential near- and mid-term challenges.

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 (EST) / 13.00 (BST) / 14.00 (CET).

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 more than 7 600 people in approximately 40 countries, the company generated revenue of € 5.3 billion in 2020. 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 any market, or at any particular time, nor can there be any guarantee that such products will be or will continue to be commercially successful in the future.

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