BioInvent enrolls first patient in Phase 1/2a trial of BI-1607 in HER2 positive solid tumors

- **Study of BI-1607 in combination with trastuzumab in HER2 positive solid tumors**
- **First patient recruited in Spain**
- **Preclinical data indicate BI-1607 enhances the effect of trastuzumab (Herceptin®)**
- **BioInvent's fifth clinical trial; four distinct drug candidates in ongoing trials**

Lund, Sweden – August 1, 2022 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a biotech company focused on the discovery and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, today announces treatment of the first patient in a Phase 1/2a trial of its second anti-FcyRIIB antibody BI-1607 in combination with trastuzumab in HER2+ solid tumors.

The first-in-human Phase 1 trial is a dose escalation study of BI-1607 combined with trastuzumab in HER2+ advanced or metastatic solid tumors. The selected dose of BI-1607 will be studied in a subsequent Phase 2a part of the trial along with trastuzumab in advanced breast, metastatic gastric and gastroesophageal junction HER2+ cancers.

The first patient has been recruited to the Phase 1 part of the study which is expected to recruit between 12 and 26 subjects. The Phase 2a aims to recruit 30 patients in two cohorts of 15 subjects each (one cohort in breast and one in gastric and gastroesophageal cancers). The study will be carried out at 7-12 sites in Spain, the UK, Germany, and in the U.S.

"This new study with our exciting anti-FcyRIIB antibody BI-1607 marks BioInvent's fifth clinical trial, with four distinct drug candidates, and it is a further demonstration of the productivity of our technology platform. Preclinical data have shown that a BI-1607 surrogate antibody enhances the therapeutic efficacy of anti-HER2 antibodies, and we look forward to further investigating this effect in human subjects," said **Martin Welschof, CEO of BioInvent.**

Like BI-1206, BioInvent's lead FcyRIIB antibody, BI-1607 is intended to enhance the efficacy and overcome resistance to existing cancer treatments such as trastuzumab. Trastuzumab alone or in combination with chemotherapy significantly improves overall survival of HER2+ breast cancer patients. However, many patients remain uncured and develop resistance to trastuzumab resulting in relapse or progression of the disease. BI-1607 differs from BI-1206 in that BI-1607 has been engineered for reduced Fc-binding to FcyRs. This alteration generates a major differentiating factor between the two antibodies, and specifically with respect to the best combination partners.

Preclinical data presented at this year's AACR, indicate that treatment with BI-1607 enhances the efficacy of current anti-HER2 regimens such as trastuzumab. HER2 is a driver of tumor formation and growth in approximately 20% of breast cancers, the most common cancer worldwide in women, and in gastric and gastroesophageal junction adenocarcinoma.

About BioInvent
BioInvent International AB (Nasdaq Stockholm: BINV) is a clinical-stage biotech company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapy, with currently four drug candidates in five ongoing clinical programs in Phase 1/2 trials for the treatment of hematological cancer and solid tumors, respectively. 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. Follow on Twitter: @BioInvent.

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Attachments

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