UCB News

UCB Full-Year Report 2021, Brussels (Belgium), 24 February 2022 – 7:00 (CET) – regulated information

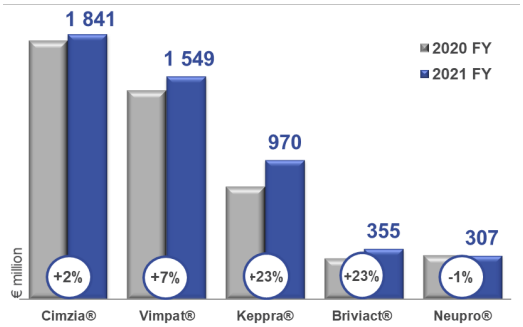
2021 – Delivering on UCB's Strategy and Commitments

- Unprecedented string of 6 positive Phase 3 study results: bimekizumab in psoriatic arthritis and across the full spectrum of axial spondyloarthritis (axSpA); both, rozanolixizumab and zilucoplan in generalized myasthenia gravis (gMG)
- Revenue increased to € 5.78 billion (+8%; +10% CER[1]), net sales to € 5.47 billion (+8%; +11% CER)
- Underlying profitability (adj. EBITDA[2]) was € 1.64 billion (+14%; +21% CER), 28% of revenue
- Financial guidance for 2022: Revenue expected to reach € 5.15 - 5.4 billion, adjusted EBITDA[2] 26 - 27% of revenue, Core EPS[3] of € 4.80 - 5.30

Jean-Christophe Tellier, CEO UCB says: "*We are very satisfied with the continued performance of UCB – we reached more than 3.7 million patients. We are entering a transition phase, to be followed by accelerated company growth, from a position of strength – also underlined by six very positive Phase 3 study read-outs from our late-stage pipeline. We thank our employees and partners for their great contributions. The coming months will be marked by expected impacts from the loss of exclusivity for E KEPPRA® in Japan since January, for VIMPAT® in the U.S. in March and the EU in September. We are confident to bring BIMZELX® to people living with psoriasis in the U.S. based on a regulatory decision expected within the first half this year. We continue to make progress towards our extra-financial targets, also recognized by key ESG ratings. We are very confident in our strong growth ahead and our ability in creating value for all stakeholders – now and into the future.*"

UCB's FY 2021 financial results & Core product net sales

€ million	2021 FY	2020 FY	Act	CER[1]
Revenue	5 777	5 347	8%	10%
Net sales	5 471	5 052	8%	11%
Adj. EBITDA[2]	1 641	1 441	14%	21%
Number of shares (m)	189	189	0%	
Core EPS[3] (€)	6.49	5.36	21%	26%
Dividend per share (€)	1.30	1.27	2%	



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

Inspired by patients.
Driven by science.

FY 2021 revenue reached € 5.78 billion (+8%; +10% CER[1]). **Net sales** went up by 8% to € 5.47 billion (+11% CER[1]), driven by the continued growth of UCB's product portfolio.

Underlying profitability (adjusted EBITDA[2]) reached € 1.64 billion (+14%; +21% CER[1]) reflecting higher revenue, higher marketing and selling – due to upcoming launches – slightly higher research and development expenses and a strong increase in other operating income due to Evenity® (romosozumab).

Profit increased to € 1 058 million (+39%; +51% CER[1]). **Core EPS[3]** were € 6.49 after € 5.36 in 2020. The Board of Directors of UCB proposes a dividend of € 1.30 per share (gross), +2%.

Regulatory and R&D update

BIMZELX® (bimekizumab) - In August 2021, BIMZELX® (bimekizumab) was approved in the European Union for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. In August, BIMZELX® also received its marketing authorization in Great Britain.

On October 15, 2021, the U.S. Food and Drug Administration (FDA) deferred the Prescription Drug User Fee Act (PDUFA) date for bimekizumab. The FDA indicated that they were unable to finish the current review cycle due to COVID-19-related restrictions on travel. UCB is expecting an FDA decision in the first half of 2022.

In January and February 2022, BIMZELX® was approved in Japan and Canada respectively.

