UCB News

UCB demonstrates commitment to immunology with strong presence at EULAR 2014

For the attention of European Medical Journalists

- Presentations to include new clinical data on Cimzia® (certolizumab pegol) across three indications: rheumatoid arthritis, psoriatic arthritis and axial spondyloarthritis
- Phase 3 investigational data to be presented on the first study to evaluate the efficacy and safety of certolizumab pegol in early rheumatoid arthritis
- Scientific data to be presented on the investigational medicine epratuzumab in systemic lupus erythematosus

Brussels (Belgium), June 6th, 2014 – 0700 (CEST) – UCB, a global biopharmaceutical company with a focus on immunology treatment and research, is proud to sponsor 25 data presentations across a broad spectrum of rheumatic diseases at the European League Against Rheumatism (EULAR) 2014 Annual Congress in Paris, France (11th-14th June 2014). The presentations will highlight the latest research findings on Cimzia® (certolizumab pegol) in rheumatoid arthritis (RA), psoriatic arthritis (PsA) and axial spondyloarthritis (axSpA) as well as data on epratuzumab, an investigational therapy for the treatment of systemic lupus erythematosus (SLE), also known as lupus.

“UCB is pleased to sponsor multiple clinical and scientific data presentations at EULAR 2014,” said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President, UCB. “These presentations highlight our ongoing research, with the ultimate aim of providing new data insights and developing innovative treatment options to address the unmet needs of people living with severe immunological diseases.”

The UCB-sponsored EULAR presentations include 96-week open-label results from the RAPID™-PsA and RAPID™-axSpA Phase 3 studies, evaluating the efficacy and safety of Cimzia® in the treatment of PsA and axSpA, respectively. Data will also be presented from post-hoc analyses of these studies, examining the association between disease activity, clinical response and long-term treatment outcomes in people living with PsA and people living with axSpA. From an investigational perspective, there will be the first presentation of data from a Phase 3 study evaluating the efficacy and safety of certolizumab pegol in Japanese patients with early RA.*

Cimzia®, in combination with methotrexate (MTX), is approved in the EU for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients inadequately responsive to disease-modifying antirheumatic drugs (DMARDs) including MTX. Cimzia® can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate.

Cimzia®, in combination with MTX, is indicated for the treatment of active PsA in adults when the response to previous DMARD therapy has been inadequate. Cimzia® can be given as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate. Cimzia® is also approved in the EU for the treatment of adult patients with severe active 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 without radiographic evidence of AS - adults with severe active axSpA without radiographic evidence of AS but with objective signs of inflammation by elevated CRP and/or MRI, who have had an inadequate response to, or are intolerant to NSAIDs.[1]

Epratuzumab, licensed from Immunomedics Inc., is an investigational medicine in Phase 3 clinical development for the treatment of SLE. Epratuzumab is a monoclonal antibody that targets CD22 - a B-cell specific protein which regulates B-cell activity.[2,3] Epratuzumab is not approved for the treatment of SLE by any regulatory authority worldwide.

Following is a guide to the 25 UCB-sponsored data presentations being presented as oral presentations, posters or abstracts at EULAR 2014:

Cimzia® in axial spondyloarthritis

1. **[SAT0351]: Long-Term Safety and Efficacy of Certolizumab Pegol in Patients with Axial Spondyloarthritis, including Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis: 96-Week Outcomes of the RAPID-axSpA Trial**
   Sieper, J. *et al.*
   - Date/Time: Saturday June 14th; 10:15 – 12:00
   - Session Info: Poster Session, Poster Area D, Level 4
   - Date/Time: Friday June 13th; 12:00 – 13:15
   - Session Info: Poster Tour, Room 253

2. **[SAT0338]: Disease Activity and Clinical Response Early in the Course of Treatment Predict Long-Term Outcomes in Axial Spondyloarthritis Patients Treated with Certolizumab Pegol**
   van der Heijde, D. *et al.*
   - Date/Time: Saturday June 14th; 10:15 – 12:00
   - Session Info: Poster Session, Poster Area D, Level 4

3. **[SAT0355]: Observed Incidence Rates of Uveitis Following Certolizumab Pegol Treatment in Patients with Axial Spondyloarthritis**
   Rudwaleit, M. *et al.*
   - Date/Time: Saturday June 14th; 10:15 – 12:00
   - Session Info: Poster Session, Poster Area D, Level 4

4. **[SAT0362]: Certolizumab Pegol Rapidly Reduces Peripheral Enthesitis and the Incidence of Tender and Swollen Joints in Patients with Active Axial Spondyloarthritis, Including both Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis**
   Mease, P. J. *et al.*
   - Date/Time: Saturday June 14th; 10:15 – 12:00
   - Session Info: Poster Session, Poster Area D, Level 4

Cimzia® in psoriatic arthritis

5. **[OP0077]: Long-Term Safety and Efficacy of Certolizumab Pegol in Patients with Psoriatic Arthritis with and without Prior Anti-Tumor Necrosis Factor Exposure: 96-Week outcomes from the RAPID-PsA Trial**
   Mease, P. J. *et al.*
   - Date/Time: Thursday June 12th; 11:00
   - Session Info: Oral presentation

