UCB News

UCB Full-Year Report 2022, Brussels (Belgium), 22 February 2023 – 7:00 (CET) – regulated information

UCB managed 2022 headwinds and is ready for 2023 launches

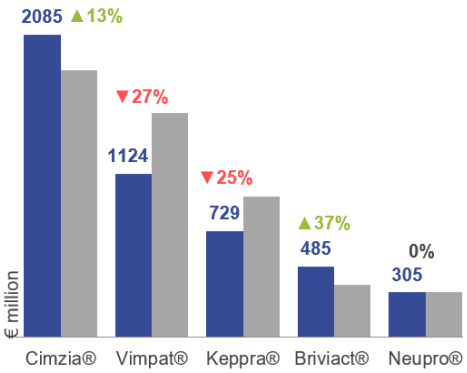
- Revenue reached € 5.52 billion (-4%; -7% CER[1]), net sales were € 5.14 billion (-6%; -8% CER[1]). CIMZIA has reached UCB's projected peak sales target of € two billion ahead of 2024
- Underlying profitability (adj. EBITDA[2]) was € 1.26 billion (-23%; -21% CER[1]), 22.8% of revenue
- Multiple launches in 2023 expected: in psoriasis in the U.S., in psoriatic arthritis (PsA) and across the full spectrum of axial spondyloarthritis (axSpA) in the EU and Japan, in generalized myasthenia gravis (gMG) in the U.S., EU and Japan and in Lennox Gastaut Syndrome (LGS) in the EU - already approved
- Financial guidance for 2023: Revenue expected to reach € 5.15 - 5.35 billion, adjusted EBITDA[2] 22.5 - 23.5% of revenue, Core EPS[3] of € 3.40 - 3.80

"In 2022 we reached more than 3.4 million people living with severe immunological and neurological diseases and we are in full preparation to bring new treatment options in the future, all of this while managing the headwinds. In 2022, we were confronted with a delay launching bimekizumab in the U.S. Today, UCB is very confident to bring bimekizumab to people living with psoriasis in the U.S. – with regulatory feedback expected in Q2 2023. In 2023, we also aim to bring new treatment options to people living with generalized myasthenia gravis. What guides us is our belief that everyone deserves to live the best live that they can," **Jean-Christophe Tellier, CEO UCB commented**. *"Acting with focus and care, keeping our impact on society and the planet in mind, we are pleased with the progress we made towards our extra-financial targets, recognized by key ESG ratings. Together with our employees and partners we are working towards our strong long-term growth and our ambition to create value for all stakeholders, now and into the future."*

UCB's FY 2022 financial results

€ million	2022 FY	2021 FY	Act	CER[1]
Revenue	5 517	5 777	-4%	-7%
Net sales	5 140	5 471	-6%	-8%
Adj. EBITDA[2]	1 260	1 641	-23%	-21%
Number of shares (m)	190	189	1%	
Core EPS[3] (€)	4.37	6.49	-33%	
Dividend per share (€)	1.33	1.30	2%	

Top Product net sales



[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 2022 revenue reached € 5.52 billion (-4%; -7% CER[1]). **Net sales** reached € 5.14 billion (-6%; -8% CER[1]), based on the continued growth of UCB's product portfolio and the newly acquired product FINTEPLA®. This was more than offset by the contracting effects of the loss of exclusivity of two products.

Underlying profitability (adjusted EBITDA[2]) reached € 1.26 billion (-23%; -21% CER[1]), reflecting lower revenue due to the loss of exclusivity and the integration of Zogenix, which explains higher total operating expenses. Strong cost discipline allowed the absorption of inflation costs. Marketing and selling expenses reflect investments behind ongoing and upcoming launches, research and development expenses reflect the pipeline progress. Higher other operating income was driven by EVENITY®.

Profit decreased to € 418 million (-61%; -55% CER[1]). **Core EPS[3]** were € 4.37 after € 6.49 in 2021. The Board of Directors of UCB proposes a dividend of € 1.33 per share (gross), +2%.

Sandrine Dufour, CFO UCB says: *"We are pleased to deliver 2022 financial results at the upper end of our financial guidance shared in June 2022. We successfully integrated Zogenix - diluting our earnings significantly but slightly less than anticipated. As expected, we're seeing the impacts from the loss of exclusivity for E KEPPRA® in Japan and VIMPAT® in the U.S. and Europe reflected in our topline. Smart resource allocation enabled us to invest behind the planned product launches and strong cost discipline mitigated the impacts from inflation. In 2023, although we will see the full annualized effect of the loss of exclusivity to VIMPAT® and the inflation costs, we will continue to invest behind multiple launches also benefiting from the Zogenix acquisition becoming earnings accretive."*

Regulatory and Clinical Pipeline Update

UCB continuously innovates and strives to find new ways to deliver solutions to people living with severe immunological and neurological diseases, leading in 2022 to an unprecedented regulatory and clinical pipeline, set to help people live their best possible lives.

