UCB announces start of phase III programme with epratuzumab for patients with moderate to severe systemic lupus erythematosus

- **Two phase III studies, EMBODY™ 1 and 2, underway for pipeline drug *epratuzumab***
- **Phase III programme follows positive phase IIb study EMBLEM™, which showed that *epratuzumab* reduced disease activity over a 12 week treatment period**

Brussels, and Morris Plains, New Jersey, 14th December, 2010, 07:00 (CET) - **regulated information** - UCB (EURONEXT: UCB) and U.S. based partner Immunomedics Inc. (NASDAQ: IMMU) today announced the enrollment of the first patient into EMBODY™ 1, one of two pivotal phase III studies of *epratuzumab* in patients with moderate to severe systemic lupus erythematosus (SLE). Patient enrollment for EMBODY™ 2 has also begun.

“We are pleased to announce the launch of our phase III programme with *epratuzumab* which marks UCB’s intent to develop this compound for such a severe disease,” said Prof. Dr. Iris Loew-Friedrich, Chief Medical Officer of UCB. She added, “The consistency of improvements demonstrated by *epratuzumab* in the clinical studies to date is an encouraging platform to start the next phase of trials, and is a hopeful sign of the drug’s potential to become an effective new treatment option for lupus.”

Both studies (EMBODY™ 1 and EMBODY™ 2) are multicenter, placebo-controlled, randomized, double-blind studies designed to evaluate the efficacy, safety, tolerability, and immunogenicity of *epratuzumab* in patients with moderate to severe SLE. Each study will last a maximum of 54 weeks and will randomize 780 patients in the study, with approximately 130 planned investigational sites per study. The phase III programme has undergone the relevant regulatory advice procedures.

The primary objective of the studies is to confirm the clinical efficacy of *epratuzumab* in the treatment of patients with moderate to severe general SLE, in addition to continuing standard of care treatments.

The results from the phase IIb study, EMBLEM™, showed that all *epratuzumab* doses, which ranged from 200mg to 3,600mg cumulative dose administered during one 12-week treatment cycle had numerically superior response rates compared to placebo at week 12. For patients receiving *epratuzumab* at a cumulative dose of 2,400mg there were meaningful and statistically significant* reductions in SLE disease activity, with responder rates more than double those of placebo.

The EMBLEM™ results showed that in a patient population with predominantly high disease activity, *epratuzumab* improved patients’ health at week 12, with the emergence of improvements as early as week 8.

Epratuzumab was associated with a similar incidence of serious adverse events (including infections) and infusion reactions compared to placebo.

** This study was not powered to detect statistical differences between treatment arms (p values were not adjusted for multiple comparisons and are based on an exploratory post-hoc analysis)*

References

1. *Arthritis and Rheumatism* 2010; 62(10): S605. ACR 2010 American College of Rheumatology (ACR) Annual Scientific Meeting, November 7–11, 2010, Atlanta, GA, USA.

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About Epratuzumab

Epratuzumab is a humanized anti-CD22 monoclonal antibody under investigation for the treatment of SLE. CD22 is a B cell specific surface protein that is considered to be involved in B cell function. The product was licensed from Immunomedics, Inc., Morris Plains, NJ, USA. Under the license agreement, UCB owns the rights and is responsible for the clinical development, and commercialization of epratuzumab in all autoimmune disorders including SLE.

About EMBLEM™

In EMBLEM™ (n= 227), patients were randomized to 1 of 6 intravenous regimens: placebo (PBO), epratuzumab cumulative dose (cd) 200, 800, 2400, or 3600 mg in equal divided doses using 2 every other week (EOW) infusions or epratuzumab cd 2400 mg delivered as 4 equal infusions 1 week apart. Concomitant oral corticosteroids (CS) and immunosuppressives (IS) were stable for at least 5 and 28 days, respectively, prior to first study drug infusion. Primary endpoint was responder rate on a combined index of clinical disease activity at week 12 (defined as reduction of all baseline (BL) BILAG 2004 A to B/C/D and BL BILAG B to C/D, no BILAG worsening in other organ systems, and no deterioration in SLEDAI or physician global assessment [VAS]), with no CS, IS and antimalarials increase over BL dose. The study was not powered to detect statistical differences between treatment arms.

About systemic lupus erythematosus (SLE)

SLE, commonly referred to as lupus, is a chronic and potentially fatal autoimmune disease with a variable and unpredictable course. Antibodies are generated against the body's own nuclear proteins causing the immune system to attack its own cells and tissues resulting in inflammation and tissue damage. This can occur in any part of the body, but most often targets the heart, joints, skin, lungs, blood vessels, liver, kidneys and nervous system.

Lupus is characterized by periods of flares, or exacerbations, interspersed with periods of improvement or remission. The Lupus Foundation of America estimated that between 1.5 and 2 million Americans have a form of lupus, 90 percent of whom are women. Symptoms and diagnosis occur most often between the ages of 15 and 45. In the U.S., lupus is more common in African Americans, Latinos, Asians, and Native Americans than in Caucasians.

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 3.1 billion in 2009. UCB is listed on Euronext Brussels (symbol: UCB).

About Immunomedics

Immunomedics (NASDAQ: IMMU) is a New Jersey-based biopharmaceutical company primarily focused on the development of monoclonal antibody-based products for the targeted treatment of cancer, autoimmune and other serious diseases. Immunomedics has built a pipeline of therapeutic product candidates that utilize several different mechanisms of action. Immunomedics is developing epratuzumab for the therapy of B-cell hematopoietic tumors, such as non-Hodgkin lymphoma and acute lymphoblastic lymphoma.

Forward-looking statements - UCB

This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different 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, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.

Forward looking statements - Immunomedics

This release, in addition to historical information, may contain forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Such statements, including statements regarding clinical trials, out-licensing arrangements (including the timing and amount of contingent payments), forecasts of future operating results, and capital raising activities, involve significant risks and uncertainties and actual results could differ materially from those expressed or implied herein. Factors that could cause such differences include, but are not limited to, risks associated with new product development (including clinical trials outcome and regulatory requirements/actions), our dependence on our licensing partners for the further development of epratuzumab for autoimmune indications and veltuzumab for non-cancer indications, competitive risks to marketed products and availability of required financing and other sources of funds on acceptable terms, if at all, as well as the risks discussed in the Company's filings with the Securities and Exchange Commission. The Company is not under any obligation, and the Company expressly disclaims any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise.