BioInvent Announces Initiation of BI-1206 Phase 2a Trial in Advanced or Metastatic NSCLC and Uveal Melanoma

Lund, Sweden – October 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 announced the initiation of a Phase 2a clinical trial evaluating BI-1206 in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced or metastatic non-small cell lung cancer (NSCLC) and uveal melanoma in the first-line setting.

As presented at ASCO 2024, in Phase 1, BI-1206 was deemed to be safe and well-tolerated and demonstrated promising clinical activity in heavily pre-treated patients, with one complete response (CR), one long-lasting partial response (PR), and 11 patients with stable disease (SD) out of 36 evaluable patients. All patients had progressed after previous treatments with anti-PD1 /L1 agents. The subcutaneous formulation provided slower systemic entry and prolonged time on target while improving safety and tolerability.

"We are very pleased to initiate Phase 2a studies, which marks a significant milestone in our mission to bring BI-1206 to patients," said Martin Welschof, Chief Executive Officer of BioInvent. "The early clinical signs of efficacy observed in the Phase 1 trial provide a strong rationale for moving forward in the first line setting in NSCLC and uveal melanoma, two areas of important medical need. Since BI-1206 addresses a mechanism of resistance to anti-PD1, the potential of BI-1206 extends to all indications where pembrolizumab is approved."

The Phase 2a trial (NCT04219254) will evaluate the safety and efficacy of BI-1206 in combination with pembrolizumab in patients with advanced or metastatic NSCLC and uveal melanoma. Patients will be enrolled at sites in Georgia, Germany, Poland, Rumania, Spain, Sweden and the US, with first data expected in H2 2026.

The trial will be conducted in two parts. In the first part, or signal-seeking phase, up to 30 NSCLC and 12 uveal melanoma patients will receive BI-1206 and pembrolizumab every 21 days for up to 2 years. Following the signal-seeking phase, the study will proceed to a dose optimization phase, designed to refine the dosing strategy to maximize both efficacy and tolerability of the combination. During dose optimization, patients will be randomized to receive a higher or a lower dose of BI-1206. A third cohort will receive pembrolizumab alone.

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, uveal melanoma and combination treatment with targeting FcyRIIB
NSCLC is the most common type of lung cancer, accounting for about 85 percent 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 percent.

Uveal melanoma is a rare and difficult-to-treat cancer but the most frequent non-cutaneous melanoma and primary malignancy of the eye in adults. Globally, it is estimated that there are approximately 7000 new cases of uveal melanoma annually.

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
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.

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 stable disease throughout the two-year study duration with BI-1206 and pembrolizumab.

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 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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