Bimekizumab

In September 2022, the European Medicines Agency (EMA) accepted for regulatory review the two marketing authorization applications (MAA) for bimekizumab for the treatment of adult patients with active **psoriatic arthritis** (PsA), and adult patients with active **axial spondyloarthritis** (axSpA).

In May 2022, UCB announced that the U.S. Food and Drug Administration (FDA) 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 indicated 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. **In November 2022**, UCB announced that it had resubmitted the BLA to the FDA for bimekizumab for the treatment of adults with moderate to severe plaque psoriasis. **In December 2022**, the FDA accepted the BLA resubmission for review. The FDA validated the resubmission as 'Class 2' with a six-month review period. UCB expects the FDA action in Q2 2023.

In December 2022, UCB announced positive top-line results from two Phase 3 studies, BE HEARD I and BE HEARD II, evaluating the efficacy and safety of bimekizumab in adults with moderate to severe **hidradenitis suppurativa (HS)**. HS is a chronic, recurring, painful, and debilitating inflammatory skin disease. The two Phase 3 studies met their primary and key secondary endpoints with statistical significance and consistent clinical relevance. The positive results from these two studies will form the basis of global regulatory license application submissions for bimekizumab in hidradenitis suppurativa starting in Q3 2023.

Brivaracetam

In October 2022, UCB announced positive top-line results from the latest Phase 3 study of brivaracetam.

The study was designed to evaluate the efficacy and safety of adjunctive brivaracetam in participants from Asia (≥16 to 80 years of age) with **partial epilepsy seizures** with or without secondary generalization. The study met the primary and all secondary endpoints. UCB plans regulatory submissions in Japan in Q3 2023.

FINTEPLA® (fenfluramine)

In September 2022, FINTEPLA® (fenfluramine) oral solution was approved by the Japanese Ministry of Health, Labour and Welfare (MHLW) for the treatment of seizures associated with **Dravet syndrome** as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older. Fenfluramine will be marketed by Nippon Shinyaku Co., Ltd. based on the exclusive sales agreement signed in 2019 between Zogenix Inc., (acquired by UCB in 2022) and Nippon Shinyaku Co., Ltd. UCB is now the Marketing Authorization holder.

In December 2022, FINTEPLA® was recommended by the Committee for Medicinal Products for Human Use (CHMP) for marketing authorization in the European Union (EU) for the adjunctive treatment of seizures associated with **Lennox-Gastaut syndrome (LGS)** as an add-on therapy to other anti-epileptic medicines for patients two years of age and older. **In February 2023**, UCB announced the European marketing authorization for FINTEPLA® (fenfluramine) in LGS. Additionally, the European Commission has also adopted the EMA Committee for Orphan Medicinal Products (COMP) recommendation that the orphan designation for fenfluramine be maintained.

Zilucoplan

In November 2022, the NDA and the MAA for zilucoplan, a self-administered (via subcutaneous injection) peptide inhibitor of complement component 5 (C5 inhibitor), were accepted by FDA and EMA, respectively, for review seeking approval for the treatment of **generalized myasthenia gravis (gMG)** in adult patients who are acetylcholine receptor antibody positive (AChR-Ab+). UCB expects to receive feedback from the agencies in Q4 2023.

Doxecitine and doxribtimine (doxTM, MT1621)

Doxecitine and doxribtimine (doxTM), a dual substrate pyrimidine nucleoside enhancement therapy being developed for the treatment of patients with thymidine kinase 2 deficiency (TK2d), an ultra-rare debilitating and life-threatening genetic mitochondrial disorder, causing progressive and severe muscle weakness. Following in-depth evaluation and alignment meetings with key regulatory agencies on the filing strategy for doxTM, regulatory submissions are now planned for H1 2024.

Rozanolixizumab

In **January 2023**, FDA accepted the filing and granted priority review for the BLA for rozanolixizumab - a subcutaneously infused monoclonal antibody targeting the neonatal Fc receptor (FcRn), for the treatment of adults with **generalized myasthenia gravis (gMG)** who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. UCB expects to receive feedback from the FDA in Q2 2023.
The FDA Priority Review designation follows the **December 2022** EMA validation of the MAA for rozanolixizumab for the treatment of adults with AChR or MuSK antibody positive gMG. UCB expects to receive initial feedback for Europe in Q1/Q2 2024.

