UCB News

UCB demonstrates scientific excellence with multiple presentations from immunology portfolio at EULAR 2015

- New clinical data on CIMZIA® (certolizumab pegol) across three diseases: rheumatoid arthritis, psoriatic arthritis and axial spondyloarthritis
- First presentation of Phase 3 investigational data evaluating certolizumab pegol in the treatment of patients naïve to disease modifying anti-rheumatic drugs with severe active and progressive rheumatoid arthritis
- Presentations include latest data from investigational immunology pipeline

Brussels, Belgium – 10 June, 6:00 CET – UCB, a global biopharmaceutical company, is sponsoring multiple presentations across a spectrum of rheumatic diseases at the European League Against Rheumatism Annual Congress (EULAR 2015) in Rome, Italy (10th – 13th June 2015).

“Data to be presented at EULAR 2015 include the latest research on CIMZIA in the treatment of adults with moderate to severe rheumatoid arthritis, active psoriatic arthritis and severe active axial spondyloarthritis,” said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President, UCB. “We will share the most recent data from our investigational immunology pipeline. Overall the UCB-sponsored clinical and scientific presentations at EULAR 2015 highlight our dedication to scientific excellence as the basis for improving the lives of people with severe diseases.”

Data highlights will include the first presentation of Phase 3 investigational data assessing the efficacy and safety of certolizumab pegol in combination with optimized methotrexate (MTX), meaning the highest dose the patient can tolerate up to a maximum of 25mg weekly , in patients with severe, active and progressive rheumatoid arthritis who have not been treated with disease modifying anti-rheumatic drugs (DMARD-naïve).

Pre-clinical data will also be shown on epratuzumab, an investigational medicine in Phase 3 clinical development for systemic lupus erythematosus (SLE) and on UCB5857, an investigational medicine for immune-inflammatory diseases.

In the EU, CIMZIA in combination with methotrexate (MTX) is indicated for the treatment of moderate to severe active RA in adult patients inadequately responsive to disease-modifying anti-rheumatic drugs (DMARDs) including MTX.[1] CIMZIA can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. CIMZIA 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.

CIMZIA, 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. CIMZIA can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate.[1]

CIMZIA is also indicated in the EU for the treatment of adult patients with severe active axial spondyloarthritis (axSpA), comprising:[1]

- 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.[1]

Epratuzumab was licensed from Immunomedics Inc. (Morris Plains, NJ, USA) by UCB Pharma for clinical development and commercialization in all autoimmune disorders. Epratuzumab is not approved for the treatment of SLE by any regulatory authority worldwide.

UCB5857 is an investigational medicine for the treatment of immune-inflammatory diseases and is not approved by any regulatory authority worldwide.

Following is a guide to the UCB-sponsored data presentations:

Presentations on CIMZIA® in Rheumatoid Arthritis

1. **[SAT0164]: The first study of certolizumab pegol in combination with methotrexate in DMARD-naïve early rheumatoid arthritis patients led to sustained clinical response and inhibition of radiographic progression at 52 weeks: the C-EARLY randomized, double-blind, controlled phase 3 study**
   Emery, P. *et al.*
   - Date/Time: Saturday 13 June, 10:15–12:00
   - Session Info: Rheumatoid arthritis - anti-TNF therapy; Hall 6 (poster presentation)

2. **[SAT0165]: Improvements in patient-reported outcomes and workplace and household productivity following 52 weeks of treatment with certolizumab pegol in combination with methotrexate in DMARD-naïve early rheumatoid arthritis patients: results from the C-EARLY randomized, double-blind, controlled phase 3 study**
   Emery, P. *et al.*
   - Date/Time: Saturday 13 June, 10:15–12:00
   - Session Info: Rheumatoid arthritis - anti-TNF therapy; Hall 6 (poster presentation)

3. **[SAT0149]: Identification of time-dependent risk factors for serious infectious events in rheumatoid arthritis patients treated with certolizumab pegol**
   Curtis, J. *et al.*
   - Date/Time: Saturday 13 June, 10:15–12:00

- Session Info: Rheumatoid arthritis - anti-TNF therapy; Hall 6 (poster presentation)

4. **[SAT0173]: Baseline parameters identified in early, methotrexate-naïve rheumatoid arthritis patients with better outcomes with certolizumab pegol+methotrexate compared to placebo+methotrexate: post-hoc analyses of C-OPERA, a randomized, controlled, phase 3 study**
   Atsumi, T. *et al.*
   - Date/Time: Saturday 13 June, 10:15–12:00
   - Session Info: Rheumatoid arthritis - anti-TNF therapy; Hall 6 (poster presentation)

5. **[FRI0144]: Analysis of the association between cigarette smoking and the clinical response to certolizumab pegol treatment in Hungarian patients with rheumatoid arthritis**
   Szekanecz, Z. *et al.*
   - Date/Time: Friday 12 June, 12:00–13:45
   - Session Info: Rheumatoid arthritis - anti-TNF therapy; Hall 6 (poster presentation)

6. **[AB1101]: Baseline characteristics of rheumatoid arthritis patients starting certolizumab pegol therapy and glucocorticoid prescription in the ECLAIR study in 2012–2013**
   Saraux, A. *et al.*
   - Abstract book

Presentations on CIMZIA® in Psoriatic Arthritis

7. **[THU0417]: Improvements in extra-articular manifestations of psoriatic arthritis over 96 weeks of certolizumab pegol treatment**
   FitzGerald, O. *et al.*
   - Date/Time: Thursday 11 June, 12:00–13:45
   - Session Info: Psoriatic arthritis - outcomes and treatment 1; Hall 5 (poster tour)

8. **[THU0427]: Sustained improvements in skin outcomes following certolizumab pegol treatment of psoriatic arthritis patients with prior anti-TNF exposure or severe skin involvement at baseline**
   Khraishi, M. *et al.*
   - Date/Time: Thursday 11 June, 12:00–13:45
   - Session Info: Psoriatic arthritis; Hall 5 (poster presentation)

9. **[SAT0564]: Clinical responses in joint and skin outcomes and patient-reported outcomes are associated with increased productivity in the workplace and at home in psoriatic arthritis patients treated with certolizumab pegol**
   Kavanaugh, A. *et al.*
   - Date/Time: Saturday 13 June, 10:15–12:00
   - Session Info: Psoriatic arthritis; Hall 5 (poster presentation)

Presentations on CIMZIA® in Axial Spondyloarthritis, including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis

10. **[OP0171]: Achievement of remission of inflammation in the spine and sacroiliac joints measured by magnetic resonance imaging (MRI) in patients with axial spondyloarthritis, and associations between MRI and clinical remission, over 96 weeks of treatment with certolizumab pegol**
    Braun, J. *et al.*
    - Date/Time: Friday 12 June, 10:30–12:00
    - Session Info: Spondyloarthritis and Psoriatic arthritis treatment; Hall 3 (oral presentation)

11. **[THU0201]: Factors associated with structural damage in the spine, as measured by X-ray, in patients with axial spondyloarthritis treated with certolizumab pegol over 96 weeks**
    van der Heijde, D. *et al.*
    - Date/Time: Thursday 11 June, 12:00–13:45
    - Session Info: Spondyloarthritis - treatment; Hall 6 (poster presentation)

12. **[THU0202]: Clinical responses and improvements in patient-reported outcomes are associated with increased productivity in the workplace and at home in axial spondyloarthritis patients treated with certolizumab pegol**
    van der Heijde, D. *et al.*
    - Date/Time: Thursday 11 June, 12:00–13:45
    - Session Info: Spondyloarthritis - treatment; Hall 6 (poster presentation)

13. **[FRI0224]: Prevalence determination of severe ankylosing spondylitis and its co-morbidities in 2012 in France: analysis of a national public health insurance database**
    Breban, M. *et al.*
    - Date/Time: Friday 12 June, 12:00–13:45
    - Session Info: Spondyloarthritis - clinical aspects (other than treatment); Hall 6 (poster presentation)

Presentations on CIMZIA® Across Indications

14. **[THU0575]: The most frequent fears and beliefs of 226 patients with rheumatoid arthritis or spondyloarthritis, using a novel questionnaire**
    Gossec, L. *et al.*
    - Date/Time: Thursday June 11, 12:00–13:45
    - Session Info: Education in rheumatology; Hall 5 (poster tour)

