

# Announcement of topline results from the GLACIER study

# BI-204 did not meet the primary end-point

**Lund, Sweden – 11 July 2012 –** BioInvent International AB (OMXS: BINV) today announced data from the GLACIER phase IIa study evaluating BI-204 in patients with stable atherosclerotic vascular disease. BioInvent is developing BI-204 in collaboration with Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY).

In the study, BI-204 was administered either as a single dose or in multiple doses over a twelve week period in addition to standard-of-care. The primary endpoint of the study was the relative change in inflammatory activity in an index arterial vessel after twelve weeks, as measured by FDG-PET/CT imaging ([18F]-2-deoxyglucose positron emission-tomography/computed tomography). No statistically significant reduction between placebo and the two active treatment arms was observed. Thus, the study did not meet its primary endpoint.

Based on preliminary safety data review, BI-204 was well-tolerated and no drug-related safety signals were identified. An analysis of additional safety and efficacy data will be available at a later date.

Svein Mathisen, CEO of BioInvent, comments: "We conclude that BI-204 did not meet the primary objective set out in the GLACIER study. Before deciding on the future of BI-204, we and our partner Genentech need to finalize the full data analysis. We expect to provide an update later this year."

BioInvent will host a teleconference today at 11 am CET addressing the outcome of the study. Participants are invited to dial in at: 08 505 20424 (Sweden) or +44 (0)203 003 2666 (International), password BioInvent.

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# To the editors:

#### About GLACIER

GLACIER (**G**oal of oxidised **L**dl and **AC**tivated macrophage **I**nhibition by **E**xposure to a **R**ecombinant antibody) enrolled 147 patients, exploring the anti-inflammatory effect of BI-204, administered either as a single dose or in multiple doses, compared to placebo on top of standard of care, including statins, in patients with stable atherosclerotic cardiovascular disease. Vascular inflammation was quantified by FDG-PET/CT imaging, with the primary endpoint defined as the target-to-background ratio in the most diseased segment (MDS-TBR), a ratio between the FDG uptake signal in the vessel wall and the background blood pool.

# About BI-204

BI-204 (anti-oxLDL, MLDL1278A, RG7418) is a monoclonal antibody derived from BioInvent's proprietary n-CoDeR<sup>®</sup> technology. It is designed to target pro-inflammatory macrophage activity in the atherosclerotic plaque by binding to Oxidised LDL (Low-Density Lipoprotein). Vessel wall inflammation is regarded as the underlying cause of the development of atherosclerosis and coronary artery disease.

#### **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 clinical development projects within the areas of 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 and ThromboGenics.

The company's competitive position is underpinned by n-CoDeR<sup>®</sup>, a proprietary antibody development platform. The scope and strength of this platform is also utilised by partners, such as Bayer HealthCare, Daiichi Sankyo, Mitsubishi Tanabe and Servier. More information is available at <a href="https://www.bioinvent.com">www.bioinvent.com</a>.

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