UCB News

New BIMZELX® (bimekizumab-bkzx) data at ACR Convergence 2024 highlights UCB's efforts to deliver differentiated care for patients with psoriatic arthritis and axial spondyloarthritis

- ACR Convergence 2024 marks UCB's first presentation of data in psoriatic arthritis (PsA), non-radiographic axial spondyloarthritis (nr-axSpA) and ankylosing spondylitis (AS) since the recent approvals of BIMZELX® (bimekizumab-bkzx) in these indications in the U.S.
- New two-year data demonstrated sustained improvements in clinical and patient-reported outcomes in PsA, nr-axSpA and AS patients treated with bimekizumab-bkzx
- UCB will present 19 bimekizumab-bkzx abstracts, including 2 oral presentations, across PsA, nr-axSpA and AS, as well as plaque psoriasis (PSO)

Brussels (Belgium), November 14, 2024 – 18:00 (CEST) – UCB, a global biopharmaceutical company, today announced the presentation of new two-year data confirming a sustained clinical response for the IL-17A and IL-17F inhibitor bimekizumab-bkzx, in adults with active psoriatic arthritis (PsA) and those with active non-radiographic axial spondyloarthritis with objective signs of inflammation (nr-axSpA) and active radiographic axial spondyloarthritis (r-axSpA), also known as ankylosing spondylitis (AS). These results are the latest from the Phase 3 studies BE OPTIMAL (PsA), BE COMPLETE (PsA) and their open-label extension BE VITAL, as well as BE MOBILE 1 (nr-axSpA), BE MOBILE 2 (AS) and their open-label extension BE MOVING.[1,2,3]

Additionally, new one-year data demonstrated significant reduction in inflammation and structural lesions in nr-axSpA and AS, as assessed by magnetic resonance imaging (MRI), while two-year data confirmed minimal spinal radiographic progression in nr-axSpA and AS.[4,5] These findings will be highlighted in oral presentations at the American College of Rheumatology (ACR) Convergence 2024, in Washington, D.C., November 14–19.[4,5]

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Bimekizumab-bkzx received FDA approval for PsA, nr-axSpA and AS indications in September this year. The research presented at ACR demonstrates the long-term efficacy of bimekizumab-bkzx, building on the breadth and depth of available data and reinforcing UCB's continued commitment to people living with rheumatic diseases.[6,7,8,9]

"A major challenge for practicing rheumatologists is that existing treatments may lose efficacy over time, leaving patients vulnerable to debilitating symptoms. The new results presented at ACR Convergence 2024 show that bimekizumab-bkzx met stringent clinical endpoints, with high levels of efficacy across multiple domains of axial spondyloarthritis and psoriatic arthritis, and were sustained for two years, demonstrating bimekizumab-bkzx's ability to remain effective over the long term," said Dr Fabian Proft, Department of Gastroenterology, Infectiology and Rheumatology, Charité Universitätsmedizin Berlin, Germany.

"These new two-year data, revealing high levels of response, offer exciting insights into bimekizumab-bkzx's sustained efficacy in non-radiographic axial spondyloarthritis, ankylosing spondylitis and psoriatic arthritis," said Fiona du Monceau, Head of Patient Evidence, UCB. "The results reinforce the potential of bimekizumab-bkzx as an effective approach to targeting key inflammatory pathways involved in PsA, nr-axSpA and AS through dual inhibition of IL-17A and IL-17F, reflecting our ambition to provide differentiated treatments for people living with chronic inflammatory diseases."

For people living with psoriatic arthritis, the new data demonstrated robust maintenance of clinical responses, including complete skin clearance (PASI100), minimal disease activity, improvements in joint pain, and patient reported outcomes to two years.[1,2] More than 7 in 10 of Week 16 responders sustained a 50% improvement in ACR response criteria (ACR50) at two years.[1*] Maintenance of response was consistent regardless of whether patients were biologic disease-modifying anti-rheumatic drug-naïve (bDMARD-naïve: BE OPTIMAL), or had a previous inadequate response or intolerance to tumor necrosis factor inhibitors (TNFi-IR: BE COMPLETE).[1*]

For people living with nr-axSpA and AS the two-year data demonstrated sustained, high levels of efficacy across all domains of axSpA and long-term maintenance of low disease activity and remission.[3,4] More than 8 in 10 patients who achieved ASAS40 at Week 16 sustained this response at two years.[3**]

New one-year data demonstrated that a higher proportion of patients with nr-axSpA or AS treated with bimekizumab-bkzx achieved remission when defined by objective signs of inflammation (OSI) compared to ASDAS-Inactive Disease (ASDAS-ID).[10] Remission based on OSI was defined as MRI

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remission in the sacroiliac joints and spine, normalization of C-reactive protein (CRP) levels, and resolution of swollen joints (see "Notes to Editors").[10†] These findings highlight a potential need for optimized endpoints to guide clinical treatment management in axSpA.[10†]

