

# BioInvent Reports Positive Phase I Results for BI-204, in development for prevention of cardiovascular conditions associated with atherosclerosis

**Lund, Sweden – 6 May 2009** - BioInvent International AB (OMXS:BINV) today announces that its therapeutic antibody product candidate BI-204 (anti-oxLDL), has reached the primary endpoint in its Phase I trial, and was safe and well tolerated. These positive Phase I results will now support a decision regarding whether to progress to Phase II.

The objectives of the double-blind, within-group randomised dose-escalation trial were to determine the safety and tolerability of BI-204, as well as evaluation of pharmacokinetic parameters in order to help set dosage of the drug in future Phase II trials. Pharmacokinetic results showed the halflife was in the expected range for fully human antibodies. The study, conducted in Denmark, involved a total of 80 healthy patients with elevated LDL cholesterol. The drug is being co-developed with Genentech, Inc., a wholly-owned member of the Roche Group, under an agreement signed in January 2007. Under the terms of the agreement, Genentech obtained commercialisation rights for North America while BioInvent has retained the rights for the rest of the world.

BI-204 is a monoclonal antibody which targets oxidised forms of LDL cholesterol. In preclinical studies it has reduced inflammatory processes and plaque formation significantly. It is being developed as a potential drug for secondary prevention of cardiac events, such as death, heart attack or stroke, in high-risk patients.

**Svein Mathisen, CEO of BioInvent, commented,** "These Phase I results showing safety and tolerability, along with the preclinical data indicating a significant reduction in atherosclerotic plaque burden, add to our belief that BI-204 could reduce mortality and morbidity for patients with acute coronary artery disease. We believe that there are no effective drugs currently available that have a significant effect on the root cause of the disease once it is established. We are finalising preparations for a potential Phase II clinical trial program and hope to bring this candidate a step closer to potential commercialisation with our collaborator Genentech."

- END -

## About BI-204

BI-204 is a human antibody derived from BioInvent's proprietary antibody library n-CoDeR<sup>®</sup>. 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. BI-204 is being developed in collaboration with Genentech, Inc., a wholly-owned member of the Roche Group.

# For further information, please contact:

#### BioInvent International AB

Svein Mathisen President & CEO

Tel: +46 (0)46-286 85 67 Mobile: +46 (0)708-97 82 13

E-mail: <a href="mailto:svein.mathisen@bioinvent.com">svein.mathisen@bioinvent.com</a>

College Hill (media enquiries)

Holly Griffiths, Sue Charles and John McIntyre

Tel: +44 (0)20 7457 2020

E-mail: bioinvent@collegehill.com

Cristina Glad
Executive Vice President
Tel: +46 (0)46-286 85 51
Mobile: +46 (0)708-16 85 70

E-mail: <a href="mailto:cristina.glad@bioinvent.com">cristina.glad@bioinvent.com</a>

# Legal disclaimer

This press release contains statements about the future, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as of the date they are made and are, by their very nature, in the same way as research and development work in the biotech segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios described in this press release.

## **Notes to Editors:**

## **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 is currently running innovative drug projects within the areas of thrombosis, cancer and atherosclerosis. The Company has signed various strategic alliances around these product candidates and is developing them in collaboration with partners including Genentech, Roche and ThromboGenics.

These projects are based around a competitive and in substance patented antibody development platform. The scope and strength of this platform is also utilised by partners, such as ALK-Abelló, Bayer HealthCare, ImmunoGen, OrbusNeich, Sanofi-Aventis, UCB and XOMA. More information is available at <a href="https://www.bioinvent.com">www.bioinvent.com</a>.

# **BioInvent International AB (publ)**

Co. reg. No. 556537-7263, Address: Sölvegatan 41

Mailing address: SE-223 70 LUND

Tel: +46 (0)46 286 85 50 info@bioinvent.com www.bioinvent.com

Information disclosed in this press release is provided herein pursuant to the Swedish Securities Markets Act and/or the Swedish Financial Instruments Trading Act. The information was submitted for publication at 7.00 a.m. CET, on 6 May, 2009.