6. **[SAT0403]: Further Analysis of Psoriatic Arthritis Disease Activity Score (PASDAS) and Composite Psoriatic Disease Activity Index (CPDAI) using Data from a Placebo-Controlled Trial of Certolizumab Pegol in Psoriatic Arthritis**
   Helliwell, P. *et al.*
   - Date/time: Saturday June 14th; 10:15 – 12:00
   - Session Info: Poster session, Poster Area D, Level 4
   - Date/time: Thursday June 12th; 12:00 – 13:15
   - Session Info: Poster Tour, Level 3

7. **[SAT0405]: Disease Activity and Clinical Response Early in The Course of Treatment Predict Long-Term Outcomes in Psoriatic Arthritis Patients Treated with Certolizumab Pegol**
   Mease, P. J. *et al.*
   - Date/Time: Saturday June 14th; 10:15 – 12:00
   - Session Info: Poster Session, Poster Area D, Level 4

Cimzia® in rheumatoid arthritis

8. **[OP0067]: Pregnancy Outcomes after Exposure to Certolizumab Pegol: Updated Results from Safety Surveillance**
   Clowse, M. *et al.*
   - Date/Time: Thursday June 12th; 10:40
   - Session Info: Oral Presentation

9. **[FRI0246]: Magnetic Resonance Imaging-Assessment of Early Response to Certolizumab Pegol in Rheumatoid Arthritis: a Randomized, Double-Blind, Placebo-Controlled Phase IIIb study applying Magnetic Resonance Imaging at Weeks 0, 1, 2, 4, 8 and 16**
   Ostergaard, M. *et al.*

- Date/Time: Friday June 13th; 11:45 – 13:30
- Session Info: Poster Session, Poster Area D, Level 4
- Date/Time: Saturday June 14th; 10:30 – 11:45
- Session Info: Poster Tour, Level 3

10. **[FRI0278]: The First Early Rheumatoid Arthritis, Certolizumab Pegol, Multicenter, Double-Blind, Randomized, Parallel-Group Study: C-OPERA, in Patients Fulfilling the 2010 ACR/EULAR Classification Criteria, Demonstrates Inhibition of Joint Damage Progression**
    Atsumi, T. *et al.*
    - Date/Time: Friday June 13th; 11:45 – 13:30
    - Session Info: Poster Session, Poster Area D, Level 4
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11. **[THU0190]: Better Clinical Responses Seen Early with the Loading Dose of Certolizumab Pegol are Maintained until One Year**
    Takeuchi, T. *et al.*
    - Date/Time: Thursday June 12th; 11:45 – 13:30
    - Session Info: Poster Session, Poster Area B, Level 1

12. **[THU0162]: Multiple Approaches for Implementation of Long-Term Efficacy Interpretation of Certolizumab Pegol Data: RAPID1 and RAPID2 Case Study**
    Keystone, E. *et al.*
    - Date/Time: Thursday June 12th; 11:45 – 13:30
    - Session Info: Poster Session, Poster Area B, Level 1

13. **[FRI0004]: Randomization to Patient-Reported RAPID3 versus Physician-Based CDAI Tools for Prediction of Treatment Response and Assessment of Patient-Reported Outcomes in Rheumatoid Arthritis Patients Receiving Certolizumab Pegol: Results from the PREDICT study**
    Curtis, J. R. *et al.*
    - Date/Time: Friday June 13th; 11:45 – 13:30
    - Session Info: Poster Session, Poster Area A, Level 1

14. **[AB0374]: Long-Term Safety in Rheumatoid Arthritis Before and After Certolizumab Pegol Dose Increase/Decrease: Analysis of Data Pooled from the RAPID1 and RAPID2 Randomized Trials**
    Haraoui, B. *et al.*
    - Abstract book

15. **[AB0372]: Effect of Certolizumab Pegol on Workplace and Household Productivity in US Patients with Rheumatoid Arthritis With or Without prior Anti-Tumor Necrosis Factor Exposure: Results from the PREDICT Study**
    Kavanaugh, A. *et al.*
    - Abstract book

Rheumatoid arthritis

16. **[THU0269]: Validity and Responsiveness of the Bristol Rheumatoid Arthritis Fatigue Multidimensional Questionnaire (BRAF-MDQ) in a Randomized Controlled Clinical Trial**
Kirwan, J. *et al.*
    - Date/Time: Thursday June 12th; 11:45 – 13:30
    - Session Info: Poster Session, Poster Area D, Level 4

17. **[FRI0175]: Indirect Treatment Comparisons and Network Meta-Analysis among Biological Agents for Rheumatoid Arthritis: A Systematic Review of Published Literature**
Carlos, F. *et al.*
    - Date/Time: Friday June 13th; 11:45 – 13:30
    - Session Info: Poster Session, Poster Area B, Level 1

