



## **BioInvent presents promising new clinical and preclinical data on anti-FcγRIIB antibody, BI-1206, at the ASH Annual Meeting**

- **Signs of efficacy as first responses observed in lymphoma patients who have relapsed after treatment with rituximab**
- **Preclinical data further reinforce efficacy and tolerability profile**

**Lund, Sweden – November 4, 2020** – BioInvent International AB (“BioInvent” or the “Company”) (OMXS: BINV), a biotech company focused on the discovery and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, today announces it will present new clinical and preclinical data on its novel anti-FcγRIIB antibody, BI-1206, at the 62<sup>nd</sup> American Society of Hematology (ASH) Annual Meeting and Exposition, taking place virtually on December 5-8, 2020.

This includes preliminary data from a Phase I/IIa trial of BI-1206 in combination with rituximab in patients with follicular lymphoma (FL), marginal zone lymphoma (MZL) and mantle cell lymphoma (MCL) who have relapsed or are refractory to rituximab.

The data demonstrate that increasing doses of BI-1206 from 30 mg to 70 or 100 mg gave rise to a supra-proportional increase in the maximum concentration recorded, as well as an increase in the half-life of BI-1206. In addition, the higher dose levels (70 or 100 mg) showed close to full receptor saturation up to 72 hours. Increasing the dose further will likely give rise to sustained receptor saturation over an extended period. Furthermore, complete (CR) and partial (PR) clinical responses, as assessed by reduction of tumor size, were observed, in particular in the 70 mg cohort, where 3 of 5 patients have shown clinical responses.

“These data are very encouraging and indicate the strong potential of BI-1206 to make a significant difference to patients with relapsed or refractory indolent NHL. In particular, these preliminary data suggest that BI-1206 is generating the first signs of clinical responses in patients who have relapsed after treatment with rituximab. Importantly, overcoming target-mediated drug disposition will allow weekly or even less frequent dosing,” said Martin Welschhof, CEO of BioInvent.

“Our recent China licensing agreement for BI-1206 with CASI Pharmaceuticals is an important validation of BioInvent’s technology, expertise and business model. It provides further impetus to our lead drug candidate, and we look forward to continuing development of this novel treatment option in hematological cancers and solid tumors, and bringing it closer to the market.”

BioInvent will also present results from two preclinical studies with BI-1206. Results from the first study show that BI-1206 had single agent activity in a patient-derived xenograft (PDX) model comprising ibrutinib-venetoclax resistant MCL cells *in vivo*. BI-1206 enhanced the *in vivo* efficacy of ibrutinib plus rituximab and venetoclax plus rituximab and overcame resistance to these treatments, resulting in enhanced anti-tumor effects.

In the second preclinical study in mice, pre-medication with two doses of corticosteroids (16-24h and 1h prior to infusion) prevented infusion-related reactions associated with intravenous anti-FcγRIIB administration. This pre-medication regimen has been implemented in the clinical trials of BI-1206 and shown to greatly improve the tolerability profile.

BI-1206 has a novel mode-of-action, blocking the single inhibitory antibody checkpoint receptor FcγRIIB to unlock anti-cancer immunity in both liquid and solid tumors. BI-1206 is BioInvent’s lead drug candidate and is being investigated in a Phase I/II trial, in combination with anti-PD1 therapy Keytruda® (pembrolizumab), in solid tumors, and in a Phase I/IIa trial in combination with MabThera® (rituximab) for the treatment of non-Hodgkin lymphoma (NHL).

### **Details of the abstracts:**

17-BI-1206-02 Phase 1/2a Clinical Trial of BI-1206, a Monoclonal Antibody to FcyRIIB, in Combination with Rituximab in Subjects with Indolent B-Cell Non-Hodgkin Lymphoma That has Relapsed or is Refractory to Rituximab > [Link](#)

Targeting Antibody Checkpoint FcyRIIB Using Monoclonal Antibody BI-1206 to Overcome Therapeutic Resistance in Mantle Cell Lymphoma > [Link](#)

Establishment of an in vivo mouse model to study and overcome infusion related reactions associated with FcyRIIB antibody administration > [Link](#)

### **About BioInvent**

BioInvent International AB (OMXS: BINV) is a clinical stage company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapies, with two ongoing programs in Phase I/II clinical trials for the treatment of hematological cancer and solid tumors, respectively. Two preclinical programs in solid tumors are expected to enter clinical trials by the end of 2020. The Company's validated, proprietary F.I.R.S.T™ technology platform simultaneously identifies both targets and the antibodies that bind to them, generating many promising new drug candidates to fuel the Company's own clinical development pipeline or for additional licensing and partnering.

The Company generates revenues from research collaborations and license agreements with multiple top-tier pharmaceutical companies, as well as from producing antibodies for third parties in the Company's fully integrated manufacturing unit. More information is available at [www.bioinvent.com](http://www.bioinvent.com).

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