PRESS RELEASE
June 30, 2020

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

Lund, Sweden – June 30, 2020 - BioInvent International AB ("BioInvent") (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 has submitted a clinical trial application (CTA) to begin a Phase I/IIa, first-in-human study of BI-1808, a monoclonal antibody to tumor necrosis factor receptor 2 (TNFR2), as a single agent and in combination with KEYTRUDA® (pembrolizumab) for the treatment of solid tumors and cutaneous T-cell lymphoma (CTCL).

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 cutaneous T cell lymphoma. It will also investigate the expression of potential immunological markers that might be associated with clinical responses. It 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 sections. Part A is a dose escalation of BI-1808 to assess safety, tolerability, and 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®. 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).

Martin Welschof, CEO of BioInvent, says, "Targeting TNFR2 for cancer therapy is a very promising approach and BI-1808 is a further demonstration of the ability of our proprietary n-CoDeR® and F.I.R.S.T™ platforms to generate antibodies with novel, first-in-class mechanisms of action. This Phase I/IIa study of BI-1808 marks the first anti-TNFR2 antibody to enter clinical evaluation. With CTAs filed in Europe, we expect to submit a U.S. IND in the coming months, and to enroll the first patient in Q4 2020."

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.

For further information, please contact:
Martin Welschof, CEO
+46 (0)46 286 85 50
martin.welschof@bioinvent.com

Hans Herklots, LifeSci Advisors
+41 79 598 71 49
hherklots@lifesciadvisors.com

BioInvent International AB (publ)
Co. Reg. No. Org nr: 556537-7263
Visiting address: Ideongatan 1
Mailing address: 223 70 LUND
Phone: +46 (0)46 286 85 50
www.bioinvent.com

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