In an unprecedented string of events, UCB announced positive topline results of four Phase 3 readouts towards the end of 2021 and early 2022. The safety profile of bimekizumab in all four studies was consistent with safety findings seen in previous studies with no new observed safety signals:

- Two positive study results for bimekizumab in psoriatic arthritis (biologic disease-modifying anti-rheumatic drug-naïve patients and patients with inadequate response or intolerant to anti-TNF treatment). Both studies in the treatment of adults with active psoriatic arthritis met the primary and all ranked secondary endpoints with statistically significant and clinically meaningful results.
- Positive results of two Phase 3 studies evaluating bimekizumab across the full spectrum of axial spondyloarthritis (axSpA), which includes both radiographic (also known as ankylosing spondylitis or AS) and non-radiographic (nr)-axSpA. Both studies met the primary and all ranked secondary endpoints with statistically significant and clinically meaningful results, supporting that bimekizumab improved outcomes in patients across the full disease spectrum of axSpA.

The ongoing Phase 3 program with bimekizumab in moderate to severe hidradenitis suppurativa (HS), a chronic, inflammatory, and debilitating follicular skin disease, showed an accelerated patient recruitment, hence, the first topline results are now projected for H2 2022.

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

Rozanolixizumab - a subcutaneously infused monoclonal antibody targeting the neonatal Fc receptor (FcRn), showed positive topline results from the Phase 3 study in patients with generalized myasthenia gravis (gMG). The study met the primary and all secondary endpoints with statistically significant and clinically meaningful results. Rozanolixizumab was well-tolerated with no new observed safety signals. Maintaining UCB's focus on autoantibody-mediated neuroinflammation, UCB announced investigating two additional patient populations using its rozanolixizumab platform:

- 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 started in Q3 2021; first topline results are expected in H1 2024.
- 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 started in Q4 2021; first topline results are expected H2 2024.

Zilucoplan - a self-administered, subcutaneous peptide inhibitor of complement component 5 (C5 inhibitor), reported positive topline results from the Phase 3 study in patients with generalized myasthenia gravis (gMG). The study met the primary and all key secondary endpoints with statistically significant and clinically meaningful results. Zilucoplan was well-tolerated with no new observed safety signals.

STACCATO® Alprazolam - an investigational drug-device combination using Staccato® delivery technology with alprazolam, a benzodiazepine, that has the potential to be the first rescue treatment to be administered by a patient or caregiver in an out-patient setting to rapidly (within 90 seconds) terminate an active epileptic seizure. The Phase 3 trial to assess the efficacy and safety in study participants with stereotypical prolonged seizures started in Q4 2021 and topline results are expected in H1 2024.

UCB0599 - In collaboration with UCB's new partner Novartis a Phase 2a study with UCB0599 for study participants with early-stage PD started, first topline results are expected in H2 2023.

All other clinical development programs are continuing as planned. In 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 product

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

€ million	2021 FY	2020 FY	Act	CER1
U.S.	1 183	1 174	1%	4%
Europe	420	431	-3%	-3%
International markets	238	194	22%	27%
Total Cimzia®	1 841	1 799	2%	5%

CIMZIA® (certolizumab pegol) reached 170 000 people living with inflammatory TNF-mediated diseases, driven by continued growth in the U.S. – despite a reimbursement decrease since July, overcompensated by a volume increase – and a slight decline in Europe, reflecting the mandated price decrease in Germany in April and a strong growth in other markets.

€ million	2021 FY	2020 FY	Act	CER1
U.S.	1 130	1 072	5%	9%
Europe	294	263	12%	11%
International markets	124	115	8%	12%
Total Vimpat®	1 549	1 451	7%	10%

VIMPAT® (lacosamide) was accessed by over 800 000 people living with epilepsy and showed strong growth in all regions, reaching the expected peak sales of at least € 1.5bn, ahead of the loss of exclusivity in 2022 in the U.S. and Europe.

€ million	2021 FY	2020 FY	Act	CER1
U.S.	156	167	-7%	-3%
Europe	218	223	-2%	-3%
International markets	597	398	50%	57%
Total Keppra®	970	788	23%	27%

KEPPRA® (levetiracetam) reached over 2 million people living with epilepsy. The continued generic erosion in the U.S. and Europe has been overcompensated by the performance in Japan, where UCB took over distribution of E Keppra® from partner Otsuka in October 2020. Generic entries to the Japanese market occurred early 2022.

