BioInvent Announces Promising Phase 1 Data of BI-1206 in Combination with KEYTRUDA® (pembrolizumab) in Solid Tumors

- *The Phase 1 dose escalation has been completed, and results show encouraging early signs of clinical activity in solid tumors with one complete response, one long-lasting partial response, and 11 patients with stable disease.*
- *Based on this promising data, BioInvent plans to initiate Phase 2a expansion cohorts to treat patients with advanced or metastatic non-small cell lung cancer (NSCLC) or uveal melanoma, in the front line in combination with KEYTRUDA® (pembrolizumab). Patient enrollment is expected to begin H2 2025.*

Lund, Sweden – June 11, 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 announced updated, positive Phase 1 data of intravenous (IV) and subcutaneous (SC) 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. Based on the encouraging data, the company intends to expand its investigation of BI-1206 SC in combination with pembrolizumab in earlier lines of treatment, by initiating a Phase 2a study arm with focus on first-line patients with advanced or metastatic NSCLC and uveal melanoma. The Phase 2a study is planned to be initiated during H2 2025.

The updated Phase 1 data in heavily pre-treated patients - including several lines of IO agents - show encouraging clinical activity of the combination, with one patient with metastatic cutaneous melanoma experiencing a complete response (CR), one patient with metastatic uveal melanoma achieving a long-lasting partial response (PR) and 11 patients experiencing stable disease (SD) out of a total of 36 evaluable patients. The product was well-tolerated, enabling continued dose expansion exploring the use of higher dose levels. The trial is part of BioInvent's strategy to transition from IV dosing to SC formulation for BI-1206 allowing slower systemic entry and prolonged time on target to enhance the products therapeutic impact and improve safety and tolerability of the combination.

The Phase 1 data in solid tumors corroborate preclinical findings that BI-1206 significantly enhances the effect of anti-PD-1. Based on this evidence, MSD and BioInvent have agreed to further investigate the synergies between BI-1206 and pembrolizumab in earlier lines of treatment. The upcoming Phase 2a study of BI-1206 in combination with pembrolizumab is planned to be performed in treatment-naïve patients with NSCLC and uveal melanoma.

"We are highly encouraged by the clinical responses emerging from our solid tumor program which support the broad utility of combining subcutaneous BI-1206 with pembrolizumab in a range of solid tumors," said Martin Welschof, Chief Executive Officer of BioInvent. "The strong signals we have observed in heavily pre-treated patients support the idea that BI-1206 could be used to improve the activity of pembrolizumab across different tumor types, and we therefore look forward to initiating our Phase 2a study in the high unmet medical need of non-small cell lung cancer."

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

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About NSCLC and combination treatment with targeting FcγRIIB

NSCLC is the most common type of lung cancer, accounting for about 85% of all lung cancer cases. While checkpoint inhibitors are widely accepted and can produce durable responses in NSCLC, the overall response rate remains low, rarely exceeding 25%. A common resistance mechanism in cancer is the binding and degradation of therapeutic antibodies against PD-1 such as pembrolizumab by FcγRIIB expressing immune cells. Therefore, based on preclinical and early clinical data, the company believes that resistance or lack of response to anti-PD-1 treatment may be overcome by FcγRIIB blockade in particular in subjects who have never been exposed to anti PD-1 agents.

About BI-1206

BI-1206 is one of BioInvent's lead drug candidates and is developed to re-establish the clinical effect of existing cancer treatments such as pembrolizumab and rituximab. The drug candidate is evaluated in two separate clinical programs, one for the treatment of solid tumors and one for the treatment of non-Hodgkin's lymphoma (NHL, a type of blood cancer).

BI-1206 in solid tumors

Clinical Phase 1/2a study with 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 (NCT04219254) is ongoing.

The concluded Phase 1 dose escalation study in heavily pre-treated patients shows encouraging clinical activity of the combination, including one CR in metastatic melanoma, one PR in uveal melanoma and 11 patients experiencing SD out of a total of 36 evaluable patients. The product was well-tolerated, enabling continued dose expansion exploring the use of higher dose levels. For further details, please refer to the ASCO 2024 poster on the company web site: https://www.bioinvent.com/sites/bioinvent/files/BioInvent_ASCO_Poster_BI-1206_FINAL.pdf.

Out of the patients with stable disease as best response, one patient with long-lasting metastatic melanoma, who had previously progressed on nivolumab treatment, remained a stable disease throughout the two-year study duration with BI-1206 and pembrolizumab.

The planned Phase 2a study of BI-1206 in combination with pembrolizumab for treatment-naïve patients with NSCLC and uveal melanoma consists of two parts: a signal seeking phase and a dose optimization phase. In the first signal seeking phase, up to 30 NSCLC and 12 uveal melanoma patients will receive fixed doses of BI-1206 and pembrolizumab every 21 days for three treatment cycles. Patients showing clinical benefit by Week 9 can continue therapy for up to 32 additional cycles, while those with disease progression will not proceed further.

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.

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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.

Attachments

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