



BioInvent has enrolled first patient in a Phase I/IIa trial of the first-in-class anti-TNFR2 antibody BI-1808 for the treatment of patients with solid tumors and CTCL

Lund, Sweden – January 26, 2021 – 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 the enrollment of the first patient in 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). The first patient in the Phase I/IIa study has been enrolled in Denmark.

BI-1808 is the lead development candidate from a panel of TNFR2-specific antibodies that BioInvent has generated from its proprietary n-CoDeR® library and unique F.I.R.S.T™ discovery tool. TNFR2 is particularly upregulated on tumor-associated regulatory T cells (Tregs) and has been shown to be important for tumor expansion and survival, representing a new and important target for cancer immunotherapies.

“The start of this Phase I/IIa trial of BI-1808 is an important milestone for BioInvent’s third program in clinical development. It also further validates BioInvent’s proprietary n-CoDeR®/F.I.R.S.T™ platforms and their ability to produce novel, differentiating drug candidates. We have generated a solid preclinical data set for BI-1808, showing exceptionally strong anti-tumor effect in several murine tumor models, and we are excited to now evaluate the potential of this unique antibody in the clinic,” said Martin Welschof, CEO of BioInvent.

The Phase I/IIa study will evaluate 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 immunological markers that may predict 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 study of BI-1808 to assess safety, tolerability, pharmacokinetics/pharmacodynamics, and to determine the recommended dose as a single agent for Phase II trials. Part B will explore the safety, tolerability and recommended dose of BI-1808 in combination with Keytruda®. The Phase IIa stage 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. Another cohort will explore the activity as single agent in CTCL.

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 three ongoing programs in Phase I/II clinical trials for the treatment of hematological cancer and solid tumors, respectively. An additional preclinical programs in solid tumors is expected to enter clinical trials in Q1 2021. 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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