



BioInvent announces approval to start Phase II trial for its novel cardiovascular drug BI-204

Lund, Sweden – 10 November 2010 – BioInvent International AB (OMXS: BINV) today announces IND clearance from the U.S. Food & Drug Administration (FDA) to initiate a Phase II study for BI-204. BI-204 is a human monoclonal antibody that specifically targets oxidized forms of a low-density lipoprotein (LDL) which has been linked to increased inflammatory processes leading to plaque formation in the blood vessel walls. BI-204 is being co-developed with Genentech for secondary prevention of cardiovascular events in patients with acute coronary syndrome (ACS).

The Phase II study is a multicenter, randomized, double-blind, placebo-controlled study of intravenous BI-204 in patients on standard-of-care therapy for stable atherosclerotic cardiovascular disease. Inflammation plays a critical role in the pathogenesis of atherosclerosis. The trial is designed to demonstrate a significant reduction in plaque inflammation following treatment with BI-204 as quantified by FDG-PET (^{18}F 2-deoxyglucose positron emission tomography). The trial will enrol 120 patients with stable coronary vascular disease in centers in the United States and Canada. The topline results of the study are expected to be reported in the first half of 2012. Additional trials are being contemplated in patients with ACS prior to commencing Phase III.

BioInvent will receive a milestone payment of \$ 15 million when the first patient is dosed in the phase II study, expected to happen by the end of the year or early first quarter next year.

A Phase I study for BI-204 was successfully completed in 2009. The study was a double-blind, within-group randomised dose-escalation trial testing both single and multiple doses of BI-204 administered either intravenously or subcutaneously. In total, 80 healthy male or female subjects with elevated levels of LDL cholesterol were included in the trial. BI-204 was well tolerated and pharmacokinetic results showed the half-life was in the expected range for fully human antibodies.

Svein Mathisen, CEO of BioInvent, commented: "Despite the development of a wide array of therapeutic interventions for coronary artery disease, including statins, this disease remains a major cause of death in the developed world and represents a significant unmet medical need. BI-204, derived from BioInvent's proprietary n-CoDeR[®] antibody library, provides a novel and unique therapeutic approach potentially reducing cardiac events in high risk patients. Following successful FDA approval of the IND for our clinical program, we are optimistic for the future commercialisation of BI-204, in partnership with Genentech, which we hope will provide improved outcome for patients."

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Notes to Editors:

About BI-204

BI-204 (anti-oxLDL, MLDL1278A,) is a human antibody derived from BioInvent's proprietary antibody library n-CoDeR[®]. The antibody targets oxidised forms of a lipoprotein (apoB100), which is a component of the LDL particle. LDL is known as "bad cholesterol". Research in recent years has shown strong links between these oxidised particles and harmful inflammatory processes in the vessel walls. Such inflammation results in the formation of atherosclerotic plaque that may fragment and cause blood clots. Results support that the mechanism behind BI-204 is a modulation of the inflammatory process, resulting in a reduction of pro-

inflammatory cells in treated plaques, which in turn leads to a reduction in new plaque formation and the regression of existing plaques. It is being developed as a drug for the secondary prevention of cardiac events, such as heart attack or stroke, in high-risk patients, with acute coronary syndrome. BI-204 is being developed in collaboration with Genentech, Inc., a wholly-owned member of the Roche Group.

About BioInvent

BioInvent International AB, listed on the NASDAQ OMX Stockholm (BINV), is a research-based pharmaceutical company that focuses on developing antibody drugs. The Company currently has four clinical development projects within the areas of thrombosis, cancer and atherosclerosis. The Company has signed various strategic alliances to strengthen the product pipeline and increase the likelihood of success. These partners include Genentech, Human Genome Sciences, Roche and ThromboGenics.

The company's competitive position is underpinned by an in substance patented antibody development platform. The scope and strength of this platform is also utilised by partners, such as Bayer HealthCare, Daiichi Sankyo, Mitsubishi Tanabe, UCB and XOMA.

More information is available at www.bioinvent.com.

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