18. **[AB1088]: Impact of Rheumatoid Arthritis on Work Capacity: Results of a Survey in a Population of Patients Under 60 Years**
Bertin, P. *et al.*
    - Abstract book

Investigational studies of epratuzumab in systemic lupus erythematosus

19. **[THU0023]: Correlation of Laboratory and Clinical Parameters with British Isles Lupus Assessment Group Response in an Open-Label Extension Study of Epratuzumab in Systemic Lupus Erythematosus**
Furie, R. A. *et al.*
    - Date/Time: Thursday June 12th; 11:45 – 13:30
    - Session Info: Poster session, Poster Area, Level 1
    - Date/Time: Friday June 13th; 12:00 – 13:15
    - Session Info: Poster Tour, Level 2

20. **[FRI0383]: Safety, Pharmacokinetics, and Pharmacodynamics of Epratuzumab in Japanese Patients with Moderate-to-Severe Systemic Lupus Erythematosus: Results from a Phase 1/2 Study**
Yamamoto, J. *et al.*
    - Date/Time: Friday June 13th; 11:45 – 13:30
    - Session Info: Poster Session, Poster Area D, Level 4

21. **[AB0023]: In Vivo Effects of Epratuzumab, a Monoclonal Antibody Targeting Human CD22, on B Cell Function in Human CD22 Knock-in (Huki) Mice**
Brandl, C. *et al.*
    - Abstract book

Systemic lupus erythematosus

22. **[SAT0101]: A 'Real-World' Characterization of 'Moderate-to-severe' Systemic Lupus Erythematosus**
    Strand, V. *et al.*
    - Date/Time: Saturday June 14th; 10:15 – 12:00
    - Session Info: Poster Session, Poster Area A, Level 1

23. **[AB1117]: Burden of Disease in Systemic Lupus Erythematosus Patients Treated with Corticosteroids**
    Strand, V. *et al.*
    - Abstract book

24. **[AB1116]: Treatment of Patients with 'Moderate-to-severe' Systemic Lupus Erythematosus**
    Strand, V. *et al.*
    - Abstract book

Family Planning and Pregnancy in Immunological Diseases

25. **[THU0430]: Survey on Patient and Physician Perspectives on Family Planning and Pregnancy Issues – Does Condition Matter?**
    Gordon, C. *et al.*
    - Date/Time: Thursday June 12th; 11:45 – 13:30
    - Session Info: Poster Session, Poster Area D, Level 4

Following is a guide to UCB-sponsored symposia at EULAR 2014:

- **Understanding the Current and Future Management of SpA**
  Date/Time: Wednesday 11th June, 13:00 – 14:30
  Venue: Amphi Bleu

- **Updated EULAR Recommendations: Evolution or Revolution?**
  Date/Time: Thursday 12th June, 17:30 – 19:00
  Venue: Amphi Havane

In addition, UCB has provided an unrestricted educational grant to support a continuing medical education accredited symposium on SLE at EULAR 2014.

** In February 2012, Astellas and UCB signed an agreement to jointly develop and commercialize Cimzia® (certolizumab pegol) in Japan. In December 2012, Cimzia® was granted Japanese marketing approval for the treatment of adult patients with RA who have had an inadequate response to conventional treatment. Cimzia® was launched in Japan for this indication in March 2013.*

About CIMZIA®

Cimzia® is the only Fc-free, PEGylated anti-TNF (Tumour Necrosis Factor). Cimzia® has a high affinity for human TNF-alpha, selectively neutralizing the pathophysiological effects of TNF-alpha. Over the past decade, TNF-alpha has emerged as a major target of basic research and clinical investigation. This cytokine plays a key role in mediating pathological inflammation, and excess TNF-alpha production has been directly implicated in a wide variety of diseases. Cimzia® is a registered trademark of UCB PHARMA S.A.

Cimzia® (certolizumab pegol) EU/EEA Important Safety Information[1]

Cimzia® was studied in 4,049 patients with 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 25th November 2013.

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

References

1. Cimzia® EU Summary of Product Characteristics, European Medicines Agency. Accessed 18th May, 2014 from http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001037/WC500069763.pdf
2. Sanz I. & Lee F. Eun-Hyung B cells as therapeutic targets in SLE. Nat. Rev. Rheumatology; 6. 2010; 326-337
3. Walker J. & Smith K. CD22: an inhibitory enigma. Immunology; 123. 2008; 314-325

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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 more than 8500 people in approximately 40 countries, the company generated revenue of € 3.4 billion in 2013. UCB is listed on Euronext Brussels (symbol: UCB). Follow us on Twitter: @UCB_news

Forward looking statements

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.

There is no guarantee that new product candidates in the pipeline will progress to product approval or that new indications for existing products will be developed and approved. Products or potential products which are the subject of partnerships, joint ventures or licensing collaborations may be subject to differences between the partners. Also, UCB or others could discover safety, side effects or manufacturing problems with its products after they are marketed.

Moreover, sales may be impacted by international and domestic trends toward managed care and health care cost containment and the reimbursement policies imposed by third-party payers as well as legislation affecting biopharmaceutical pricing and reimbursement.