UCB News

BIMZELX®▼ (bimekizumab) Receives First Positive Health Technology Assessment Worldwide

- The UK's National Institute for Health and Care Excellence published its final Technology Appraisal Guidance recommending bimekizumab as a treatment option for adults with severe plaque psoriasis
- This first positive health technology assessment worldwide recognizes the value that bimekizumab can bring to patients, healthcare systems and societies

Brussels, Belgium – 6th September 2021 – 0700 CEST – UCB, a global biopharmaceutical company, today announced that the National Institute for Health and Care Excellence (NICE), the UK health technology assessment body that appraises new medicines for use in England and Wales, has published its final Technology Appraisal Guidance (TAG) recommending BIMZELX® (bimekizumab) as a treatment option for adults with severe plaque psoriasis who have not responded to other systemic treatments, or if these treatments are contraindicated, or not tolerated.[1] This positive guidance is the outcome of the first health technology assessment for bimekizumab worldwide.

"The positive health technology assessment by NICE recognizes the value that bimekizumab can bring to patients, to healthcare systems and to societies, and is underpinned by UCB's commitment to ensuring access to our innovative medicines in a timely manner," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. "We are delighted with the speed in which bimekizumab could be available to psoriasis patients in England and Wales, and support NICE's appraisal of our new psoriasis treatment option."

Bimekizumab is the first medicine to be evaluated and recommended through NICE's new Expedited Low-Risk Fast Track Appraisal, and National Health Service (NHS) funding for bimekizumab could be available in England and Wales within approximately one month.[1]

NICE made its recommendations based on a submission that included efficacy and safety data from the bimekizumab Phase 3 clinical program in psoriasis.[1] It considered that evidence from these trials showed that bimekizumab was more effective than adalimumab, secukinumab and ustekinumab.[1] NICE also concluded that indirect comparisons suggested that bimekizumab was similarly or more effective than other biological treatments, including risankizumab, brodalumab and ixekizumab.[1]

Further health technology assessments of bimekizumab are underway in countries in the European Union (EU), with decisions anticipated later in the year.

In August 2021, bimekizumab received marketing authorization in Great Britain,[2] and in countries of the EU,[3] for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Notes to Editors:

About BIMZELX (bimekizumab)
Bimekizumab is a humanized IgG1 monoclonal antibody that selectively binds with high affinity to IL-17A, IL-17F and IL-17AF cytokines, blocking their interaction with the IL-17RA/IL-17RC receptor complex.[3] Elevated concentrations of IL-17A and IL-17F have been implicated in the pathogenesis of several immune-mediated inflammatory diseases including plaque psoriasis.[3] Bimekizumab inhibits these proinflammatory cytokines, resulting in the normalization of skin inflammation and, as a consequence, improvement in clinical symptoms associated with psoriasis.[3]

Bimzelx®▼ (bimekizumab) EU/EEA* Important Safety Information
The most frequently reported adverse reactions with bimekizumab were upper respiratory tract infections (14.5%) (most frequently nasopharyngitis) and oral candidiasis (7.3%). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, headache, 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.

*EU/EEA means European Union/European Economic Area

Bimekizumab is contraindicated in patients with hypersensitivity to the active substance or 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 administered 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. Prior to initiating treatment with bimekizumab, patients should be evaluated for tuberculosis (TB) infection. Bimekizumab should not be given in patients with active TB and 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. https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf

Last accessed: September 2021.

▼ *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.*

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 8,400 people in nearly 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 UCB
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: 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, 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.

UCB is providing this information, including forward-looking statements, only as of the date of this press release and it does not reflect any potential impact from the evolving COVID-19 pandemic, unless indicated otherwise. UCB is following the worldwide developments diligently to assess the financial significance of this pandemic to UCB. UCB 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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References

[1] NICE Technology Appraisal Guidance. Bimekizumab for treating moderate to severe plaque psoriasis. https://www.nice.org.uk/guidance/ta723 Last accessed September 2021

[2] BIMZELX (bimekizumab) GB Summary of Product Characteristics https://bit.ly/Bimzelx-SmPC-Pre-filled-Syringe https://bit.ly/Bimzelx-SmPC-Pre-filled-Pen. Last accessed September 2021

[3] BIMZELX (bimekizumab) EU Summary of Product Characteristics https://www.ema.europa.eu/en/documents/product-information/bimzelx-epar-product-information_en.pdf. Last accessed September 2021