In Q4 2022, UCB initiated a Phase 2a (proof-of-concept) study to evaluate the efficacy and safety of rozanolixizumab to treat adult study participants with **severe fibromyalgia syndrome**. First topline results are expected in H2 2024. Fibromyalgia is a common, severe and debilitating disorder of unknown etiology characterized by widespread musculoskeletal pain, fatigue, sleep disturbances, and mood disorders.

Bepranemab is a recombinant, humanized, full-length immunoglobulin G4 monoclonal anti-tau antibody currently under clinical investigation for the treatment of patients with **Alzheimer's disease (AD)** in

partnership with Roche/Genentech. The efficacy, safety and tolerability of bepranemab in patients with early AD are investigated in a Phase 2 study, which started in Q2 2021. Recruitment for this study was completed ahead of time and topline results are now expected earlier, in Q4 2024.

UCB0599 is an orally bioavailable and brain-barrier-penetrant small molecule that prevents the pathological misfolding and accumulation of alpha-synuclein, a protein which plays a key role in **Parkinson's disease (PD)** pathology. By inhibiting the disease-causing biology of alpha-synuclein misfolding, it is believed that the progression of PD can be slowed or halted. Under a global co-development and co-commercialization agreement with Novartis, UCB is conducting a phase 2a study with UCB0599 for study participants with early-stage PD. In 2022, an additional dosing arm was introduced into the study. Recruitment is complete and topline results are now expected in Q4 2024.

UCB initiated Phase 1b studies in **atopic dermatitis** addressing two different targeted immune pathways with **UCB9741 and UCB1381**. These early studies evaluate the safety, pharmacokinetics and efficacy in people with moderate-to-severe atopic dermatitis. Atopic dermatitis is a chronic condition that causes dry, itchy and inflamed skin and can affect people at all ages.

All other clinical development programs are continuing as planned.

Net sales break-down by product

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

€ million	2022 FY	2021 FY	Act	CER[1]
U.S.	1 381	1 183	17%	4%
Europe	416	420	-1%	-1%
Japan	51	44	15%	22%
International markets	237	193	23%	18%
Total Cimzia®	2 085	1 841	13%	5%

CIMZIA® (certolizumab pegol) reached 180 000 people living with inflammatory TNF-mediated diseases. CIMZIA is showing a stronger growth than the anti-TNF market – based on differentiation and driven by double-digit growth in the U.S. and Japan. CIMZIA has reached UCB's projected peak sales target of € two billion - ahead of time.

€ million	2022 FY	2021 FY	Act	CER[1]
U.S.	706	1 130	-38%	-44%
Europe	272	294	-8%	-8%
Japan	68	62	10%	17%
International markets	77	62	25%	17%
Total Vimpat®	1 124	1 549	-27%	-33%

VIMPAT® (lacosamide) was accessed by over 600 000 people living with epilepsy and is experiencing generic competition since end of March 2022 in the U.S. and since September 2022 in Europe due to loss of exclusivity in these two regions. In Japan and international markets, the net sales show continued solid growth.

€ million	2022 FY	2021 FY	Act	CER[1]
U.S.	156	156	0%	-11%
Europe	206	218	-5%	-6%
Japan	149	404	-63%	-61%
International markets	217	193	13%	11%
Total Keppra®	729	970	-25%	-26%

KEPPRA® (levetiracetam) reached over 1.8 million people living with epilepsy. The generic erosion due to loss of exclusivity in Japan started early January 2022 and was stronger than expected due to multiple generics and governmental support for generic levetiracetam. Also, in the U.S. and Europe the performance is reflecting generic competition.

€ million	2022 FY	2021 FY	Act	CER[1]
U.S.	380	267	43%	27%
Europe	88	77	13%	13%
International markets	17	11	55%	43%
Total Briviact®	485	355	37%	24%

BRIVIACT® (brivaracetam), was used by 190 000 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	2022 FY	2021 FY	Act	CER[1]
U.S.	94	95	0%	-11%
Europe	163	167	-2%	-3%
Japan	27	26	1%	6%
International markets	22	19	14%	6%
Total Neupro®	305	307	0%	-4%

NEUPRO® (rotigotine), the patch for Parkinson's disease and restless legs syndrome, used by over 340 000 patients, recorded stable net sales in a competitive market environment.

