UCB News

UCB Showcases Strength of the Expanding Dermatology Portfolio at the 31st EADV Congress

- 20 abstracts highlight research in key disease areas including psoriasis and psoriatic arthritis
- New three-year data to be presented on BIMZELX®▼(bimekizumab) in the treatment of moderate to severe plaque psoriasis

Brussels (Belgium), 1st September 2022 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced that it will present 20 abstracts across its dermatology portfolio at the 31st European Academy of Dermatology and Venereology (EADV) Congress being held in Milan, Italy from September 7-10. The abstracts, accepted for poster presentation, underscore UCB's commitment to delivering innovative solutions that aim to address the unmet needs of people living with dermatological diseases.

"We are proud to present new data from our expanding dermatology portfolio at the 31st EADV Congress. At UCB, our ambition is to transform the lives of people living with severe diseases such as psoriasis and psoriatic arthritis, and the strength of scientific data at this year's congress reaffirms our long-standing commitment to raising standards of care," said Emmanuel Caeymaex, Executive Vice President, Immunology Solutions and Head of U.S., UCB.

Key data to be presented on bimekizumab include new results from the BE BRIGHT open-label extension study evaluating maintenance of response with bimekizumab through three years in patients with moderate to severe plaque psoriasis who responded at week 16. New analysis of pooled safety data from up to three years of treatment with bimekizumab in the treatment of moderate to severe plaque psoriasis across Phase 2 and 3 clinical trials will also be presented.

For certolizumab pegol, data to be presented include three year data from three Phase 3 trials evaluating the association of patient reported outcomes (Dermatology Life Quality Index, DLQI 0/1) with relative skin clearance improvements (Psoriasis Area and Severity Index, PASI) in subgroups of adult patients with moderate to severe plaque psoriasis.

The following is a guide to the UCB-sponsored data presentations at the 31st EADV Congress:

Bimekizumab e-Posters: Psoriasis

- Bimekizumab maintenance of response through three years in patients with moderate to severe plaque psoriasis who responded at Week 16: Results from the BE BRIGHT open-label extension

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B. Strober, Y. Tada, U. Mrowietz, M. Lebwohl, P. Foley, R.G. Langley, J. Barker, M. Wang, V. Vanvoorden, B. Szilagyi, V. Ciaravino, C. Paul
#P1491

- Bimekizumab safety in patients with moderate to severe plaque psoriasis: Analysis of pooled data from up to three years of treatment in Phase 2 and 3 clinical trials
  K.B. Gordon, R.G. Langley, R.B. Warren, Y. Okubo, D. Rosmarin, M. Lebwohl, L. Peterson, C. Madden, D. de Cuyper, N. Nunez Gomez, D. Thaçi
  #P1569

- Bimekizumab versus secukinumab in plaque psoriasis: Cumulative clinical and health related quality of life benefit through 2 years of the BE RADIANT Phase 3b trial and open label extension
  M. Lebwohl, P. Brunner, J. Soung, K. Ghoreschi, J. Weisman, L. Peterson, B. Szilagyi, F. Staelens, V. Ciaravino, WH. Boehncke
  #P1561

- Bimekizumab efficacy through 96 weeks in patients with moderate to severe plaque psoriasis: patient-reported outcomes from the BE RADIANT Phase 3b trial
  G. Kokolakis, R.G. Langley, A.B. Gottlieb, M. Augustin, N. Magnolo, B. Elewski, R. Vender, A. López Ferrer, R. Warham, S. Wiegratz, V. Ciaravino, S.R. Feldman
  #P1595

- Bimekizumab efficacy and safety through two years in patients with moderate psoriasis: Analysis of pooled data from five Phase 3/3b clinical trials
  A. Blauvelt, L. Stein Gold, M. Gooderham, B. Strober, A. Pinter, J.M. Carrascosa, P. Gisondi, J. Bleier, C. Madden, D. Deherder, N. Nunez Gomez, R.B. Warren
  #1573

- Bimekizumab efficacy in high-impact areas for patients with moderate to severe plaque psoriasis: Pooled results through two years from the BE SURE and BE RADIANT Phase 3 trials
  J.F. Merola, A.B. Gottlieb, A. Morita, J.M. Carrascosa, B. Elewski, N. Tilt, S. Wiegratz, K. Wixted, U. Mrowietz
  #P1467