15. **[THU0353]: Development and validation of a questionnaire assessing the fears and beliefs of patients suffering from chronic rheumatic diseases**

Gossec, L. *et al.*

- Date/Time: Thursday June 11, 12:00–13:45
- Session Info: Epidemiology, health services and outcome research; Hall 5 (poster presentation)

Presentations on Pregnancy and Rheumatological Conditions

16. **[OP0018]: Pregnancy outcomes with trimesters of maternal exposure to certolizumab pegol: prospective and retrospective reports from safety surveillance**
    Clowse, M. *et al.*
    - Date/Time: Wednesday 10 June, 17:00–18:30
    - Session Info: Pregnancy in rheumatic diseases; Hall 2 (oral presentation)

17. **[OP0299-PARE]: Attitudes of patients and physicians in the treatment of rheumatological disease during pregnancy**
    Khamashta, M. *et al.*
    - Date/Time: Saturday 13 June, 8:30–10:00
    - Session Info: Family business; SC2 - Room A (oral presentation)

Presentations on Investigational Studies of Epratuzumab in SLE

18. **[FRI0002]: Pharmacodynamic effects of the CD22-targeted monoclonal antibody epratuzumab on B cells in Cynomolgus monkeys and in patients with systemic lupus erythematosus**
    Shock, A. *et al.*
    - Date/Time: Friday 12 June, 12:00–13:45
    - Session Info: Adaptative immunity (T cells and B cells) in rheumatic diseases; Hall 6 (poster presentation)

Presentations on Investigational Studies of UCB5857

19. **[SAT0370]: PI3Kδ pathway; a novel therapeutic target for Sjögren's syndrome**
    Nayar, S. *et al.*
    - Date/Time: Saturday 13 June, 10:15–12:00
    - Session Info: Sjögren's - pathogenesis and treatment targets; Hall 5 (poster tour)

Presentation 19 represents the results from academic research collaboration.

About CIMZIA®

CIMZIA is the only Fc-free, PEGylated anti-TNF (Tumor Necrosis Factor). CIMZIA has a high affinity for human TNF-alpha, selectively neutralizing the pathophysiological effects of TNF-alpha.

Important Safety Information about CIMZIA® in the EU/EEA[1]

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, papillomavirus, influenza), bacterial infections (including abscess), rash, headache (including migraine), asthaenia, leukopaenia (including lymphopaenia, neutropaenia), 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, herpes zoster, lymphoma, leukaemia, solid organ tumours, angioneurotic oedema, cardiomyopathies (includes heart failure), ischemic coronary artery disorders, pancytopaenia, 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 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 or moderate-to-severe heart failure.

Serious infections including sepsis, tuberculosis and opportunistic infections have been reported in patients receiving CIMZIA. Some of these events have been fatal. Monitor patients closely for signs and symptoms of infections including tuberculosis before, during and after treatment with CIMZIA. Treatment with CIMZIA must not be initiated in patients with a clinically important active infection. If an infection develops, monitor carefully and stop CIMZIA if infection becomes serious. 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. Patients should be instructed to seek medical advice if signs/symptoms (e.g. persistent cough, wasting/weight loss, low grade fever, listlessness) suggestive of tuberculosis occur during or after therapy with CIMZIA.

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; 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 hematologic system, including medically significant cytopaenia, have been infrequently 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.

CIMZIA was studied in 325 patients with active axial spondyloarthritis (axSpA) in a placebo-controlled clinical trial for up to 30 months and in 409 patients with psoriatic arthritis (PsA) in a placebo-controlled clinical trial for up to 30 months. The safety profile for axSpA and PsA patients treated with CIMZIA was consistent with the safety profile in RA and previous experience with CIMZIA.

Please consult the full prescribing information in relation to other side effects, full safety and prescribing information. European SmPC date of revision 16th December 2014..

http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

References

CIMZIA® EU Summary of Product Characteristics. Accessed 14th March 2015 from http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf

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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 more than 8500 people in approximately 40 countries, the company generated revenue of € 3.3 billion in 2014. 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.
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