UCB News

New EULAR 2026 data show CIMZIA® (certolizumab pegol) delivered consistent effect in rheumatoid arthritis, regardless of rheumatoid factor (RF) levels

- New *in vitro* and electron microscope data provide further explanation as to why Fc-free CIMZIA® (certolizumab pegol) concentrations and effect may be maintained across RF levels in rheumatoid arthritis.[1] High RF has been linked with lower exposure and reduced responses to Fc-containing TNF inhibitors (e.g., adalimumab)[5,6]
- Findings provide mechanistic support for clinical observations of consistent CIMZIA outcomes across RF levels[1]
- The relevance of CIMZIA's Fc-free molecular structure was reflected in a recent SmPC update confirming that CIMZIA is not bound by rheumatoid factor, does not form immune complexes with RF and is not subject to RF-dependent clearance by macrophages *in vitro*[8]

Brussels (Belgium), 5 June 2026 – 07:00 (CEST) – UCB, a global biopharmaceutical company, today announced the presentation of new data at the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress addressing the clinical relevance of rheumatoid factor (RF) in rheumatoid arthritis (RA) and its implications for TNF inhibitor treatment selection.[1]

The *in vitro* data demonstrated that inflammatory signals increase with other biologics but not Fc-free CIMZIA in patients with high RF, providing mechanistic support to previous clinical observations of CIMZIA efficacy regardless of RF level.[2,3,4]

Elevated RF levels remain common in clinical practice,[5] and high RF has been linked with lower exposure and reduced responses to Fc-containing TNF inhibitors (e.g., adalimumab).[4,6] It is estimated that around one in four patients treated with biologic therapies have high RF levels,[7] which have historically been associated with poorer prognosis and reduced effectiveness of some Fc-containing biologics.[3,7]

The new EULAR data, together with a recent update to the EU Summary of Product Characteristics (SmPC) and Medicines and Healthcare products Regulatory Agency (MHRA), reinforce CIMZIA's differentiated Fc-free structure and its relevance when initiating TNF inhibitor (TNFi) therapy.[8]

"Rheumatoid factor is more than a diagnostic marker, it can meaningfully influence how patients respond to therapy," said Dr. James Galloway, Professor of Rheumatology at King's College London and Honorary Consultant Rheumatologist at King's College Hospital, London. "These EULAR data help explain differences in treatment response seen in patients with high RF and highlight the value of RF-informed decision-making."

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Date of preparation: June 2026 | GL-CZ-2600047

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New EULAR 2026 data clarify the clinical relevance of rheumatoid factor

The new *in vitro* study, presented at EULAR, demonstrated that RF antibodies bind to Fc-containing biologic DMARDs, forming immune complexes that stimulate pro-inflammatory cytokine release from peripheral blood mononuclear cells (PBMCs). In contrast, RF did not bind to Fc-free certolizumab pegol, and no immune complex formation or cytokine induction was observed.[1] These findings provide mechanistic insight into previously reported observations that certolizumab pegol demonstrates consistent efficacy irrespective of RF levels.[2,3,4]

"At UCB, we are committed to generating robust, meaningful evidence that helps support informed and personalized treatment decisions for people living with immune-mediated diseases," said Donatello Crocetta, Chief Medical Officer and Global Head of Medical Affairs, UCB. "The EULAR data, together with the recent EU and MHRA label updates, underscore our continued focus differentiating CIMZIA through science and addressing the diverse needs of people living with rheumatoid arthritis."

These data form part of UCB's broader presence at the 2026 EULAR Annual Meeting, where a total of 27 abstracts will be presented across the UCB immunology portfolio assets in PsA, psoriasis, axial spondyloarthritis, rheumatoid arthritis, and systemic lupus erythematosus.

EU SmPC update reflects Fc-free mechanism

The EU Summary of Product Characteristics (SmPC) for CIMZIA has been updated in Section 5.1 to further describe its Fc-free mechanism of action, reinforcing mechanistic differences from Fc-containing biologics. This update is also reflected in UK product information[8] maintained by the Medicines and Healthcare products Regulatory Agency (MHRA), which publishes the most up-to-date SmPCs as part of a medicine's licensed information.[9] Together with emerging *in vitro* evidence, these data support differentiation of certolizumab pegol in patients with varying RF profiles.