- Bimekizumab efficacy and safety through three years in patients with moderate to severe plaque psoriasis: Long-term results from the BE SURE randomised controlled trial and the BE BRIGHT open-label extension
  D. Thaçi, R. Vender, M. de Rie, C. Conrad, J. Soung, B. Strober, M. Wang, N. Cross, D. Deherder, N. Nunez Gomez, A.B. Gottlieb
  #P1572

- Bimekizumab efficacy over two years in patients with moderate to severe plaque psoriasis with scalp and nail involvement who switched from adalimumab, ustekinumab, or secukinumab: Results from the BE SURE, BE VIVID, BE BRIGHT, and BE RADIANT Phase 3/3b trials

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R.B. Warren, B. Strober, A. Pinter, A. Blauvelt, M. Sebastian, L. Davis, V. Vanvoorden, S. Wiegratz, M. Gooderham
#P1478

- A network meta-analysis of cumulative clinical benefit of anti-IL biologics for the treatment of moderate to severe psoriasis over 48–52 weeks
  R.B. Warren, A. Armstrong, M. Lebwohl, K. Gordon, C. Leonardi, N. Nunez Gomez, V. Taieb, S. Vermeersch, S. Kiri, A. Körber
  #P1571

- Both IL-17RA and IL-17RC receptor complexes are required for IL-17A- and IL-17F-driven inflammation
  A. Maroof, A. Manghera, S. Shaw
  #P1562

- Single-cell sequencing of freshly isolated cells from lesional and peri-lesional skin to explore cellular origins of IL-17 isoforms in psoriasis
  A. Skelton, K. Pappelbaum, X. Li, V. Oji, A. Tsianakas, M. Page, M. Bertolini, S. Shaw, A. Maroof
  #P1563

Bimekizumab e-Posters: Psoriatic Arthritis

- Efficacy and safety of bimekizumab in patients with active psoriatic arthritis and inadequate response to tumour necrosis factor inhibitors: 16-week results from BE COMPLETE, a Phase 3, randomised, double-blind placebo-controlled study
  R.B. Warren, A. Asahina, P. Gisondi, L.E. Kristensen, D. McGonagle, P.J. Mease, J.F. Merola, B. Strober, D. Thaçi, B. Ink, D. Assudani, R. Bajracharya, J. Coarse, A.B. Gottlieb
  #P0479

- Efficacy and safety of bimekizumab in bDMARD-naïve patients with psoriatic arthritis: 24-week results from BE OPTIMAL, a Phase 3, multicentre, randomised, placebo-controlled, active reference study
  J.F. Merola, A. Asahina, F. Behrens, A.B. Gottlieb, M. Lebwohl, D. McGonagle, P.J. Mease, L. Puig, W.H. Boehncke, B. Ink, D. Assudani, R. Bajracharya, J. Coarse, P. Gisondi
  #P0480

Bimekizumab e-Posters: Axial Spondyloarthritis

- Bimekizumab in patients with active non-radiographic axial spondyloarthritis and active ankylosing spondylitis: 24-week efficacy and safety from the BE MOBILE Phase 3 studies
  D. Thaçi, X. Baraliakos, J.F. Merola, D. Poddubnyy, F. van den Bosch, M. Oortgiesen, C. Fleurinck, A.M. Ellis, T. Vaux, J. Shepherd-Smith, A. Marten, D. van der Heijde
  #P0477

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Certolizumab pegol e-Posters*: Psoriasis

- Stable plasma concentration of certolizumab pegol is associated with clinical improvement among patients with moderate to severe plaque psoriasis: Data from CIMPASI-1 and CIMPASI-2
  L. Puig, P. Gisondi, A. Pinter, J.M. López Pinto, I.D. Pousa, J. Sidhu, N. Tilt, M. Lebwohl
  #P1570

- Association of DLQI 0/1 with relative PASI improvements in subgroups of patients with moderate to severe plaque psoriasis treated with certolizumab pegol: Three-year results from three Phase 3 trials (CIMPASI-1, CIMPASI-2, and CIMPACT)
  S. McBride, J. Węgłowska, P. Wolf, P. Foley, F. Fierens, N. Tilt, C. de la Loge, B. Elewski
  #P1492

- Certolizumab pegol for psoriasis in routine clinical practice (CIMREAL): Patient characteristics and interim results
  R.B. Warren, E. Lazaridou, D. Vidal Sarro, O. Vanhooteghem, G. Fabbrocini, L. Bianchi, M. Perrussel, H. Kadima, T. Kumke, J. Hee, M. Bari, F. Fierens, B. Korge
  #P1621

