UCB Reinforces Commitment to Advancing Care in Hidradenitis Suppurativa with Six Abstracts at SHSA 2023

• Results from the Phase 3 studies evaluating impact of bimekizumab on pain and health-related quality of life in moderate to severe hidradenitis suppurativa will be shared in two oral presentations

Brussels (Belgium), 13 October 2023 – 18:00 (CEST) – UCB, a global biopharmaceutical company, today announced that it will present six abstracts in hidradenitis suppurativa (HS) at the 8th Annual Symposium on Hidradenitis Suppurativa Advances (SHSA), October 13–15th in Phoenix, Arizona, U.S. Data and analyses in HS will be presented across two oral presentations and four posters.

“The data to be presented at SHSA reinforce our commitment to advancing medicines in areas where patients have the greatest need,” said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB. “These new analyses complement and build on the bimekizumab Phase 3 evidence in hidradenitis suppurativa shared to date and further highlight the potential of bimekizumab for the treatment of this chronic, painful, inflammatory condition.”

An oral presentation will showcase 16-Week data from the BE HEARD I and BE HEARD II Phase 3 studies evaluating the impact of bimekizumab on pain in moderate to severe HS. In a second oral presentation, 48-Week data evaluating the impact of bimekizumab on health-related quality of life will be shared. Three poster presentations will include subgroup analyses from the two Phase 3 studies, including 48 Week data in U.S. patients. A disease-focused poster presentation will share barriers to accessing timely and adequate treatment, care and resources for HS patients in select U.S. states.

The safety and efficacy of bimekizumab in HS have not been established, and it is not approved for use in HS by any regulatory authority worldwide.

**UCB-sponsored data presentations at SHSA 2023**

• Bimekizumab in Moderate to Severe Hidradenitis Suppurativa: 48-Week HiSQoL data from BE HEARD I & II
  Kirby JS, Jemec GB, Thorlacius L, Garg A, Kimball AB, Rolleri R, Muller E, Lambert J, Ingram JR
  Oral presentation: Saturday, October 14, 16:05–16:15 MST

• Bimekizumab Impact on Pain in Moderate to Severe Hidradenitis Suppurativa: Week 16 Results from BE HEARD I & II
  Oral presentation: Saturday, October 14, 16:35–16:45 MST

• Bimekizumab in Black/African-American Patients with Moderate to Severe Hidradenitis Suppurativa in BE HEARD I & II

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Poster

- Bimekizumab in Patients with Moderate to Severe Hidradenitis Suppurativa by Subgroup: Week 16
  Data from BE HEARD I & II
  Poster

- Bimekizumab in Moderate to Severe Hidradenitis Suppurativa: 48-Week Efficacy in US Patients from BE HEARD I & II
  Poster

- Barriers to Accessing Timely and Adequate Treatment, Care, and Resources for Patients with HS in Select US States
  Poster

Notes to editors:

About Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS) is a chronic, recurring, painful, and debilitating inflammatory skin disease, that is associated with systemic manifestations.1,2 The main symptoms are nodules, abscesses, and pus-discharging fistulas (channels leading out of the skin) which typically occur in the armpits, groin, and buttocks.1,2 People with HS experience flare-ups of the disease as well as severe pain, which can have a major impact on quality of life.1,2 HS, most commonly develops in early adulthood and affects approximately one percent of the population in most studied countries.1,2 Approximately one-third of people with HS have a family history of HS, and lifestyle factors such as smoking and obesity can also play a crucial role in the clinical course of HS.1,2 The symptoms of pain, discharge and scarring are not only a physical burden. People with HS also experience stigma: worrying about, or directly experiencing, negative attitudes and reactions from society in response to their symptoms.3 These feelings can lead to embarrassment, social isolation, low self-esteem and sexual life impairment, and impact all areas of life, including interpersonal relationships, education, and work.4

About BE HEARD I and BE HEARD II

BE HEARD I and BE HEARD II are randomized, double-blind, placebo-controlled, parallel-group, multicenter, Phase 3 studies designed to evaluate the efficacy and safety of bimekizumab in adults with moderate to severe hidradenitis suppurativa (HS).5,6 The two studies had a combined enrolment of 1,014 participants with a diagnosis of moderate to severe HS.5,6 The primary endpoint in both studies was HiSCR50 at Week 16.5,6

About bimekizumab

Bimekizumab 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.7 The therapeutic indications in the European Union are:

- Plaque psoriasis: Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.8
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 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.

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

In the U.S., the efficacy and safety of bimekizumab have not been established for any indication and it is not approved by the U.S. Food and Drug Administration.

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% in plaque psoriasis (PSO), psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA), respectively) and oral candidiasis (7.3%, 2.3%, 3.7% in PSO, PsA and axSpA, respectively). Common adverse reactions (≥1/100 to <1/10) were oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, 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 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) 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: June 2023.

*EU/EEA means European Union/European Economic Area
▼ 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
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References