A two pooled safety analysis, each comprising three Phase 2b/3 studies and their open-label extensions, in patients with active nr-axSpA, AS and active PsA confirmed that the long-term safety profile was consistent with previous studies.[11]

* Non-responder imputation

** Multiple imputation

†Observed case

Notes to Editors:

Bimekizumab-bkzx two-year data in PsA presented at ACR Convergence 2024:

- **ACR50:** Of patients who experienced ≥50% improvement from baseline in American College of Rheumatology response criteria (ACR50) at Week 16 (43.9% of 189 patients in BE OPTIMAL and 43.1% of 115 patients in BE COMPLETE), 79.4% of 150 bDMARD-naïve patients and 75.7% of 87 TNFi-IR patients maintained response to two years (Week 104/100 respectively).[1*]
- **PASI100:** Complete skin clearance (Psoriasis Area and Severity Index [PASI]100) experienced at Week 16 in patients with baseline psoriasis affecting ≥3% body surface area (47.5% of 103 patients in BE OPTIMAL and 58.5% of 103 patients in BE COMPLETE) was maintained to two years by 70.9% of 73 bDMARD-naïve patients in BE OPTIMAL and 80.6% of 83 TNFi-IR patients in BE COMPLETE.[1*]
- **MDA:** Similar trends were seen for minimal disease activity (MDA) response. Of those who experienced MDA at Week 16 (45.0% of 194 patients in BE OPTIMAL and 43.8% of 117 patients in BE COMPLETE), 75.8% of 147 bDMARD-naïve patients and 74.4% of 87 TNFi-IR patients maintained response to two years.[1*]
- **Pain:** Improvements in pain at one year were sustained up to two years, with approximately half of patients in all treatment groups experiencing a ≥50% reduction in Pain Visual Analogue Scale (Pain VAS) at two years.[2*]
- **Fatigue**: Fatigue was assessed using the Functional Assessment of Chronic Illness Therapy-Fatigue subscale (FACIT-Fatigue). Minimal clinically important difference (MCID) in FACIT-Fatigue scores (as defined by ≥4-point increase from baseline in patients with FACIT-Fatigue ≤48 at

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baseline) were achieved by nearly 5 in 10 patients in both BE OPTIMAL and BE COMPLETE with results sustained from Week 52.[2*]

Bimekizumab-bkzx two-year data in axSpA presented at ACR Convergence 2024:

- **ASAS40:** Of patients who achieved an Assessment of SpondyloArthritis international Society 40% improvement (ASAS40) at Week 16 (45.8% of 349 patients), 85.7% of 160 patients maintained this response over two years (Week 104).[3**]
- **Low Disease Activity:** Of patients who achieved Ankylosing Spondylitis Disease Activity Score (ASDAS) low disease activity (LDA <2.1) at Week 16 (43.6% of 349 patients), 89.3% of 152 patients maintained the response to two years.[3**]
- **Inactive disease and remission:** Of patients who reached ASDAS inactive disease (ASDAS <1.3) at Week 16 (16.6% of 349 patients), 76.0% of 58 patients maintained the response to two years.[3**]
- **Resolution of objective signs of inflammation:** More than 50% of patients with nr-axSpA and AS treated with bimekizumab-bkzx achieved remission defined by the resolution of objective signs of inflammation (MRI of the sacroiliac joints and spine (SPARCC score <2), low C-reactive protein levels (≤5 mg/L) and a swollen joint count (SJC) of 0) at 52 weeks.[10†] Among placebo-randomized patients who switched to bimekizumab-bkzx at 16 weeks, 35% of patients with nr-axSpA and 50% of patients with AS achieved remission defined by the resolution of objective signs of inflammation.[10†]

Bimekizumab-bkzx in PsA and axSpA presented at ACR Convergence 2024:

- **Low uveitis rates:** In a pooling of the safety data from three bimekizumab-bkzx studies in axSpA and their open-label extensions, 15.3% of 848 axSpA patients had a history of uveitis.[11] Uveitis occurred in 3.7% of 848 patients, with a higher rate in those with a history of uveitis (13.8% of 130 patients) compared to those without (1.8% of 718 patients).[11]
- **Safety profile:** In a pooling of the total safety data from six bimekizumab-bkzx studies and their open-label extensions in PsA and axSpA, the three most frequently reported treatment-emergent adverse events after 2 years (≥6% of patients in both the axSpA and PsA pools) were: SARS-CoV-2 (COVID-19) infection (20.9%), nasopharyngitis (15.7%), and upper respiratory tract infection (13.6%).[11] After an additional year of exposure, the long-term safety profile of bimekizumab-bkzx was consistent with previous studies.[11]

