BioInvent Presents Promising Clinical Efficacy and Safety for anti-TNFR2 agent BI-1808 at ASCO 2024

BI-1808 could represent a new class of immunomodulatory agent with the potential to improve efficacy of cancer therapy.

- *Initial efficacy and safety data from the ongoing Phase 1/2a study show:*
  - *One complete response (CR), one partial response (PR) that is still improving, and nine patients with stable disease (SD) in single agent arm of BI-1808*
  - *Promising signs of efficacy and favorable safety profile in the Phase 1 dose escalation part studying BI-1808 in combination with KEYTRUDA® (pembrolizumab)*
- *Data to be presented at the American Society for Clinical Oncology to be held May 31 to June 4, 2024.*

Lund, Sweden – May 23, 2024 – 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 the treatment of cancer, today announced further promising early signs of single agent efficacy and a robust safety profile for the company's anti-TNFR2 program BI-1808. The data will be presented in a poster at the 2024 ASCO Annual Meeting (ASCO 2024) held in Chicago, Illinois from May 31 to June 4, 2024.

"We are pleased to present these early data from the Phase 1/2a study evaluating BI-1808 as single agent and in combination with pembrolizumab in patients with solid tumors, which support our belief that the product could represent a new class of immunomodulatory agent with the potential to improve the efficacy of cancer therapy. These strong signals of antitumoral activity, especially in these heavily pre-treated patients, are very encouraging," said Martin Welschof, Chief Executive Officer of BioInvent.

BI-1808 is being studied as both a single agent and in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors or T-cell lymphomas, including CTCL. The ongoing Phase 1 combination part is in the final stage of the dose escalation phase. The Phase 2a single agent part is in the dose expansion phase testing the activity in four different tumor types: ovarian cancer (OC), melanoma, non-small cell lung cancer (NSCLC) and other tumor types (e.g., gastrointestinal stromal tumors (GIST)), and TCL/CTCL.

Poster summary

- **Single agent Safety and Efficacy**
  Safety: Across the dose range (25 to 1000 mg dose), no Grade 3/4 adverse events (AEs) related to BI-1808 were observed. A number of potentially related Grade 1/2 AEs were evenly distributed across the dose range (no target organ class identified) with five Gr 1/2 infusion-related reactions (IRR) observed.
  Efficacy: Of 26 evaluable patients treated with monotherapy, best clinical responses were

one complete response (CR), one partial response (PR) and nine patients with stable disease (SD). The CR was observed in the ongoing Phase 2a part of the study, in an ovarian cancer patient with disease progression after three previous lines of treatments. As previously reported, the PR was observed in a heavily pre-treated patient with metastatic GIST (12 prior lines of treatment). This PR represents a robust response and is still improving. Another patient with NSCLC (treatment terminated for unrelated reasons) showed a reduction in several target lesions at three months. The patient with the PR and the patient with NSCLC showed in analyses clear signs of T cell activation in blood and tumor, suggesting that T cell responses underlie tumor regression.

- Pembrolizumab combination Safety and Efficacy
  Safety: BI-1808 in combination with pembrolizumab is well tolerated. With 19 patients dosed, two DLTs (Dose-limiting toxicities) have been observed (1 colitis and 1 fatigue).
  Efficacy: 3 of 8 evaluable patients showed SD after combination treatment.
- Pharmacology: At doses of 675 mg every three weeks, the half-life of BI-1808 was approximately one week leading to drug accumulation, complete receptor occupancy during the treatment interval, an increase in soluble TNFR2 and a significant reduction in Tregs.

Poster title: 19-BI-1808-01, a Phase 1/2a Clinical Trial of BI-1808, a Tumor Necrosis Factor Receptor 2 (TNFR2) Blocker/Depleter with or without Pembrolizumab
Abstract Number: 2641
Session: Developmental Therapeutics – Immunotherapy
Date: June 1, 2024
Time: 9:00 AM – 12:00 PM CDT
The full poster will be posted to the company's website https://www.bioinvent.com/en/our-science/scientific-publications shortly after the presentation.

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 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 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 2024-05-23 23:00 CEST.

Attachments

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