

## **FDA approval allows BioInvent to open up U.S. sites in the new Phase I/IIa study of BI-1206**

**To date, no dose limiting toxicity has been reported in the ongoing phase I/IIa study conducted by Cancer Research UK**

**Lund, Sweden – 12 July 2018** – BioInvent International AB (OMXS: BINV) announced today that the U.S. Food and Drug Administration (FDA) has accepted BioInvent's Investigational New Drug (IND) Application for its new clinical study that will explore the activity of its proprietary monoclonal antibody BI-1206 in combination with rituximab. The Swedish Medical Product Agency recently approved the initiation of the same study in Sweden.

"The FDA's acceptance of the IND application and the Phase I/IIa clinical study protocol is an important milestone for BioInvent. We have received positive expressions of interest from a number of investigators and clinical institutions in the US as well as Europe. It is encouraging that no signs of safety issues or dose limiting toxicity have so far been reported in the ongoing study of BI-1206", **says Björn Frendéus, acting CEO of BioInvent.**

The new BioInvent sponsored study will run in parallel with the ongoing Phase I/IIa study of BI-1206 in patients with chronic lymphocytic leukemia and non-Hodgkin's lymphoma conducted in the UK by the Cancer Research UK. The ongoing study is currently testing single agent activity and is open for enrollment of additional patients. To date, no dose limiting toxicity has been reported.

BI-1206 was brought to Cancer Research UK through the charity's Clinical Development Partnership (CDP) scheme. The trial, which is co-funded by the charity Bloodwise, is being run by Cancer Research UK's Centre for Drug Development.

### **About the new clinical study**

The new clinical study is a Phase I/IIa, dose escalation, consecutive-cohort, open-label study of BI-1206 in combination with rituximab in patients with indolent relapsed or refractory B-cell non-Hodgkin's lymphoma (NHL). The trial is estimated to recruit approximately 30 patients. The targeted sub-indications are mantle cell lymphoma, follicular lymphoma, and marginal zone lymphoma. The study will explore safety and tolerability, dose and regimen of BI-1206, and will determine a recommended phase II dose (RP2D) to be used in the Phase IIa part of the study. Pharmacokinetics and pharmacodynamics of BI-1206 will be investigated closely to identify the RP2D, and expression of biomarkers will be assessed to explore potential correlation with activity.

### **About BI-1206**

BI-1206 is a monoclonal antibody that recognizes with high affinity and selectivity FcγRIIB (CD32B), the only inhibitory member of the FcγR family. CD32B is highly overexpressed by a number of NHL tumors, and overexpression has been shown to be associated with poor prognosis in difficult-to-treat forms of NHL, such as mantle cell lymphoma or follicular lymphoma. By blocking FcγRIIB, BI-1206 is expected to recover and enhance the activity of rituximab or other anti-CD20 monoclonal antibodies. The combination of the two drugs could provide a new and interesting option for patients suffering from NHL.

## **Notes to editors:**

### **About BioInvent**

BioInvent International AB (OMXS: BINV) is focused on the discovery and development of novel and first-in-class immuno-regulatory antibodies to treat cancer. The Company's clinical programmes are BI-1206, currently in a Phase I/II for non-Hodgkin's lymphoma and chronic lymphatic leukaemia and TB-403, in cooperation with Oncurios, currently in Phase I/II for medulloblastoma. BioInvent has an exciting pre-clinical portfolio based on novel immuno-modulatory antibodies that target regulatory T cells (T-regs) and tumour-associated myeloid cells. The Company has a strategic research collaboration with Pfizer Inc. and BioInvent also works with leading academic institutions including the University of Southampton, Cancer Research UK, and Penn Medicine. BioInvent generates revenues from global partnerships, including Bayer Pharma, Daiichi Sankyo, and Mitsubishi Tanabe Pharma and from its manufacturing facility for the production of antibodies for research through to late-stage clinical trials. More information is available at [www.bioinvent.com](http://www.bioinvent.com)

### **About Cancer Research UK's Clinical Development Partnerships**

CDP is a Cancer Research UK initiative that aims to develop promising anti-cancer agents from companies that are not able to take them through early phase clinical trials themselves. Under the scheme, Cancer Research UK sponsors and funds early clinical development, while companies retain all underlying rights to their programmes. At the end of the study, companies can decide if they wish to develop the drug further based on the clinical trial results. If they choose not to, the charity may secure an alternative partner and ensure the drug has every possible chance of reaching patients, with a share of future income returned to Cancer Research UK. Cancer Research UK's commercial activity operates through Cancer Research Technology Ltd. (CRT), a wholly owned subsidiary of Cancer Research UK. It is the legal entity which pursues drug discovery research in themed alliance partnerships and delivers varied commercial partnering arrangements.

### **About Cancer Research UK's Centre for Drug Development**

Cancer Research UK has an impressive record of developing novel treatments for cancer. The Cancer Research UK Centre for Drug Development, formerly the Drug Development Office, has been pioneering the development of new cancer treatments for 25 years, taking over 140 potential new anti-cancer agents into clinical trials in patients. It currently has a portfolio of around 30 new anti-cancer agents in preclinical development, Phase I or early Phase II clinical trials. Six of these new agents have made it to market including temozolomide for brain cancer, abiraterone for prostate cancer and rucaparib for ovarian cancer. Two other drugs are in late development Phase III trials. This rate of success is comparable to that of any pharmaceutical company.

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*This information is information that BioInvent International AB is obliged to make public*

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