- Certolizumab pegol for psoriasis in routine clinical practice (CIMREAL): Interim results in women of child-bearing potential
  K. Asadullah, M. Concetta Fargnoli, C. De Simone, T. Boyé, T. Hillary, A. Machovcova, A. Makrygeorgou, K. Papp, M. Bari, T. Kumke, I.D. Pousa, F. Fierens, A. Flórez, E. Papadavid
  #P1623

**Certolizumab pegol should only be used during pregnancy if clinically needed*

Disease State e-Posters: Psoriasis

- Treatment preferences in young bio-naïve patients with moderate to severe psoriasis – preliminary results from a mixed-method study across the Nordic countries
  G.L. Mortensen, F. Balieva, L. Catton, B. Wilson Claréus, K. Danielsen, F. Fierens, L. Iversen, L. Koulu, R. Pasternack, A. Osmancevic, L. Skov
  #P1529

- Practical tools to manage women with psoriasis: From dermatologists to dermatologists
  A. Dattola, M.M. Constantin, I.D. Pousa, Á. González-Cantero, T. Hillary, C.E. Kleyn, N. Magnolo
  #P1535

Notes to editors:

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.[1]

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In August 2021, bimekizumab was approved in the European Union (EU)/European Economic Area (EEA) and in Great Britain, for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.[2,3] The label information may differ in other countries. Please check local prescribing information.

The safety and efficacy of bimekizumab in psoriatic arthritis and axial spondyloarthritis have not been established, and it is not approved for use in psoriatic arthritis or axial spondyloarthritis by any regulatory authority worldwide.

BIMZELX® ▼ (bimekizumab) EU/EEA Important Safety Information in Psoriasis[2]

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.

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

EU summary of product characteristics date of revision May 2022.

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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.*

About Certolizumab pegol in the EU/EEA[4]

In the EU, CIMZIA® (certolizumab pegol) in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active RA in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including MTX, has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Certolizumab pegol in combination with MTX is also indicated for the treatment of severe, active and progressive RA in adults not previously treated with MTX or other DMARDs. Certolizumab pegol has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with MTX.

Certolizumab pegol, in combination with MTX, is also indicated for the treatment of active psoriatic arthritis in adults when the response to previous DMARD therapy has been inadequate. Certolizumab pegol can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

Certolizumab pegol is also indicated in the EU for the treatment of adult patients with severe active axial spondyloarthritis (axSpA), comprising:

- Ankylosing spondylitis (AS) – adults with severe active AS who have had an inadequate response to, or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs).
- Axial spondyloarthritis (axSpA) without radiographic evidence of AS – adults with severe active axSpA without radiographic evidence of AS but with objective signs of inflammation by elevated C-reactive protein (CRP) and/or Magnetic Resonance Imaging (MRI) who have had an inadequate response to, or are intolerant to NSAIDs.

Certolizumab pegol is also indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Cimzia® (certolizumab pegol) EU/EEA Important Safety Information[4]

Cimzia® was studied in 4,049 patients with rheumatoid arthritis (RA) in controlled and open label trials for up to 92 months. The commonly reported adverse reactions (1-10%) in clinical trials with certolizumab pegol and post-marketing were viral infections (includes herpes zoster, papillomavirus, influenza), bacterial infections (including abscess), rash, headache (including migraine), asthenia, leukopenia (including lymphopenia, neutropenia), eosinophilic disorder, pain (any sites), pyrexia, sensory abnormalities, hypertension, pruritus (any sites), hepatitis (including hepatic enzyme increase), injection site reactions, and nausea. Serious adverse reactions include sepsis, opportunistic infections, tuberculosis (including miliary, disseminated and extrapulmonary), herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic oedema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopenia, hypercoagulation (including thrombophlebitis, pulmonary embolism), cerebrovascular accident,

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vasculitis, hepatitis/hepatopathy (includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 4.4% of patients discontinued taking certolizumab pegol due to adverse events vs. 2.7% for placebo.

