UCB News

New data support the value of CIMZIA® for women living with chronic rheumatic diseases throughout pregnancy and post-partum, and for people living with RA and high rheumatoid factor levels

- Pharmacokinetic data from the CHERISH study presented at EULAR 2024 suggest that women living with chronic immune-mediated diseases can maintain certolizumab pegol dosing regimens throughout pregnancy and post-partum
- An *in vitro* study found that RF antibodies bind to Fc-containing tumor necrosis factor inhibitors (TNFis) but are not able to bind to Fc-free certolizumab pegol – providing molecular insights towards more personalized therapeutic approaches in RA
- A separate post hoc analysis of the phase 3b REALISTIC trial suggests high rheumatoid factor (RF) levels do not affect clinical responses to certolizumab pegol in people living with rheumatoid arthritis (RA) and high rheumatoid factor (RF) levels, who experience consistent disease activity

Brussels (Belgium), 13 June 2024 – 07:00 (CEST) – UCB, a global biopharmaceutical company, will present results from three studies supporting the value of CIMZIA® (certolizumab pegol), a PEGylated fragment crystalized (Fc)-free TNFi, for women of childbearing age living with chronic immune-mediated diseases and people with rheumatoid arthritis (RA) and high rheumatoid factor (RF) levels.[1,2,3] These data will be presented at the European Congress of Rheumatology, EULAR 2024, and provide important evidence to support informed, personalized treatment decisions for patient populations with high unmet need.

CHERISH study results (abstract POS0888)
Results from the open-label, phase 1b CHERISH study in women with immune-mediated diseases, including psoriatic arthritis (PsA), axial spondyloarthritis (axSpA) and rheumatoid arthritis, found that the range of blood plasma concentrations of certolizumab pegol throughout and after pregnancy were similar to those observed in studies of non-pregnant women with PsA, axSpA and RA, suggesting that women may maintain stable therapeutic levels of certolizumab pegol throughout pregnancy and post-partum.[1] While plasma levels were lower during pregnancy than post-partum, they remained consistent throughout pregnancy.[1]

These data build on the comprehensive suite of evidence exploring the use of certolizumab pegol for women of childbearing age living with chronic immune-mediated diseases. Previous studies – CRIB and CRADLE – showed minimal to no transfer from mother to baby through the placenta or breast milk.[4,5] The latest study, CHERISH, expands on the data available by focusing on certolizumab pegol and stability of exposure for the mother.[1] The safety profile observed in the CHERISH study was consistent with the known safety profile of certolizumab pegol, which includes extensive pharmacovigilance data.[1]

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"Women of childbearing age living with chronic immune-mediated diseases are understandably concerned about how to ensure adequate disease control throughout pregnancy while preventing or minimizing exposure for their baby," said Emmanuel Caeymaex, Executive Vice President, Head of Patient Impact, Chief Commercial Officer, UCB. "Through CHERISH and the full body of evidence we have built, we are equipping women and healthcare professionals with the data they need to make informed, personalized decisions around treatment continuation during family planning, pregnancy and breastfeeding. These studies underscore our commitment to serving specific subpopulations of patients with information that is directly relevant to them."

RF-drug interaction research (abstract POS0722)
A further study presented at EULAR provided molecular insights into why individuals living with RA and high RF levels maintain consistent drug concentrations and may experience consistent clinical outcomes when treated with certolizumab pegol compared with Fc-containing TNFis.[3,6] An *in vitro* study found that three different RF antibodies all bound to Fc-containing TNFi adalimumab and enabled the formation of large immune complexes. Conversely, the RFs were unable to interact with certolizumab pegol, due to its lack of Fc domain, and no complexes with RF were formed.[3]

REALISTIC trial results (abstract AB0638)
Insights into the effects of certolizumab pegol in people living with RA and high RF levels were investigated in a post hoc analysis of the double-blind, placebo-controlled, phase 3b REALISTIC trial – also accepted as an abstract at EULAR. Clinical response to certolizumab pegol was analyzed according to the highest quartile RF level compared with the lowest and in people with a previous inadequate response to TNFi versus those with no prior TNFi exposure.[2] Responses were greater with certolizumab pegol versus placebo in all groups. In patients who previously had an inadequate response to TNFis, responses among those who were randomized to placebo were lower in the high RF group compared with the low RF group. By contrast, clinical responses to certolizumab pegol treatment were similar between those with high and with low RF levels, indicating that RF level does not influence a patient's response to certolizumab pegol.[2]

"For people living with RA, high RF levels are associated with more severe disease activity, risk of progression and loss of treatment efficacy, so the encouraging results of the REALISTIC study may impact treatment choices for people living with RA and high RF levels who have previously had an inadequate response to TNFis," said Dr James Galloway, investigator on the REALISTIC trial, Professor of Rheumatology at King's College London and an honorary Consultant in Rheumatology at King's College Hospital, London. "The RF-drug interaction research also presented at EULAR provides important molecular insights in to why we see more consistent drug concentrations among high RF patients treated with certolizumab pegol compared with Fc-containing TNFis."