Notes to editors

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About CIMZIA® (certolizumab pegol) in the EU/EEA[8]
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 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
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 Cimzia® 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, vasculitis, hepatitis/hepatopathy (includes cirrhosis), and renal impairment/nephropathy (includes nephritis). In RA controlled clinical trials, 4.4% of patients discontinued taking Cimzia® due to adverse events vs. 2.7% for placebo.

Cimzia 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. Cimzia was subsequently studied in 317 patients with non-radiographic axial spondyloarthritis in a placebo-controlled study for 52 weeks (AS0006). Cimzia 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). Cimzia 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 Cimzia. Cimzia® 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 Cimzia® was consistent with the safety profile in RA and previous experience with Cimzia®.

Cimzia® 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 Cimzia® 400 mg every 2 weeks and Cimzia® 200 mg every 2 weeks was generally similar and consistent with previous experience with Cimzia.

Cimzia® 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 Cimzia®. Some of these events have been fatal. Before initiation of therapy with Cimzia®, all patients must be evaluated for both active and inactive (latent) tuberculosis infection. If active tuberculosis is diagnosed prior to or during treatment, Cimzia® 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 Cimzia®.

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Date of preparation: June 2026 | GL-CZ-2600047

Reactivation of hepatitis B has occurred in patients receiving a TNF-antagonist including Cimzia® 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 Cimzia®. Carriers of HBV who require treatment with Cimzia® should be closely monitored and in the case of HBV reactivation Cimzia® should be stopped and effective anti-viral therapy with appropriate supportive treatment should be initiated.

TNF antagonists including Cimzia® 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, Cimzia® 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 Cimzia®. Adverse reactions of the haematologic system, including medically significant cytopenia, have been reported with Cimzia®. 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 Cimzia®. Consider discontinuation of Cimzia® therapy in patients with confirmed significant haematological abnormalities.

The use of Cimzia® in combination with anakinra or abatacept is not recommended due to a potential increased risk of serious infections. As no data are available, Cimzia® should not be administered concurrently with live vaccines. The 14-day half-life of Cimzia® should be taken into consideration if a surgical procedure is planned. A patient who requires surgery while on Cimzia® 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 April 2026.
https://www.ema.europa.eu/en/documents/product-information/cimzia-epar-productinformation_en.pdf

* EU/EEA means European Union/European Economic Area

Abbreviations: ACR: American College of Rheumatology; AS: ankylosing spondylitis; axSpA: axial spondyloarthritis; CD28: cluster of differentiation 28 (a protein expressed on T cells); CRP: C-reactive protein; DMARDs: disease-modifying antirheumatic drugs; EEA: European Economic Area; EU: European Union; HBV: hepatitis B virus; MRI: magnetic resonance imaging; MTX: methotrexate; NSAIDs: non-steroidal anti-inflammatory drugs; RA: rheumatoid arthritis; RF: rheumatoid factor; TNFis: tumor necrosis factor inhibitors.

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 9,000 people in approximately 40 countries, the company generated revenue of € 7.7 billion in 2025. UCB is listed on Euronext Brussels (symbol: UCB)

Forward-looking statements
This document contains forward-looking statements, including, without limitation, statements containing the words "potential", "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 guaranteeing 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 be materially different from any future results, performance, or achievements expressed or implied by such forward-looking statements contained in this document.
Important factors that could result in such differences include but are not limited to: global spread and impacts of wars, pandemics and terrorism, the general geopolitical environment, climate change, 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, supply chain disruption and business continuity risks; potential or actual data security and data privacy breaches, or disruptions of UCB's information technology systems, product liability claims, challenges to patent protection for products or product candidates, competition from other products including biosimilars or disruptive technologies/business models, changes in laws or regulations, exchange rate fluctuations, changes or uncertainties in laws and/or rules pertaining to tax and duties or the administration of such laws and/or rules, and hiring, retention and compliance of employees. There is no guarantee that new product candidates will be discovered or identified in the pipeline, 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 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

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Given these uncertainties, the public is cautioned not to place any undue reliance on such forward-looking statements. These forward-looking statements are made only as of the date of this document, and do not reflect any potential impacts from the evolving event or risk as mentioned above as well as any other adversity, unless indicated otherwise. The company continues to follow the development diligently to assess the financial significance of these events, as the case may be, to UCB.
UCB expressly disclaims any obligation to update any forward-looking statements in this document, 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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Date of preparation: June 2026 | GL-CZ-2600047