

BioInvent presents positive data at SITC from clinical Phase 1/2a trial of BI-1808 as single agent

- **Preliminary data from Phase 1 part show encouraging early efficacy signals**
- **Robust partial response in one patient with gastrointestinal tumor; 7 cases of stable disease**
- **Favorable safety profile with no dose-limiting toxicity**
- **Further strengthens BioInvent pipeline with additional milestones expected 2023**

Lund, Sweden – November 3, 2023 – 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 presents the latest data from a Phase 1/2a trial of its first-in-class anti-tumor necrosis factor receptor 2 (TNFR2) antibody BI-1808 as a single agent, at the Society of Immunotherapy for Cancer (SITC) 38th Annual Meeting in San Diego, California.

The poster presentation, entitled *“Phase 1/2a Clinical Trial of BI-1808, a Monoclonal Antibody to Tumor Necrosis Factor Receptor 2 (TNFR2) as Single Agent and in Combination with Pembrolizumab”* include data from the BI-1808 monotherapy arm of the Phase 1 study and display encouraging results in the form of early efficacy signals. Furthermore, BI-1808 exhibited a favorable safety profile with no dose-limiting toxicity observed in the monotherapy arm and no maximum tolerated dose could be found. BI-1808 was well tolerated across all dose levels studied. The data strengthens the outlook for the ongoing Phase 2 part of the clinical trial and positions BI-1808 as the best-in-class.

BI-1808 administered as single agent induced a robust partial response (PR) in a patient with a gastrointestinal tumor (GIST) who had received 12 previous lines of treatment. Immune checkpoint inhibitors have previously shown very limited activity in this tumor type. The patient is still receiving BI-1808 treatment, and the most recent scan showed a tumor burden reduced to 48% compared to baseline, with 2/4 target lesions no longer detectable. There are a further 7 cases of stable disease out of 21 evaluable patients and pharmacokinetic/pharmacodynamic data has enabled identification of a wide dose range where complete target coverage can be achieved with a remarkable safety profile.

“We are excited to present these promising results on BI-1808 to the scientific community at the SITC Annual Meeting. The data generated so far show a strong safety profile and we are encouraged by the early signs of efficacy as single agent. Overall, the data provide a compelling case to expand the clinical development of BI-1808 to different tumor types. This adds further to BioInvent’s momentum, with four products in five clinical trials and the pipeline soon to be expanded further. We are expecting additional significant milestones through the rest of this year and 2024 which will very likely generate significant value for the company,” said Martin Welschof, CEO of BioInvent.

The title and number of the SITC poster presentation is as follows:

Title: *Phase 1/2a Clinical Trial of BI-1808, a Monoclonal Antibody to Tumor Necrosis Factor Receptor 2 (TNFR2) as Single Agent and in Combination with Pembrolizumab*

Number: 757

BI-1808 and the second anti-TNFR2 antibody BI-1910, are part of BioInvent's tumor-associated regulatory T cells (Treg)-targeting program. TNFR2 is particularly upregulated on Tregs of the tumor microenvironment and has been shown to be determinant for tumor growth and survival, representing a new and promising target for cancer immunotherapy.

The dose-escalation, multicenter, first-in-human, consecutive-cohort, open-label trial of BI-1808 is investigating it as a single agent and in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in subjects with advanced malignancies, whose disease has progressed after standard therapy. It consists of Phase 1 Parts A and B (dose escalation as single agent and in combination with pembrolizumab, respectively), and Phase 2a Parts A and B (dose expansion cohorts with treatment as single agent and in combination, respectively).

The efficacy of BI-1808 as single agent is currently further explored in an ongoing Phase 2a trial in a larger sample of patients. In addition to the originally planned expansion cohorts in lung cancer, ovarian cancer and cutaneous T cell lymphoma (CTCL), BioInvent plans to enlarge the scope of the signal seeking cohorts to include new cohorts in melanoma and other forms of T cell lymphomas. This is driven by the exciting data observed so far. Phase 1 data on the combination of BI-1808 with pembrolizumab is due in H1 2024.

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

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. 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 drug 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 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 2023-11-03 17:00 CET.

Attachments

[BioInvent presents positive data at SITC from clinical Phase 1/2a trial of BI-1808 as single agent](#)