These certolizumab pegol data together demonstrate how tailored treatment approaches can support specific groups of patients.

Dr Oseme Etomi, Consultant Rheumatologist and Obstetric Physician, Guy's and St Thomas Hospitals, London, said, "Chronic rheumatological diseases such as axSpA, RA and PsA are multifactorial and present significant treatment challenges, particularly as patients progress through different stages of life, such as family planning, pregnancy and breastfeeding, or disease progression. The new clinical data we've seen at EULAR are valuable to support more personalized treatment that is tailored to the individual needs, lifestyle choices and clinical profile of each patient."

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Notes to editors

About CHERISH[1]
The CHERISH study was a multicenter, longitudinal, interventional, prospective, open-label phase 1B exploratory study evaluating the impact of pregnancy on the pharmacokinetics of certolizumab pegol. The study consisted of a screening period, pregnancy period (up to 40 weeks), post-partum period (up to 13 weeks), and a safety follow-up contact (five weeks after final study visit). CHERISH investigated the blood concentrations of certolizumab pegol during and after pregnancy, alongside monitoring any adverse events.

Twenty-one women, nine of them with rheumatoid arthritis, were enrolled into CHERISH when up to 10 weeks pregnant and having been on a stable maintenance dose of certolizumab pegol (either 200 mg or 400 mg every two weeks, or 400 mg every four weeks) for at least 12 weeks.

Blood samples were taken pre-dose every four weeks during pregnancy and once at roughly 12 weeks post-partum, as well as one week after a certolizumab pegol dose every eight weeks during pregnancy and once post-partum. The participants were contacted for a safety follow-up after another five weeks.

All observed concentrations of certolizumab pegol were within the range seen in non-pregnant patients with psoriatic arthritis, axial spondyloarthritis and rheumatoid arthritis (1.7-45.3 µg/ml). Levels of certolizumab pegol remain consistent throughout pregnancy, although they were somewhat lower during pregnancy than post-partum. The adverse event profile was consistent with the known profile of certolizumab pegol, and no safety concerns were reported.

The findings from CHERISH suggest that women may continue certolizumab pegol at their usual dose and expect to maintain stable therapeutic levels throughout pregnancy.

About CRIB[4] and CRADLE[5]
CRIB was a pharmacokinetic study of women ≥30 weeks pregnant receiving commercial certolizumab pegol for a locally approved indication (last dose ≤35 days prior to delivery).

Blood samples were taken from mother, infant and umbilical cord at birth, and again from the baby at four and eight weeks of age, to assess whether certolizumab pegol is transferred to infants via the placenta.

Of the 16 women who participated, eleven were receiving certolizumab pegol for rheumatoid arthritis, three for Crohn's disease, one for psoriatic arthritis and one for axial spondyloarthritis/ankylosing spondylitis; all had healthy pregnancies, and 14 of the babies gave samples that could be included in the study.

Using a specific, sensitive assay, levels of certolizumab pegol in the mothers at delivery were found to be in the therapeutic range, whereas the level was below measurable in 13 of the newborns. In the fourteenth infant, a minimal level of certolizumab pegol was detected, equivalent to 0.09% of the maternal level and considered unlikely to have any effect. By weeks four and eight, certolizumab pegol was undetectable in all the babies.

There were no patterns of adverse events in the babies to suggest any difference from children of mothers not treated with certolizumab pegol, while safety data in the mothers were consistent with the known profile of certolizumab pegol and of the underlying diseases in pregnancy.

Thus, CRIB showed minimal to no placental transfer of certolizumab pegol from mother to infant, supporting continuation of treatment throughout pregnancy when clinically needed.

CRADLE was a pharmacokinetic study of lactating mothers receiving certolizumab pegol.

The study assessed whether certolizumab pegol is transferred into breast milk and the level of dose an infant might be exposed to.

