BioInvent announces promising data for BI-1910 as single agent from Phase 1 study in solid tumors

- BI-1910 single agent Phase 1 Part A dose escalation has been completed and reached a biologically active dose level. Data show stable disease as best clinical response with no notable adverse events even at the highest doses tested.
- Phase 1 part B evaluating BI-1910 in combination with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) initiated
- BioInvent is developing two antibodies against TNFR2 - BI-1910 and BI-1808. Today's announcement on BI-1910, together with data on BI-1808 showing deepening responses in CTCL patients, further validates this target as a novel immune checkpoint

Lund, Sweden – January 8, 2025 – 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 first clinical data from its second anti-TNFR2 antibody, BI-1910, which further validate Tumor Necrosis Factor Receptor 2 (TNFR2) as a potential new checkpoint for cancer immunotherapy. BI-1910 is being evaluated both as single agent (Part A) and in combination (Part B) with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab).

Single agent dose escalation of BI-1910 in the ongoing Phase 1 study has successfully been completed without any notable adverse events. Out of the 12 currently evaluable patients, 6 patients display stable disease. Early results indicate favorable pharmacokinetic data and a robust target engagement, with patients in the target dose range showing evidence of induction of T cell proliferation. With the maturation of clinical response and biomarker data from the Phase 1 patients, Phase 2a studying BI-1910 as single agent is planned to start in H1 2025 and will be performed in several tumor types including HCC (hepatocellular cancer) patients.

The first patients have been enrolled in the Phase 1 Part B study of BI-1910 in combination with pembrolizumab and dose escalation has commenced at a biologically active dose level.

"The encouraging data generated during the year by both our BI-1808 and BI-1910 antibodies further validate TNFR2 as a promising new immune checkpoint and supports our strategy to develop both our assets in the TNFR2 program as we aim to provide new treatment solutions for cancer patients," said **Martin Welschof, Chief Executive Officer of BioInvent**. "We look forward to continuing the clinical development of these two differentiated monoclonal antibodies, both as single agents and also with the additive effects of anti-PD-1 therapy."

As reported in September 2024, preliminary results from the BI-1808 monotherapy study showed that three out of four evaluable patients achieved partial response (PR) in the CTCL cohort of patients who had progressed after standard therapy. These responses are currently ongoing and deepening. New clinical sites have been opened and the enrollment rate in this

cohort is expected to increase. Furthermore, the patient previously reported (ASCO 2024) that is exhibiting a PR continues to improve after more than 80 weeks (as of December 2024). The data on BI-1808 presented at ASCO in June 2024 showed one complete response (CR), one PR and nine patients with stable disease (SD) observed in 26 evaluable patients.

The Phase 2a combination arm of the study evaluating BI-1808 with pembrolizumab is ongoing with patient enrollment into the ovarian cancer cohort underway. Phase 2a data from this combination arm is expected to be presented in H2 2025.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About BI-1910

BI-1910 offers a differentiated, agonist approach to cancer treatment compared to BI-1808, BioInvent's first-in-class anti-TNFR2 antibody currently in a Phase 1/2a development. Both monoclonal antibodies were chosen as potential best-in-class, from a large family of binders generated through BioInvent's proprietary F.I.R.S.T™ technology platform.

The first part of the BI-1910 Phase 1/2a study is a dose-escalation Phase 1 study to evaluate the safety, tolerability, and potential signs of efficacy of BI-1910 as a single agent in patients with advanced solid tumors. In a subsequent part of the Phase 1 study, BI-1910 as single-agent (Part A) and in combination (Part B) with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) will be evaluated.

About BI-1808

BioInvent's anti-TNFR2 antibody BI-1808 is a first-in-class drug candidate in clinical development for the treatment of solid tumors and for a type of blood cancer. BI-1808 has shown single agent activity and excellent tolerability in an ongoing Phase 2 study and promising signs of efficacy and safety in combination with MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in Phase 1.

During the first part of the Phase 1/2a study the safety, tolerability, and potential signs of efficacy of BI-1808, both as a single agent (part A) and in combination with pembrolizumab (part B) are evaluated in patients with advanced solid tumors and T cell lymphoma. The efficacy of BI-1808 as single agent is currently explored in the Phase 2a part of the trial in a larger sample of patients. Expansion cohorts include ovarian cancer, all tumor types and T cell lymphomas (including CTCL). The dose escalation in Phase 1 combination Part B has also been completed and the Phase 2a dose expansion study for the combination is ongoing. The expansion cohorts are the same as for monotherapy, i.e., ovarian cancer, all tumor types and T-cell lymphomas (including CTCL).

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 five drug candidates in six ongoing clinical programs in Phase 1/2 trials

for the treatment of hematological cancer and solid tumors. The Company's validated, proprietary F.I.R.S.T™ technology platform identifies both targets and the antibodies that bind to them, generating many promising new immune-modulatory candidates to fuel the Company's own clinical development pipeline and providing licensing and partnering opportunities.

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 us on the social media platform X: @BioInvent.

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This information is information that BioInvent International is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-01-08 07:57 CET.

Attachments

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