FINTEPLA® (fenfluramine) is now part of the UCB epilepsy portfolio thanks to the completed acquisition of Zogenix, Inc. in early March and reached more than 1 000 patients and their families. FINTEPLA® is approved for seizures associated with rare epileptic syndromes, Dravet (since mid-2020) in U.S. Europe and Lennox-Gastaut syndrome (since late March 2022) in the U.S., providing new treatment options for patients and families living with these rare syndromes that are particularly challenging to treat. Net sales (March - December) were € 116 million. The integration of Zogenix was successfully completed as planned by the end of 2022.

NAYZILAM® (midazolam) Nasal SprayCIV, a nasal rescue treatment for epilepsy seizure clusters in the U.S. reached over 90 000 patients and net sales of € 78 million, a plus by 36% (+21% CER)

BIMZELX® (bimekizumab) reached over 4 000 people living with psoriasis and is being launched throughout Europe, the UK, Japan, Canada and further countries. Net sales were € 35 million (after € 4 million in 2021). For the U.S., the regulatory review is ongoing with an expected decision by the U.S. authority in Q2 2023.

EVENITY® (romosozumab) since launch globally reached more than 400 000 women living with severe postmenopausal osteoporosis at high risk of fracture. Net sales increased to € 25 million after € 10 million in 2021. It had its first European launch in March 2020 and was impacted by the pandemic since then. EVENITY® is being launched successfully globally by Amgen, Astellas and UCB since 2019, with net sales outside Europe reported by the partners.

2022 FY financial highlights

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

	Actual[1]		Variance	
€ million	**2022**	2021	Actual rates	CER[2]
Revenue	**5 517**	**5 777**	**-4%**	**-7%**
Net sales	5 140	5 471	-6%	-8%
Royalty income and fees	85	79	8%	-3%
Other revenue	292	227	28%	24%
Adjusted Gross Profit	**4 239**	**4 489**	**-6%**	**-7%**
Gross Profit	**3 843**	**4 339**	**-11%**	**-13%**
Marketing and selling expenses	-1 489	-1 346	11%	3%
Research and development expenses	-1 670	-1 629	3%	0%
General and administrative expenses	- 225	- 208	9%	6%
Other operating income/expenses (-)	216	162	33%	20%
Adjusted EBIT	**675**	**1 318**	**-49%**	**-44%**
Impairment, restructuring and other income/expenses (-)	- 90	- 34	>100%	>100%
EBIT (operating profit)	**585**	**1 284**	**-54%**	**-52%**
Net financial expenses	- 74	- 58	26%	26%
Profit before income taxes	**511**	**1 226**	**-58%**	**-53%**
Income tax expenses	- 91	- 170	-46%	-42%
Profit from continuing operations	**420**	**1 056**	**-60%**	**-55%**
Profit/loss (-) from discontinued operations	- 2	3	>-100%	>-100%
Profit	**418**	**1 058**	**-61%**	**-55%**
Attributable to UCB shareholders	418	1 058	-61%	-55%
Adjusted EBITDA	**1 260**	**1 641**	**-23%**	**-21%**
Capital expenditure (including intangible assets)	371	493	-25%	
Net debt (-)	-2 000	- 860	>100%	
Operating cash flow from continuing operations	1 119	1 553	-28%	
Weighted average number of shares – non diluted (million)	**190**	**189**	**1%**	
EPS (€ per weighted average number of shares – non diluted)	**2.20**	**5.60**	**-61%**	**-55%**
Core EPS (€ per weighted average number of shares – non diluted)	**4.37**	**6.49**	**-33%**	**-28%**

[1] Due to rounding, some financial data may not add up in the tables included in this management report

[2] CER: constant exchange rates and excluding hedging

"The statutory auditor has issued an unqualified report with no emphasis of matter paragraph dated 21 February 2023 on the company's consolidated accounts as of and for the year ended 31 December 2022, 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 2022 reached € 5 517 million (-4%; -7% CER[1]) and **net sales** were € 5 140 million (-6%; -8% CER[1]). This was driven by the continued growth of UCB's product portfolio – namely CIMZIA®, BRIVIACT®, NAYZILAM®; EVENITY® as well as newly launched BIMZELX® – and the addition of FINTEPLA®. This performance was slightly over-compensated by the effects of the loss of exclusivity for VIMPAT® in the U.S. and Europe and E KEPPRA® in Japan.

Royalty income and fees were € 85 million (+8%; -3% CER[1]) and other revenue went up by 28% (+24% CER[1]) to € 292 million 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 before "amortization of intangible assets linked to sales" was € 4 239 million (-6%; -7% CER[1]) and in-line with the net sales performance. The adjusted gross margin is 76.8% after 77.7% in 2021. Gross profit after "amortization of intangible assets linked to sales" reached € 3 843 million – a gross margin of 69.7% after 75.1% in 2021 and reflecting the addition of FINTEPLA® amortization.

