UCB announces Phase 3 clinical trial program for epratuzumab in Systemic Lupus Erythematosus did not meet primary endpoint

UCB remains committed to delivering value for patients living with lupus and other serious immunologic diseases

Brussels (Belgium), 28 July 2015 – 0700 (CET) – regulated information: UCB today announced that the two EMBODY™ Phase 3 clinical studies for epratuzumab in Systemic Lupus Erythematosus (SLE) did not meet their primary clinical efficacy endpoints in either dose in both studies. Treatment response in patients who received epratuzumab in addition to standard therapy was not statistically significantly higher than those who received placebo in addition to standard therapy. [1]

"Although we are disappointed with the results from the Phase 3 program, our commitment to the lupus community remains. We are focused on developing new therapies for the treatment of immunological conditions including SLE and have another SLE drug in clinical development. We would like to express our sincere thanks to the patients and clinical investigators who made the EMBODY™ program possible. It has produced a comprehensive dataset and we look forward to sharing the findings with the scientific community," said Professor Dr. Iris Loew-Friedrich, Chief Medical Officer and Executive Vice President, UCB. "Today's news does not alter UCB's strategy as we remain committed to delivering value for patients living with lupus and other immunologic diseases."

The EMBODY™ Phase 3 clinical program consisted of two identical studies – EMBODY™ 1 and EMBODY™ 2. EMBODY™ 1 and EMBODY™ 2 were multicenter, randomized, double-blind, placebo-controlled 48-week studies. In each study, patients (n= 786 for EMBODY™ 1; n=788 for EMBODY™ 2) received placebo or treatment with 2400 mg of epratuzumab over four 12-week treatment cycles, administered as 600 mg every week for four weeks or 1,200 mg every two weeks for four weeks. All patients were taking corticosteroids at the start of the trial, in addition to epratuzumab or placebo, while immunosuppressant and antimalarial therapies were administered per their standard therapy regimen. The primary endpoint of the studies was the percentage of patients meeting treatment response criteria at Week 48 according to a combined response index, the BILAG-based Combined Lupus Assessment (BICLA). [1]

A high level review of the safety data did not identify any new safety concerns. The most common adverse events in both studies were upper respiratory tract infection, urinary tract infection, headache and nausea.

Epratuzumab is an investigational medicine and is not approved for the treatment of SLE by any regulatory authority worldwide. Epratuzumab was licensed from Immunomedics Inc (NASDAQ: IMMU) by UCB for clinical development and commercialization in all autoimmune disorders.

About Epratuzumab
Epratuzumab is a monoclonal antibody to target CD22, a protein that modulates B-cells, which are

key components of the immune system and can play a central role in the pathogenesis of SLE if they become overactive. While the mechanism of action of epratuzumab is not fully elucidated, data indicate that it binds to CD22, resulting in diminished SLE-related hyperactivity of B cells without depleting them.[2]

About SLE
Systemic lupus erythematosus (SLE), also known as lupus, is a chronic autoimmune disease which can affect multiple organ systems including the skin, joints, kidneys, brain, blood, heart and lungs.[3] Common symptoms include fatigue, fever, joint pain, skin lesions and chest pain. Patients often develop a characteristic butterfly-shaped rash across their cheeks and nose.[4] Additional symptoms may be present depending on the organs affected. Patients usually experience alternating periods of remission—during which disease activity is low and symptoms may ease—and periods of high disease activity known as flares, when symptoms worsen.[3] During flares, the immune system attacks healthy tissue causing inflammation that can lead to organ damage.

It is estimated that 5 million people throughout the world have SLE, the majority of whom are women aged 15-44.[3] The disease is more common in women than men, and 2 to 3 times more common in women of color than in Caucasian populations.[3]

References

1. UCB Data on File.
2. Dorner T. et al. CD22 and autoimmune disease. International Reviews of Immunology. 31:363-378, 2012.
3. Lupus Foundation of America. What is lupus? http://www.lupus.org/answers/entry/what-is-lupus Last accessed 11 Feb 2015.
4. Lupus Foundation of America. What are the common symptoms of lupus? http://www.lupus.org/answers/entry/common-symptoms-of-lupus, reviewed 2013. Last accessed 11 Feb 2015.

For further information

France Nivelle, Global Communications, UCB
T +32.2.559.9178, france.nivelle@ucb.com

Andrea Levin Christopher, Immunology Communications, UCB
T +1. 404.483.7329, andrea.levin@ucb.com

Antje Witte, Investor Relations, UCB
T +32.2.559.94.14, antje.witte@ucb.com

Laurent Schots, Media Relations, UCB
T+32.2.559.92.64, laurent.schots@ucb.com

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.