[*] Non-responder imputation

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[†]Observed case

[**] Multiple imputation

About Psoriatic Arthritis

Psoriatic arthritis is a serious, highly heterogeneous, chronic, systemic inflammatory condition affecting both the joints and skin with a prevalence of 0.02 percent to 0.25 percent of the population.[12] Psoriatic arthritis affects approximately 30 percent of people living with psoriasis.[13] It manifests as joint pain and stiffness, skin plaques, swollen toes and fingers (dactylitis) and inflammation of the sites where tendons or ligaments insert into the bone (enthesitis).[14] The burden on those living with PsA extends beyond physical discomfort to reduced quality of life, with co-morbidities including hypertension, cardiovascular disease, anxiety, and depression.[13]

About BE OPTIMAL and BE COMPLETE

BE OPTIMAL and BE COMPLETE were two Phase 3 studies evaluating the efficacy and safety of bimekizumab in the treatment of psoriatic arthritis.[1,2] The primary endpoint in both studies was the proportion of patients reaching 50% or greater improvement in American College of Rheumatology criteria (ACR50) at Week 16 (non-responder imputation).[1,2] BE OPTIMAL (bDMARD-naïve) and BE COMPLETE (TNFi-IR) assessed subcutaneous bimekizumab 160 mg every four weeks (Q4W) in patients with PsA; both studies were placebo-controlled to Week 16, after which placebo patients switched to bimekizumab.[15,16]

BE OPTIMAL included a reference arm (adalimumab 40 mg Q2W); adalimumab patients switched to bimekizumab at Week 52 with no washout between treatments.[17] BE OPTIMAL Week 52 and BE COMPLETE Week 16 completers were eligible for BE VITAL open-label extension.[17] From BE OPTIMAL 83.3 percent of patients (n=710/852) and from BE COMPLETE 80.5 percent (n=322/400) completed Week 104 and Week 100, respectively.[17] Outcomes are reported for patients who completed to Week 100 of BE COMPLETE (not including 2 ongoing patients).[17]

About Axial Spondyloarthritis

Axial Spondyloarthritis (axSpA), which includes both non-radiographic axSpA (nr-axSpA) and ankylosing spondylitis (AS), is a chronic, immune-mediated, inflammatory disease. Nr-axSpA is defined clinically by the absence of definitive x-ray evidence of structural damage to the sacroiliac joints.[18] AxSpA is a painful condition that primarily affects the spine and the joints linking the pelvis

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and lower spine (sacroiliac joints).[18] The leading symptom of axSpA in a majority of patients is inflammatory back pain that improves with exercise, but not with rest.[18] Other common clinical features frequently include anterior uveitis, enthesitis, peripheral arthritis, psoriasis, inflammatory bowel disease and dactylitis.[18] The overall prevalence of axSpA is 0.3 percent to 1.4 percent of adults.[19,20] Approximately half of all patients with axSpA are patients with nr-axSpA.[18] AxSpA onset usually occurs before the age of 45.[18] Approximately 10 to 40 percent of patients with nr-axSpA progress to ankylosing spondylitis over 2 to 10 years.[18]

About BE MOBILE 1 and BE MOBILE 2

BE MOBILE 1 and BE MOBILE 2 were two Phase 3 studies evaluating the efficacy and safety of bimekizumab-bkzx in the treatment of nr-axSpA and r-axSpA, respectively.[9] The primary endpoint in both studies was the Assessment of SpondyloArthritis international Society 40 percent (ASAS40) response at Week 16.[9] BE MOBILE 1 and BE MOBILE 2 comprised a 16-week double-blind treatment period followed by a 36-week maintenance period.[9] In BE MOBILE 1 and BE MOBILE 2, patients were randomized to bimekizumab-bkzx (160 mg Q4W; N=128 for BE MOBILE 1 and N=221 for BE MOBILE 2) or to placebo (N=126 for BE MOBILE 1 and N=111 for BE MOBILE 2).[9] Patients initially randomized to placebo were switched to bimekizumab-bkzx (160 mg Q4W) at Week 16.[9] At Week 52, those who completed either study were eligible to be enrolled into BE MOVING.[3] Of 254 nr-axSpA patients and 332 r-axSpA patients originally randomised to bimekizumab-bkzx or placebo in BE MOBILE 1 and 2, respectively, 494 patients entered BE MOVING at Week 52.[3]

About BIMZELX (bimekizumab-bkzx)

BIMZELX is a humanized monoclonal IgG1 antibody that is designed to selectively inhibit both interleukin 17A (IL-17A) and interleukin 17F (IL-17F), two key cytokines driving inflammatory processes.[21] Elevated levels of IL-17A and IL-17F are found in lesional psoriatic skin.[21 21]

The approved indications for BIMZELX in the U.S. are:[21]

