UCB's bimekizumab demonstrates positive results in early development in patients with psoriatic arthritis

- Bimekizumab is a highly selective monoclonal antibody that inhibits the activity of both IL-17A and IL-17F, key pro-inflammatory cytokines expressed in several inflammatory diseases[1,2]
- In this early proof of concept study, bimekizumab showed fast and sustained efficacy on disease activity measures in both skin and joints and was well-tolerated[3]

Brussels, Belgium – 10 June, 11:20 CET – UCB today presented results from a Phase 1B study evaluating pharmacokinetics, safety, tolerability and preliminary efficacy of multiple doses of bimekizumab in patients with psoriatic arthritis (PsA) who had inadequate responses to at least one disease-modifying anti-rheumatic drug (DMARD) and/or one biologic. A total of 52 patients were randomized to receive either bimekizumab (N=38) or placebo (N=14). In the Phase 1B study with a limited patient and exposure set, bimekizumab showed fast and sustained efficacy on disease activity measures in both skin and joints and was well-tolerated. These findings were presented at the Annual European Congress of Rheumatology (EULAR 2016) in London, England (8th – 11th June 2016).[3]

"These data strengthen our understanding of bimekizumab and how its unique mechanism of action, which inhibits both IL-17A and IL-17F cytokines, could provide clinical benefits to patients living with immunological diseases such as PsA," said Dominique Baeten, M.D., Ph.D., Professor at the Department of Clinical Immunology and Rheumatology of the Academic Medical Centre/University of Amsterdam. "PsA is a very serious disease with a broad range of symptoms, including swelling and pain in the joints, which can significantly impact a patient's life. While we've seen advancements in the treatment of PsA with the introduction of biologics, it's crucial that we keep looking for newer and potentially better ways to control this devastating condition, especially in patients who aren't responding to existing therapies."

Psoriatic arthritis affects approximately 0.3% to 1% of the population and is primarily characterized by joint and skin manifestations, with patients typically experiencing a combination of both psoriatic and arthritic symptoms causing skin and nail abnormalities and progressive, disabling joint damage and reduced quality of life.[4,5] New treatment options are needed for this serious disease.

Bimekizumab is an investigational humanized IgG1 monoclonal antibody specifically designed to potently and selectively inhibit the biological function of both IL-17A and IL-17F, which are key pro-inflammatory cytokines involved in chronic inflammatory processes driving the pathophysiology of many severe diseases including skin and joint disorders, like PsA.[1,2]

"The results of this study demonstrate the potential of bimekizumab for patients living with PsA, who are in constant need for new treatment options that can target uncontrolled inflammation and suppress both the difficult joint and skin-related symptoms they experience," said Emmanuel

Caeymaex, Head of Immunology and Executive Vice President at UCB, Immunology Patient Value Unit, UCB. “With these study results, we can now confidently focus on progressing the bimekizumab clinical program and look forward to extending our robust immunology pipeline as part of our continued commitment to bringing more targeted treatment options to this patient community.”

The study evaluated multiple doses of bimekizumab compared to placebo for safety, tolerability, and efficacy, as measured by Psoriasis Area and Severity Index (PASI) and American College of Rheumatology (ACR) score. Bimekizumab demonstrated fast onset of response for both skin and joints with ACR20 response rates (RR) of 80% for the top 3 pooled doses (n=30) compared to a response rate of 17% in the placebo group (n=12) by Week 8. Additionally, findings showed a PASI90 RR of 87% (n=15) for patients receiving the top three doses of bimekizumab versus 0% (n=5) in the placebo group. Using a Bayesian statistical analysis, there was high posterior probability (>99%) that the ACR20 RR of bimekizumab at week 8 was greater than those reported for current standard of care biologic treatments, including anti-IL-17A therapies. All doses of bimekizumab were well-tolerated. No treatment-related serious adverse events (AEs) were reported and there were no treatment-related discontinuations.[3]

About Bimekizumab

Bimekizumab is an investigational monoclonal antibody specifically designed to potently and selectively inhibit the biological function of both IL-17A and IL-17F, two key proinflammatory cytokines. IL-17A and IL-17F are involved in chronic inflammatory processes that drive many severe skin and joint diseases. It is planned that dose-ranging studies for bimekizumab will start this year. Bimekizumab is not approved by any regulatory authority worldwide.

References

1. Johansen et al. Characterization of the interleukin-17 isoforms and receptors in lesional psoriatic skin. Br J Dermatol. 2009;160: 319-324.
2. Van Baarsen et al. Heterogeneous expression pattern of interleukin 17A (IL-17A), IL-17F and their receptors in synovium of rheumatoid arthritis, psoriatic arthritis and osteoarthritis: possible explanation for nonresponse to anti-IL-17 therapy?. Arthritis Res Ther. 2014; 16(4): 1-10.
3. Glatt S., et al. Bimekizumab, a Monoclonal Antibody that Inhibits Both IL-17A and IL-17F, Produces a Profound Response in Both Skin and Joints: Results of an Early-Phase, Proof-of-Concept Study in Psoriatic Arthritis. Presented at the European League Against Rheumatism (EULAR) 2015 Congress. Abstract # OP0108.
4. Gladman D.D., Antoni C., Mease P. et al. Psoriatic arthritis: epidemiology, clinical features, course, and outcome. Ann Rheum Dis. 2005; 64 Suppl 2: ii14-7.
5. Kavanaugh A., Fransen, A., Defining remission in psoriatic arthritis. Clin Exp Rheumatol 2006; 24 (suppl. 43): S83-S87.

# # #

UCB News

For further information, UCB:

Corporate Communications	Investor Relations	Brand Communications
France Nivelle, Global Communications, UCB T +32.2.559.9178, france.nivelle@ucb.com Laurent Schots, Media Relations, UCB T+32.2.559.92.64, Laurent.schots@ucb.com	Antje Witte, Investor Relations, UCB T +32.2.559.94.14, antje.witte@ucb.com	Andrea Levin Christopher, Immunology Communications, UCB T +1.404.483.7329 andrea.levin@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 more than 7 700 people in approximately 40 countries, the company generated revenue of € 3.9 billion in 2015. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements - UCB

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial information, expected legal, political, regulatory or clinical results and other such estimates and results. By their nature, such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions which could cause actual results to differ materially from those that may be 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, 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, product liability claims, challenges to patent protection for products or product candidates, 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. UCB is providing this information 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 a change in its expectations.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed. Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.