UCB News

UCB's Key Pipeline Molecule Bimekizumab Demonstrated Improved Outcomes for Ankylosing Spondylitis Patients

- New Phase 2b bimekizumab data showed the novel investigational molecule delivered improvements in disease activity and in important patient-reported outcomes, such as pain, fatigue, morning stiffness, function and quality of life for patients with ankylosing spondylitis.
- Improvements are hypothesized to be associated with bimekizumab's mechanism of action, which potently and selectively neutralizes both IL-17A and IL-17F cytokines.[i]

Brussels, Belgium – 14 June 2019 – UCB, a global biopharmaceutical company, announced new Phase 2b data on the company's key pipeline molecule, bimekizumab – a novel humanized monoclonal IgG1 antibody that potently and selectively neutralizes both IL-17A and IL-17F cytokines – that showed improvements in a range of important health-related domains and general well-being for patients with active ankylosing spondylitis (AS).[ii] Results from this study, which evaluated multiple treatment doses, were shared for the first time today at the Annual European Congress of Rheumatology (EULAR 2019), in Madrid.

"AS is a chronic immune-mediated inflammatory disease primarily affecting the sacroiliac joints and spine that can severely impair patients' lives.[iii] Bimekizumab, which selectively neutralizes both inflammatory cytokines IL-17A and IL-17F, has been shown to more potently suppress inflammation than targeting IL-17A alone in preclinical research.[iv] The new Week 12 data from the Phase 2b AS study suggest that bimekizumab may deliver results that improve disease activity and outcomes that are most important from the patient perspective, like pain, fatigue, stiffness, mobility, and function," said Emmanuel Caeymaex, Head of Immunology and Executive Vice President, Immunology Patient Value Unit, UCB.

The safety and efficacy of bimekizumab have not been established, and it is not approved by any regulatory authority worldwide. Bimekizumab is now in Phase 3 trials, where the safety and efficacy are being evaluated in AS, non-radiographic axial spondyloarthritis, psoriatic arthritis (PsA) and psoriasis.

Week 12 results from the Phase 2b trial showed that up to four-times the number of bimekizumab-treated patients achieved at least a 50% improvement in the key symptoms impacting patients with AS, including pain, fatigue, morning stiffness and function, compared to placebo.[ii] On the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) scale, which measures symptoms including fatigue, pain and stiffness, BASDAI 50 responses were achieved in 23.7–47.5% of patients across the different bimekizumab treatment doses, compared to 11.9% for placebo.[ii] Bimekizumab-treated patients also reported a higher level of improvement in physical function (i.e. felt less restricted by their condition) and a better quality of life, in addition to an improvement in their overall disease activity, compared to placebo.[ii] Improvements were observed in all bimekizumab-treated patients, irrespective of the dose regimen.[ii]

The safety profile was consistent with previous bimekizumab studies in AS and PsA, with no new safety findings observed.[ii,iv,v] The most frequent treatment emergent adverse events were nasopharyngitis and

headache.[v] The overall incidence of treatment emergent adverse events was similar for bimekizumab treated-patients compared to placebo.[ii,v]

About the Phase 2b trial NCT02963506[ii,v]

The main purpose of this Phase 2b study was to assess the 12-week efficacy and safety of bimekizumab in patients with active AS across a range of treatment doses. The objective of this further analysis was to assess the impact of bimekizumab on patient-reported and quality of life (QoL) outcomes at Week 12 in these patients. In this 48-week study (double blind to Week 12 then dose blind to Week 48), 303 patients with active AS (Bath Ankylosing Spondylitis Disease Activity Index [BASDAI] ≥4; spinal pain ≥4 [0–10 numerical rating scale]) were randomized 1:1:1:1:1 to receive subcutaneous bimekizumab 16mg (n=61), 64mg (n=61), 160mg (n=60), 320mg (n=61) or placebo (n=60) every four weeks for 12 weeks. Secondary and other endpoints included BASDAI, ≥50% improvement in BASDAI (BASDAI 50), Bath Ankylosing Spondylitis Functional Index (BASFI), Ankylosing Spondylitis Quality of Life (ASQoL) and Patient's Global Assessment of Disease Activity (PGADA) at Week 12. Safety was also assessed.

Overall, 297 (98.0%) patients completed the 12-week double-blind period. Baseline scores on patient-reported and QoL outcomes were similar across treatment groups. All bimekizumab doses were associated with greater reductions from baseline in individual BASDAI components, as compared to placebo, including: fatigue (-1.6 to -2.5 vs -0.8 respectively); neck, back or hip pain (-2.0 to -3.3 vs -1.2) and discomfort due to tenderness to touch or pressure (-1.6 to -3.0 vs -1.1); level of morning stiffness (-2.5 to -3.5 vs -1.2) and duration of morning stiffness (-1.7 to -3.3 vs -1.4). There were also greater improvements with bimekizumab compared to placebo respectively for BASFI (-1.4 to -2.2 vs -0.6), ASQoL (-2.3 to -4.6 vs -1.3) and PGADA (-1.9 to -3.3 vs -1.0). The overall incidence of treatment-emergent adverse events was 89/243 (36.6%) for bimekizumab-treated patients compared to 23/60 (38.3%) for placebo; the majority were of mild or moderate intensity.

About Bimekizumab

Bimekizumab is an investigational novel humanized monoclonal IgG1 antibody that potently and selectively neutralizes both IL-17A and IL-17F, two key cytokines driving inflammatory processes.[i] IL-17A and IL-17F have similar pro-inflammatory functions and independently cooperate with other inflammatory mediators to drive chronic inflammation and damage across multiple tissues.

Previous early phase clinical studies in psoriasis and psoriatic arthritis have suggested that bimekizumab's dual neutralization of both IL-17A and IL-17F may provide a new targeted approach for the treatment of immune-mediated inflammatory diseases.[i,iv,vi] Preclinical results in disease-relevant cells have shown that neutralizing IL-17F in addition to IL-17A reduces skin and joint inflammation, as well as pathological bone formation to an extent greater than inhibition of IL-17A alone.[vi,vii,viii]

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.christopher@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 in immunology and neurology. With 7,500 people in approximately 40 countries, the company generated revenue of € 4.6 billion in 2018. 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.

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