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athera biotechnologies

Athera initiates Phase I trial with its fully human antibody PC-mAb

STOCKHOLM, SWEDEN – October 21, 2014. Athera Biotechnologies AB, a Karolinska Development AB portfolio company, today announced that first dosing of healthy volunteers has been done in a Phase I study of its fully human antibody PC-mAb. This lead product candidate targets the inflammatory component of cardiovascular disease, where current therapies are considered to be inadequate.

“We are pleased to have executed our plans in a very timely manner and are looking forward to the results from this important first clinical trial with our PC-mAb” says Carina Schmidt, CEO of Athera. “This is a key achievement for the EU FP7 project CARDIMMUN, aiming to generate proof-of-activity data for PC-mAb.”

“I am delighted to see this pharmaceutical project for such life threatening conditions leaving the lab benches to enter clinical trials”, says Bruno Lucidi, CEO of Karolinska Development.

Athera’s fully human monoclonal antibody PC-mAb is intended for the treatment of patients with cardiovascular disease, who are at an increased risk of secondary events and death. It is known from previous published studies that low plasma levels of endogenous antibodies against phosphorylcholine (anti-PC) are linked to poor prognosis in acute heart attack patients, as well as in patients with peripheral arterial disease undergoing vein graft surgery. The current Phase I study will include up to 48 healthy volunteers in a single ascending dose protocol with safety outcome measures and is performed in Uppsala by CTC Clinical Trial Consultants AB.

The development costs for Athera’s lead product candidate are co-financed by the EU FP7 program, within the project CARDIMMUN.

NOTE: Karolinska Development owns 65% of Athera Biotechnologies which includes indirect ownership through KCIF Co-Investment Fund KB.

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TO THE EDITORS

About Athera Biotechnologies AB
Athera has a unique and in-depth understanding of the immunological components in atherosclerosis, the inflammatory process leading to cardiovascular disease (CVD). The lead product candidate, the fully human antibody PC-mAb, is in clinical development. In addition, Athera has developed a biomarker and companion diagnostic CVDefine® kit. The biomarker, anti-PC, is linked to increased risk for cardiovascular disease and could in the future be used for identification of patients that benefit from Athera's novel therapeutics. Future development costs for the antibody therapy will be co-financed by the EU FP7 program, in the project CARDIMMUN. The project, which has a total budget of nearly € 8 million, will run over 3 years and focus on the key preclinical and clinical development activities to show proof-of-activity in this new cardiovascular treatment. Partners in CARDIMMUN are Athera, Leiden University Medical Center (LUMC), Turku PET Center (Turku University), CTC Clinical Trial Consultants AB and Smerud Medical Research International AS.

About Karolinska Development AB
Karolinska Development aims to create value for patients, researchers, investors and society by developing innovations from world class science into differentiated products that can be partnered. The business model is to: SELECT the most commercially attractive medical innovations that can potentially satisfy unmet medical needs; DEVELOP innovations to the stage where the greatest return on investment can be achieved; and COMMERCIALIZE the innovations through the sale of companies or out-licensing of products. An exclusive deal flow agreement with Karolinska Institutet Innovations AB, along with other cooperation agreements with leading universities, delivers a continuous flow of innovations. Today, the portfolio consists of 33 projects, of which 16 are in clinical development. For more information, please visit www.karolinskadevelopment.com.

Karolinska Development is listed on NASDAQ OMX (KDEV). Karolinska Development may be required to disclose the information provided herein pursuant to the Securities Markets Act.