- **Plaque psoriasis**: BIMZELX is approved for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy
- **Psoriatic arthritis**: BIMZELX is indicated for the treatment of adult patients with active psoriatic arthritis
- **Non-radiographic axial spondyloarthritis**: BIMZELX is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation

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- **Ankylosing spondylitis**: BIMZELX is indicated for the treatment of adult patients with active ankylosing spondylitis

BIMZELX U.S. IMPORTANT SAFETY INFORMATION

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Suicidal Ideation and Behavior

BIMZELX (bimekizumab-bkzx) may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, advise to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

Infections

BIMZELX may increase the risk of infections. Do not initiate treatment with BIMZELX in patients with any clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing BIMZELX. Instruct patients to seek medical advice if signs or symptoms suggestive of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and do not administer BIMZELX until the infection resolves.

Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the use of BIMZELX in patients with active TB infection. Initiate treatment of latent TB prior to administering BIMZELX. Consider anti-TB therapy prior to initiation of BIMZELX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients for signs and symptoms of active TB during and after treatment.

Liver Biochemical Abnormalities

Elevated serum transaminases were reported in clinical trials with BIMZELX. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline, periodically during treatment with BIMZELX and according to routine patient management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt BIMZELX until a diagnosis of liver injury is excluded. Permanently discontinue use of BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Avoid use of BIMZELX in patients with acute liver disease or cirrhosis.

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Inflammatory Bowel Disease
Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX. Avoid use of BIMZELX in patients with active IBD. During BIMZELX treatment, monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

Immunizations
Prior to initiating therapy with BIMZELX, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with BIMZELX.

Most Common Adverse Reactions
Most common (≥ 1%) adverse reactions in plaque psoriasis include upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, Herpes Simplex infections, acne, folliculitis, other candida infections, and fatigue.

Most common (≥ 2%) adverse reactions in psoriatic arthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infection.

Most common (≥ 2%) adverse reactions in non-radiographic axial spondyloarthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infection.

Most common (≥ 2%) adverse reactions in ankylosing spondylitis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infection.

Please see Important Safety Information below and full U.S. prescribing information at www.ucb-usa.com/bimzelx-prescribing-information.pdf and www.BIMZELX.com.

About BIMZELX® ▼ (bimekizumab) EU/EEA*

The approved indications for bimekizumab▼ in the European Union are:[22]

- **Plaque psoriasis:** Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
- **Psoriatic arthritis:** Bimekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response

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or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).

- **Axial Spondyloarthritis:** Bimekizumab is indicated for the treatment of adults with active non radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C reactive protein (CRP), and/or magnetic resonance imaging (MRI), who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs), and for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.
- **Hidradenitis suppurativa:** Bimekizumab is indicated for the treatment of active moderate to severe hidradenitis suppurativa (HS; acne inversa) in adults with an inadequate response to conventional systemic HS therapy.

The label information may differ in other countries where approved. Please check local prescribing information.

BIMZELX® ▼ (bimekizumab) EU/EEA* Important Safety Information

The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%, 14.6%, 16.3%, 8.8% in plaque psoriasis, psoriatic arthritis, axial spondyloarthritis (axSpA) and hidradenitis suppurativa, respectively) and oral candidiasis (7.3%, 2.3%, 3.7%, 5.6% in PSO, PsA, axSpA and HS, respectively). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, vulvovaginal mycotic infection (including vulvovaginal candidiasis), headache, rash, dermatitis and eczema, acne, injection site reactions, fatigue. Elderly may be more likely to experience certain adverse reactions such as oral candidiasis, dermatitis and eczema when using bimekizumab.

Bimekizumab is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients and in patients with clinically important active infections (e.g. active tuberculosis).

Bimekizumab may increase the risk of infections. Treatment with bimekizumab must not be initiated in patients with any clinically important active infection. Patients treated with bimekizumab should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy, treatment should be discontinued until the infection resolves. Prior to initiating treatment with bimekizumab, patients should be evaluated for tuberculosis (TB)

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infection. Bimekizumab should not be given in patients with active TB. Patients receiving bimekizumab should be monitored for signs and symptoms of active TB.

Cases of new or exacerbations of inflammatory bowel disease have been reported with bimekizumab. Bimekizumab is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, bimekizumab should be discontinued and appropriate medical management should be initiated.

Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, administration of bimekizumab should be discontinued immediately and appropriate therapy initiated.
Live vaccines should not be given in patients treated with bimekizumab.

Please consult the summary of product characteristics in relation to other side effects, full safety and prescribing information.

European SmPC date of revision: August 2024. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

*EU/EEA means European Union/European Economic Area

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▼ *This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.*

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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 9,000 people in approximately 40 countries, the company generated revenue of €5.3 billion in 2023. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

Forward looking statements

This press release may contain 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: 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, will progress to product approval 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 differences 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's 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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