€ million	2021 FY	2020 FY	Act	CER1
U.S.	267	220	21%	26%
Europe	77	60	29%	29%
International markets	11	8	33%	32%
Total Briviact®	355	288	23%	27%

BRIVIACT® (brivaracetam), was used by 140 000 people living with epilepsy and showed significant growth in all regions. Briviact® has a different mode of action from Vimpat® and differentiates from Keppra®.

€ million	2021 FY	2020 FY	Act	CER1
U.S.	95	98	-3%	0%
Europe	167	168	-1%	-1%
International markets	45	45	0%	3%
Total Neupro®	307	311	-1%	0%

NEUPRO® (rotigotine), the patch for Parkinson's disease and restless legs syndrome, used by 385 000 patients, recorded stable net sales 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 over 50 000 patients.

EVENITY® (romosozumab) since launch globally reached more than 200 000 women living with severe postmenopausal osteoporosis at high risk of fracture. It had its first European launch in March 2020 impacted by the pandemic. Evenity® is being launched successfully globally by Amgen, Astellas and UCB since 2019, with net sales outside Europe reported by the partners.

BIMZELX® (bimekizumab) for people living with psoriasis had a well-received launch in autumn in Germany, the UK, Sweden and the Netherlands. Reported net sales were € 4 million. In January 2022, Bimzelx® was approved in Japan and in February in Canada. The regulatory review in the U.S. is ongoing, the FDA inspections were conducted at the manufacturing sites, a regulatory decision is expected within the first half of 2022.

2021 FY financial highlights

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

	Actual		Variance	
€ million	**2021**	2020	Actual rates	CER[1]
Revenue	**5 777**	**5 347**	**8%**	**10%**
Net sales	5 471	5 052	8%	11%
Royalty income and fees	79	96	-18%	-15%
Other revenue	227	199	14%	14%
Gross Profit	**4 339**	**3 984**	**9%**	**12%**
Marketing and selling expenses	-1 346	-1 221	10%	13%
Research and development expenses	-1 629	-1 569	4%	4%
General and administrative expenses	- 208	- 196	6%	6%
Other operating income/expenses (-)	162	95	70%	76%
Adjusted EBIT	**1 318**	**1 093**	**21%**	**30%**
Impairment, restructuring and other income/expenses (-)	- 34	- 122	-72%	-72%
EBIT (operating profit)	**1 284**	**971**	**32%**	**43%**
Net financial expenses	- 58	- 93	-37%	-37%
Share of profit/loss (-) of associates	0	2	-100%	-100%
Profit before income taxes	**1 226**	**880**	**39%**	**51%**
Income tax expenses	- 170	- 119	43%	50%
Profit from continuing operations	**1 056**	**761**	**39%**	**51%**
Profit/loss (-) from discontinued operations	3	0	N/A	N/A
Profit	**1 058**	**761**	**39%**	**51%**
Attributable to UCB shareholders	1 058	732	45%	58%
Attributable to non-controlling interests	0	29	-100%	-100%
Adjusted EBITDA	**1 641**	**1 441**	**14%**	**21%**
Capital expenditure (including intangible assets)	493	349	41%	
Net financial cash / debt (-)	- 860	-1 411	-39%	
Operating cash flow from continuing operations	1 553	1 081	44%	
Weighted average number of shares – non diluted (million)	**189**	**189**	**0%**	
EPS (€ per weighted average number of shares – non diluted)	**5.60**	**3.87**	**45%**	**52%**
Core EPS (€ per weighted average number of shares – non diluted)	**6.49**	**5.36**	**21%**	**26%**

"The statutory auditor has issued an unqualified report with no emphasis of matter paragraph dated 23 February 2022 on the company's consolidated accounts as of and for the year ended 31 December 2021, and has confirmed that the accounting data reported in the accompanying press release is consistent, in all material respects, with the accounts from which it has been derived"

Revenue in 2021 went up by 8% (+10% CER[1]) to € 5 777 million and **net sales** increased by 8% (+11% CER[1]) to € 5 471 million. This was driven by the continuous growth of UCB's product portfolio – driving company growth. One product was added to the UCB portfolio: In September, UCB launched BIMZELX® (bimekizumab) for the treatment of moderate to severe plaque psoriasis in Germany, the UK, Sweden and the Netherlands.