Certolizumab pegol was initially studied in 325 patients with active axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis) in the AS001 clinical study for up to 4 years, which includes a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 156-week open-label treatment period. Certolizumab pegol was subsequently studied in 317 patients with non-radiographic axial spondyloarthritis in a placebo-controlled study for 52 weeks (AS0006). Certolizumab pegol was also studied in patients with axial spondyloarthritis (including ankylosing spondylitis and non-radiographic axial spondyloarthritis) in a clinical study for up to 96 weeks, which included a 48-week open-label run-in phase (N=736) followed by a 48-week placebo-controlled phase (N=313) for patients in sustained remission (C-OPTIMISE). Certolizumab pegol was also studied in a 96-week open-label study in 89 axSpA patients with a history of documented anterior uveitis flares. In all 4 studies, the safety profile for these patients was consistent with the safety profile in rheumatoid arthritis and previous experience with certolizumab pegol.

Certolizumab pegol was studied in 409 patients with psoriatic arthritis (PsA) in a clinical study for up to 4 years which included a 24-week placebo-controlled phase followed by a 24-week dose-blind period and a 168-week open-label treatment period.

The safety profile for axSpA and PsA patients treated with certolizumab pegol was consistent with the safety profile in RA and previous experience with certolizumab pegol.

Certolizumab pegol was studied in 1112 patients with psoriasis in controlled and open-label studies for up to 3 years. In the Phase III program, the initial and maintenance periods were followed by a 96-week open-label treatment period. The long-term safety profile of certolizumab pegol 400 mg every 2 weeks and certolizumab pegol 200 mg every 2 weeks was generally similar and consistent with previous experience with certolizumab pegol.

Certolizumab pegol is contraindicated in patients with hypersensitivity to the active substance or any of the excipients, active tuberculosis or other severe infections such as sepsis or opportunistic infections, and moderate to severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections (e.g. histoplasmosis, nocardia, candidiasis) have been reported in patients receiving certolizumab pegol. Some of these events have been fatal. Before initiation of therapy with certolizumab pegol, all patients must be evaluated for both active and inactive (latent) tuberculosis infection. If active tuberculosis is diagnosed prior to or during treatment, certolizumab pegol therapy must not be initiated and must be discontinued. If latent tuberculosis is diagnosed, appropriate anti- tuberculosis therapy must be started before initiating treatment with certolizumab pegol.

Reactivation of hepatitis B has occurred in patients receiving a TNF-antagonist including certolizumab pegol who are chronic carriers of the virus (i.e. surface antigen positive). Some cases have had a fatal outcome. Patients should be tested for HBV infection before initiating treatment with certolizumab pegol. Carriers of HBV who require treatment with certolizumab pegol should be closely monitored and in the case of HBV reactivation Certolizumab pegol should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated.

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TNF antagonists including certolizumab pegol may increase the risk of new onset or exacerbation of clinical symptoms and/or radiographic evidence of demyelinating disease including multiple sclerosis; of formation of autoantibodies and uncommonly of the development of a lupus-like syndrome; of severe hypersensitivity reactions. If a patient develops any of these adverse reactions, certolizumab pegol should be discontinued and appropriate therapy instituted.

With the current knowledge, a possible risk for the development of lymphomas, leukaemia or other malignancies in patients treated with a TNF antagonist cannot be excluded. Rare cases of neurological disorders, including seizure disorder, neuritis and peripheral neuropathy, have been reported in patients treated with certolizumab pegol.

Adverse reactions of the haematologic system, including medically significant cytopenia, have been reported with certolizumab pegol. Advise all patients to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever, bruising, bleeding, pallor) while on certolizumab pegol. Consider discontinuation of certolizumab pegol therapy in patients with confirmed significant haematological abnormalities.

The use of certolizumab pegol in combination with anakinra or abatacept is not recommended due to a potential increased risk of serious infections. As no data are available, certolizumab pegol should not be administered concurrently with live vaccines. The 14-day half-life of certolizumab pegol should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on certolizumab pegol should be closely monitored for infections.

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

European SmPC date of revision June 2022. https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf Last Accessed August 2022

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About UCB
UCB, Brussels, Belgium (www.ucb.com) is a global biopharmaceutical company focused on the discovery and development

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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 8,600 people in approximately 40 countries, the company generated revenue of €5.8 billion in 2021. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

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3. BIMZELX® (bimekizumab) GB Summary of Product Characteristics. Available at: https://www.medicines.org.uk/emc/product/12834/smpc#gref. Last accessed: August 2022
4. CIMZIA® (certolizumab pegol) EU Summary of Product Characteristics. June 2022. https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-product-information_en.pdf. Last accessed August 2022.

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