BioInvent Presents Promising Phase 1 Data for BI-1206 in Combination with KEYTRUDA® (pembrolizumab) in Patients with Solid Tumors at ASCO 2024

BI-1206 in combination with pembrolizumab leads to responses in melanoma patients who previously failed on anti-PD1 therapy.

- Promising clinical efficacy signals in heavily pre-treated patients with solid tumors and with manageable side effects
- One complete response (CR), one partial response (PR) and seven patients with stable disease (SD) including one long-lasting, out of 24 evaluable patients
- BI-1206 is being evaluated as both an intravenous (IV) and subcutaneous (SC) administration and has the potential to overcome resistance to immune checkpoint inhibition (CPI)
- 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 cancer immunotherapy, today announced promising Phase 1 data for BI-1206 in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in heavily pre-treated patients with solid tumors. The data show promising and durable responses in patients who previously failed on anti-PD-1/L1 therapy. The combination was well-tolerated in this heavily pre-treated population of patients. 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.

"The number of targets available for antibody therapy is still limited and there is a high unmet medical need for new treatment options since the vast majority of patients do not respond or stop responding to current treatments. We believe that BI-1206 has the potential to be used in combination with CPIs to overcome immunotherapy drug resistance through its unique anti-FcγRIIB action," said Martin Welschof, Chief Executive Officer of BioInvent.

BioInvent's Chief Medical Officer Andres McAllister added, "The ability to induce responses in heavily pre-treated patients, including two durable responses and a stable disease lasting for more than 24 months, is encouraging and supports the importance of blocking FcγRIIB to enhance the activity of immune checkpoint inhibitors."

The data announced today also show that the subcutaneous (SC) administration of BI-1206, being developed in parallel to the IV administration, was well tolerated with no notable injection reactions. SC administration led to extended target coverage and shows great promise to provide a further extended duration of receptor occupancy with increased tolerability. SC dose escalation is still ongoing.

Poster summary:
The Phase 1/2a trial is performed in previously treated patients with advanced solid tumors to assess the safety and tolerability of BI-1206 in combination with pembrolizumab at ascending intravenous (IV) and subcutaneous (SC) doses.

Safety and efficacy

- Dose escalation with IV was completed with no formal maximally tolerated dose, MTD, defined. The most frequent treatment-emergent adverse events (TEAEs) were infusion-related reactions, thrombocytopenia, and elevated liver enzymes. The events were transient without any clinical consequences and corticosteroid pre-medication, or split dosing reduced the risk and/or intensity of these events.
- Dose escalation with SC is ongoing, and to date 7 patients have been dosed with no notable safety events related to the combination, including no IRR, thrombocytopenia, or elevated liver enzymes of any grade. Good target coverage was demonstrated already at entry dose level.
- In 24 evaluable patients, the combination demonstrated one CR (metastatic melanoma, 3 prior anti-PD-1 treatments including one anti-CTLA-4), one long-lasting PR (uveal melanoma, >24 months) and seven cases of stable disease, including one long-lasting (metastatic melanoma, >24 months).

An IV dose level (RP2D) has been selected for signal seeking in the subsequent Phase 2a study, while appropriate dose for use of SC in Phase 2a will be determined after completion of dose escalation. The Phase 2a part will include three expansion cohorts at the RP2D, each comprising a specific subset of subjects with advanced solid tumors (e.g., NSCLC, melanoma, and other tumors responsive to PD-1/PD-L1 inhibition).

Poster title: Phase 1/2a Clinical Trial of BI-1206, an Anti-CD32b (FcγRIIB) Antibody, in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors Previously Treated with Anti-PD-1/PD-L1
Abstract Number: 2593
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.

For further information, please contact:
Cecilia Hofvander, Senior Director Investor Relations
Phone: +46 (0)46 286 85 50
Email: cecilia.hofvander@bioinvent.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

The press release contains statements about the future, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as the date they are made and are, by their very nature, in the same way as research and development work in the biotech segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios described in this press release.

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

BioInvent Presents Promising Phase 1 Data for BI-1206 in Combination with KEYTRUDA® (pembrolizumab) in Patients with Solid Tumors at ASCO 2024