Royalty income and fees were € 79 million (-18%; -15% CER[1]) and other revenue went up by 14% (+14% CER[1]) to € 227 million due to milestones and other payments from R&D partners.

Gross profit reached € 4 339 million with a plus of 9% (+12% CER[1]) and reflecting an improved gross margin of 75.1% compared to 2020 with 74.5%.

Operating expenses increased to € 3 021 million (+4%; +5% CER[1]) reflecting:

- 10% higher marketing and selling expenses of € 1 346 million – driven by launches and pre-launch activities,
- 4% higher research and development expenses of € 1 629 million reflecting the investments in UCB's progressing pipeline encompassing five late-stage assets and ongoing earlier stage research. The R&D ratio reached 28% in 2021 after 29% in 2020,
- 6% higher general and administrative expenses of € 208 million, driven by implementation expenses for improved value-focused allocation of resources and share based payments valuation,
- significantly higher other operating income of € 162 million after € 95 million in 2020 - driven by an income of € 151 million (+57%) reflecting the net contribution from Amgen in connection with the commercialization of EVENITY®.

Underlying operational profitability – adjusted EBITDA[2] – went up to € 1 641 million (+14%; +21% CER[1]) driven by continued revenue growth and moderately growing operating expenses, reflecting the investments into the future of UCB, namely into product launches and clinical development. The adjusted EBITDA ratio for 2021 (in % of revenue) reached 28%, after 27% in 2020.

Total impairment, restructuring and other income/expenses were expenses of € 34 million. In 2020, the expenses were € 122 million which was mainly driven by fees related to acquisitions, which did not reoccur in 2021.

Net financial expenses went down to € 58 million from € 93 million, mainly due to lower hedging costs and lower interest expenses.

Income tax expenses were € 170 million compared to € 119 million in 2020. The average effective tax rate was 14% compared to 13% in 2020.

Profit amounted to € 1 058 million (+39%; +51% CER[1]), of which the full amount is attributable to UCB shareholders as the contributions to non-controlling interests have expired at the end of 2020. The growth was driven by strong revenue and EBITDA growth as well as lower other expenses and lower financial expenses. For 2020, profit was € 761 million of which € 732 million were attributable to UCB shareholders and € 29 million to non-controlling interests.

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 € 6.49 after € 5.36 in 2020, based on stable 189 million weighted average shares outstanding.

Dividend - The Board of Directors of UCB proposes a dividend of €1.30 per share (gross), +2%.

Guidance 2022: For 2022, UCB is aiming for revenues in the range of € 5.15 - 5.4 billion based on continued core product growth and taking into account estimated impacts from the loss of exclusivity for VIMPAT® in the U.S. (March 2022) and Europe (September 2022), E KEPPRA® in Japan (January 2022) as well as the U.S.

launch of BIMZELX® (bimekizumab) for people living with psoriasis – the regulatory review in the U.S. is ongoing, with a decision expected in the first half of 2022.

UCB will continue to invest into research and development to advance its late-stage development pipeline and prepare upcoming launches to offer potential new solutions for patients. Underlying profitability, adjusted EBITDA, is expected in the range of 26 - 27% of revenue, reflecting the continued high R&D and marketing & selling investment levels. Core earnings per share are therefore expected in the range of €4.80 - €5.30 per share – based on an average of 189 million shares outstanding.

The figures for the financial guidance 2022 as mentioned above are calculated on the same basis as the actual figures for 2021; they will be updated upon closing of the planned Zogenix, Inc. acquisition.

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 five specific populations by 2025, creating value for patients now and into the future. 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.

Guidance 2022 & 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 (GMT) / 14.00 (CET)

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

For further information, contact UCB:

Investor Relations

Antje Witte
T +32.2.559.9414
antje.witte@ucb.com

Julien Bayet
T: +32 2 559 9580
julien.bayet@ucb.com

Global Communications
Laurent Schots, Media Relations
T+32.2.559.9264
Laurent.schots@ucb.com

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 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.
UCB is providing this information, including forward-looking statements, only 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 or reflect any change in its forward-looking statements with regard thereto or any change in events, conditions or circumstances on which any such statement is based, unless such statement is required pursuant to applicable laws and regulations.
Additionally, information contained in this document shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any offer, solicitation or sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of such jurisdiction.