



CTA approval of BioInvent's BI-1808, a first-in-class anti-TNFR2 antibody, sets stage for Phase I/IIa trial

- **BI-1808 is a novel mechanism of action antibody discovered through BioInvent's unique proprietary F.I.R.S.T™ technology platform**
- **BI-1808 to be evaluated as monotherapy and in combination with anti-PD-1 antibody, Keytruda®**
- **The first patients expected to be enrolled before year-end**

Lund, Sweden – October 26, 2020 – BioInvent International AB ("BioInvent") (OMXS: BINV), a biotech company focused on novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, today announces it has received regulatory authority approval of its clinical trial application (CTA) in Denmark for a Phase I/IIa, first-in-human study of BI-1808, as monotherapy and in combination with the anti-PD-1 therapy Keytruda® (pembrolizumab) for the treatment of solid tumors and cutaneous T-cell lymphoma (CTCL).

Martin Welschof, CEO of BioInvent, says, "CTA approval for our Phase I/IIa trial of BI-1808 marks the first anti-TNFR2 antibody to enter clinical development. BI-1808 is a first-in-class anti-TNFR2 antibody, which we believe is a very promising approach for cancer therapy, and testament to the power of our proprietary n-CoDeR® and F.I.R.S.T™ platforms to generate antibodies to novel targets with potent anti-tumoral activity. We expect to enroll the first patient before the end of the year and to submit an investigational new drug (IND) application in the U.S. in the coming weeks."

The study will explore the safety, tolerability, and potential signs of efficacy of BI-1808 as a single agent and in combination with Keytruda® in patients with ovarian cancer, non-small cell lung cancer and CTCL. It will also investigate the expression of potential immunological markers that might be associated with clinical responses. The trial will be conducted at several sites across Europe and the U.S. and is expected to enroll approximately 120 patients.

The Phase I stage is divided into two parts. Part A is a dose escalation of BI-1808 to assess safety, tolerability, pharmacokinetics/pharmacodynamics, and to determine the recommended dose as a single agent for Phase II trials. It will be followed by part B, which will explore the safety, tolerability and recommended dose of BI-1808 in combination with Keytruda®. The Phase IIa will consist of expansion cohorts to assess signs of efficacy of BI-1808 as single agent and in combination with Keytruda® in lung cancer and ovarian cancer patients. A separate cohort will explore the activity as single agent in CTCL (Sézary syndrome and mycosis fungoides).

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 have entered 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.

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