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The 17 women involved were receiving certolizumab pegol (seven for rheumatoid arthritis, five for Crohn's disease, three for psoriatic arthritis and two for axial spondyloarthritis/ankylosing spondylitis) and had chosen to breastfeed – both decisions were made independent of the study.

Mothers provided milk samples during at-home visits starting at least six weeks post-partum, to allow breastfeeding routine to be established undisturbed, beginning with a pre-dose sample on the day of their certolizumab pegol dose, and then every two days for two weeks. One mother on a four-week dose schedule gave one additional pre-dose sample at four weeks.

Certolizumab pegol levels were below measurable in 77 of 137 milk samples tested (56%), while the remainder had minimal levels, all less than 1% of the expected level in the blood of an adult receiving a therapeutic maintenance dose. A relative infant dose (RID) below 10% is considered unlikely to be of concern to infant wellbeing. The mean RID for certolizumab pegol was calculated to be below 0.5% of the maternal dose and the median RID was 0.15%.

Adverse events in the infants of mothers treated with certolizumab pegol were consistent with those occurring in unexposed infants of similar age, while those in the mothers were consistent with the known safety profile of certolizumab pegol.

With results indicating minimal to no transfer into breast milk, CRADLE showed that continued treatment with certolizumab pegol is compatible with breastfeeding.

About REALISTIC[2]
REALISTIC (RA Evaluation in Subjects Receiving TNF Inhibitor Certolizumab Pegol) was a multicenter phase IIIb trial in patients with active rheumatoid arthritis who had shown inadequate response to disease-modifying antirheumatic drugs, including patients with/without prior TNFi exposure, with/without concomitant methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs), and varying lengths of disease duration. The study demonstrated that – in a diverse group of RA patients reflecting those seen in daily clinical practice (including those with prior TNF-inhibitor use) – addition of certolizumab pegol to current therapy was associated with a rapid clinical response consistent in all strata, improved function and reduced disease activity.

Patients with active RA with inadequate response to ≥1 DMARD were randomized 4:1 to subcutaneous injections of certolizumab pegol 400 mg at Weeks 0, 2 and 4 followed by 200 mg every 2 weeks or placebo injection (control) every 2 weeks + current therapy. Primary outcome was ACR20 at Week 12. Randomization was stratified by prior TNF inhibitor use, concomitant use of methotrexate (MTX), and disease duration (<2 y vs ≥2 y).

About CIMZIA® (certolizumab pegol) in the EU/EEA[7]
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[7]
Cimzia® (certolizumab pegol) was studied in 4,049 patients with rheumatoid arthritis (RA) in controlled and open label trials for up to 92 months. In the placebo-controlled studies, patients receiving certolizumab pegol had an approximately 4 times greater duration of exposure compared with the placebo group. This difference in exposure is primarily due to patients on placebo being more likely to withdraw early. In addition, Studies RA-I and RA-II had a mandatory withdrawal for non-responders at Week 16, the majority of whom were on placebo.

The commonly reported adverse reactions (≥1/100 to <1/10) in clinical trials with certolizumab pegol and post-marketing cases 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.

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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 the PsA001 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 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.

Serious adverse reactions, defined as an adverse reaction that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in persistent or significant disability or incapacity, or is a birth defect, include sepsis, opportunistic infections, tuberculosis (including miliary, disseminated and extrapulmonary), herpes zoster, lymphoma, leukemia, solid organ tumors, 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 certolizumab pegol due to adverse events vs. 2.7% for placebo.

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 (NYHA classes III/IV).

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 virus 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.

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 antinuclear antibodies 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, leukemia 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 hematologic 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 hematological abnormalities.

Severe infections and neutropaenia were reported in clinical trials with concurrent use of anakinra (an interleukin-1 antagonist) or abatacept (a CD28 modulator) and another TNF-antagonist, etanercept, with no added benefit compared to TNF-antagonist therapy alone. Because of the nature of the adverse events seen with the combination of another TNF-antagonist with either abatacept or anakinra therapy, similar toxicities may also result from the combination of anakinra or abatacept and other TNF-antagonists. Therefore, the use of certolizumab pegol in combination with anakinra or abatacept is not recommended.

There is limited safety experience with surgical procedures in patients treated with certolizumab pegol. 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

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for infections, and appropriate actions should be taken. Please consult the full prescribing information in relation to other side effects, full safety and prescribing information.

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 €5.3 billion in 2023. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news.

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