UCB announces top-line phase 2 results for olokizumab in rheumatoid arthritis

Olokizumab improved rheumatoid arthritis in disease activity score significantly over placebo

Olokizumab and the active comparator demonstrated comparable efficacy

Brussels, 26 September 2012, 6 pm CEST–regulated information – UCB announced today the top-line results from a phase 2b study of olokizumab (CDP6038) in adult patients suffering from rheumatoid arthritis (RA) having previously failed anti-TNF therapy. The primary objective of this study was to evaluate the efficacy of various doses and dose administration frequencies of olokizumab relative to placebo.
This phase 2b study met its primary endpoint of demonstrating a significant reduction in the disease activity score at week 12 across all olokizumab dose groups relative to placebo. All doses of olokizumab demonstrated statistically significant improvement in disease activity score (DAS 28) ($p<0.001$) when compared with placebo.
In addition, this study included an active comparator arm (tocilizumab). The exploratory analyses of these data suggest that olokizumab and tocilizumab demonstrated comparable efficacy, as measured by DAS scores in this difficult to treat population. Olokizumab was well tolerated across all doses and demonstrated a safety profile comparable to tocilizumab and consistent with known effects of IL-6 inhibitors.

"UCB is committed to developing new therapies offering breakthrough innovation to people living with severe diseases. We are very satisfied that the first results for the primary endpoint confirm our data models. However, our current data do not suggest sufficient differentiation potential versus the active comparator," says Ismail Kola, President of UCB New Medicines, UCB's research and early development division."We are now exploring appropriate options for olokizumab, including partnering. At UCB, we strive constantly to allocate our funds and resources to our very promising late and early pipeline projects in immunology and neurology."

The three-months trial was a randomized, double-blind, placebo-controlled, dose ranging study with an active comparator (tocilizumab) to evaluate the efficacy and safety of olokizumab (CDP6038) administered subcutaneously for 12 weeks. Approximately 220 patients with moderately- to severely-active RA who had an unsuccessful response to previous anti-TNF therapy were enrolled in the study. The treatment arms for olokizumab evaluated 60, 120 and 240 mg administered subcutaneously, every two weeks or every four weeks. In the active comparator arm, 8 mg/kg tocilizumab was administered intravenously every four weeks. All patients received concomitant methotrexate treatment.

Further analyses are on-going and detailed results of this study will be submitted to an appropriate future medical congress.

For further information

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Notes to the editor

About Olokizumab
Olokizumab is a humanized monoclonal antibody targeting the IL-6 cytokine. IL-6 is involved in several autoimmune and inflammatory pathways. Olokizumab is the first of a new type of IL-6 inhibitor that selectively blocks the final assembly of the IL-6 receptor signaling complex.

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 8,000 people in about 40 countries, the company generated revenue of EUR 3.2 billion in 2011. UCB is listed on Euronext Brussels (symbol: UCB).

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