Operating expenses increased to € 3 168 million (+5%; +1 CER[1]) reflecting higher expenses due to the addition and integration of Zogenix. Strong cost discipline allowed the absorption of inflation costs. Operating expenses are consisting of:

- marketing and selling expenses of € 1 489 million (+11%; +3% CER[1]) – focused reallocation and cost discipline allowed to invest behind the launches and pre-launch activities for 2023: global FINTEPLA® launch activities, global BIMZELX® launch activities as well as ongoing preparations for a launch in the U.S., global pre-launch activities for rozanolixizumab and zilucoplan for people living with generalized myasthenia gravis (gMG) and EVENITY® ongoing launches throughout Europe.
- research and development expenses of € 1 670 million (+3%; 0% CER[1]) reflecting the continued investments in UCB's progressing pipeline which resulted in several ongoing regulatory reviews: bimekizumab (several indications), rozanolixizumab, zilucoplan and FINTEPLA®. During 2022, 6 phase 3 programs and 3 phase 2 programs were ongoing as well as earlier clinical development, 3 new programs were added to the clinical pipeline. The decision to terminate the clinical development in ITP led to termination costs of € 46 million in 2022. The R&D ratio reached 30% in 2022 after 28% in 2021.
- general and administrative expenses of € 225 million (+9%; +6%), due to the integration of Zogenix
- other operating income of € 216 million following € 162 million in 2021 – driven by an income of € 240 million (+59%) reflecting the net contribution from Amgen in connection with the commercialization of EVENITY®. This was partly compensated by write-offs on receivables.

Underlying operational profitability – adjusted EBITDA[2] – reached € 1 260 million (-23%; +21% CER[1]) driven by decreased revenue and increased operating expenses, reflecting the investments into the future growth of UCB, namely into product launches and ongoing clinical development. The adjusted EBITDA ratio for 2022 (in % of revenue) reached 22.8%, after 28.4% in 2021.

Total impairment, restructuring and other expenses increased to € 90 million, after € 34 million in 2021. This was mainly driven by fees and restructuring expenses related to the acquisition of Zogenix in March 2022.

Net financial expenses went up to € 74 million from € 58 million, based on higher interest rates as well as higher interest cost due to higher net debt in connection with the acquisition of Zogenix.

Income tax expenses were € 91 million compared to € 170 million in 2021. The average effective tax rate was 17.8% compared to 13.9% in 2021, reflecting the lower earnings and earnings mix.

Profit amounted to € 418 million (-61%; -55% CER[1]). Reflecting lower revenue due to the loss of exclusivity and higher operating expenses driven by launch activities and launch preparations for the 2023 potential launches.

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 € 4.37 after € 6.49 in 2021, based on stable 190 million weighted average shares outstanding.

Dividend - The Board of Directors of UCB proposes a dividend of €1.33 per share (gross), +2%.

Guidance 2023: The year 2023 will be marked by ongoing launches and several upcoming launches in the U.S. and Europe – subject to regulatory approvals. At the same time UCB is impacted by the full annualized and ongoing generic erosion to VIMPAT®.

For 2023, UCB expects revenues in the range of € 5.15 - 5.35 billion based on expected launch contributions like the expected mid-year U.S. launch of bimekizumab for people living with psoriasis and taking into account the full annualized negative impacts from the loss of exclusivity for VIMPAT® in the U.S. and Europe as well as based on continued solid contribution from the existing product portfolio.

UCB will continue to invest in upcoming launches to offer potential new solutions for people living with severe diseases and remains committed to invest into research and development advancing its late-stage development pipeline. UCB will also continue to execute strong cost discipline, sell non-core assets and manage the significant impact of inflation in 2023. At the same time, the integration of the Zogenix acquisition will become earnings accretive during 2023. Underlying profitability, adjusted EBITDA, is expected in the range of 22.5 - 23.5% of revenue. Core earnings per share are therefore expected in the range of € 3.40 - 3.80 per share-based on an average of 190 million shares outstanding.

The figures for the financial guidance 2023 as mentioned above are calculated on the same basis as the actual figures for 2022.

Guidance for 2025 confirmed: UCB confirms its growth ambition for 2025. Based on the strong product portfolio and the promising assets currently under regulatory review – leading to multiple expected launches in all geographies. 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 2023 & 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)

Register here: https://www.ucb.com/investors

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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 8 700 people in approximately 40 countries, the company generated revenue of € 5.5 billion in 2022. 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 pandemics (such as COVID-19), wars on territories where UCB has businesses, 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.

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