BioInvent receives FDA IND approval for anti-FcγRIIB antibody BI-1607

- **Phase 1/2a trial in combination with trastuzumab is cleared to be extended to U.S. centers**
- **BioInvent has four drugs in five clinical trials, underlining productivity of proprietary technology platform**

Lund, Sweden – November 18, 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 the U. S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) application for its FcγRIIB-blocking antibody BI-1607.

BI-1607 is intended to enhance efficacy and overcome resistance to existing cancer treatments such as trastuzumab. The IND approval allows for a Phase 1/2a trial with BI-1607, in combination with trastuzumab in HER2+ solid tumors, to be extended to U.S. centers.

The study is currently in the dose-escalation phase, with the selected dose of BI-1607 to be studied in the subsequent Phase 2a part of the trial along with trastuzumab in advanced breast, metastatic gastric and gastroesophageal junction HER2+ cancers. The Phase 1 part of the study is expected to recruit between 12 and 26 subjects. The Phase 2a part 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.

"We are very pleased to receive IND approval for BI-1607, the second FcγRIIB-blocking antibody in our pipeline. Preclinical data indicate that BI-1607 has the potential to enhance the efficacy of current anti-HER2 regimens such as trastuzumab, and thus has the potential to significantly improve treatment options for patients with breast cancer and gastric and gastroesophageal junction adenocarcinoma. With BI-1607 now progressing well in its Phase 1/2a study, BioInvent has four distinct drug candidates under investigation in five clinical trials, underlining the productivity of our technology platform," said Martin Welschof, CEO of BioInvent.

HER2 is a driver of tumor formation and growth and is overexpressed in approximately 20% of breast cancers, the most common cancer worldwide in women, and in gastric and gastroesophageal junction adenocarcinoma. Like BI-1206, BioInvent's lead FcγRIIB 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 but 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.

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 and a fifth program just initiating clinical development. 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

BioInvent receives FDA IND approval for anti-FcyRIIB antibody BI-1607