BioInvent Reports Promising Data from Ongoing Phase 2a study for BI-1808 with KEYTRUDA® (pembrolizumab) in Recurrent Ovarian Cancer

- 24% ORR for BI-1808 combined with pembrolizumab represents a meaningful improvement over pembrolizumab monotherapy in recurrent ovarian cancer (8% ORR in KEYNOTE-100)
- The combination demonstrated a favorable safety and tolerability profile
- Results suggest that this combination could deliver a new immuno-oncology option for this population with high unmet need
- BioInvent will expand the ovarian cancer cohort by enrolling an additional 20 patients focusing on high-grade serous and clear cell subtypes, expected data read-out H2 2026

Lund, Sweden – January 5, 2026 – 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 encouraging interim results from its ongoing Phase 2a signal-seeking study evaluating BI-1808, a novel immuno-oncology candidate, in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with recurrent ovarian cancer who have progressed following platinum-based therapy. The interim data from the signal-seeking cohort of patients with recurrent ovarian cancer demonstrates an overall response rate (ORR) of 24%, which represents a meaningful improvement over pembrolizumab monotherapy.

Treatment of recurrent ovarian cancer remains one of the most challenging in oncology, with limited treatment options after platinum failure and historically low response rates to immunotherapy. Preclinical studies demonstrated synergistic anti-tumor activity when BI-1808 was combined with pembrolizumab, providing a strong rationale for advancing this combination into clinical development. Ovarian cancer is an exciting prospect for the combination Phase 2a signal-seeking cohort given a complete response (CR) was observed in a platinum-resistant patient treated with BI-1808 monotherapy, highlighting the potential of targeting this difficult-to-treat population.

"Recurrent ovarian cancer has few options after platinum failure and a history of unsuccessful attempts to develop chemotherapy-free immunotherapy approaches," said Martin Welschof, Chief Executive Officer of BioInvent. "Pembrolizumab has shown meaningful benefit only when combined with chemotherapy, while monotherapy in the KEYNOTE-100 study achieved an ORR of 8%. Against this backdrop, observing a 24% response rate and a 65% disease control rate with

BI-1808 in combination with pembrolizumab is highly encouraging and has led us to expand this cohort to better qualify this signal. These results suggest that our combination could deliver a new immuno-oncology option for patients who urgently need better alternatives, and we look forward to reporting more data going forward."

Overview of BI-1808 + pembrolizumab combination data:

As of December 18, 2025, 23 patients have been enrolled, and 17 have been evaluated with the BI-1808 + pembrolizumab therapy. The combination treatment achieved a disease control rate (DCR) of 65%,11/17 evaluable patients with ovarian cancer; 4 partial responses (PR), 7 patients with stable disease (SD), with several durable SD beyond eight months and ongoing. The overall response rate (ORR) is 24%. Some responses have been observed after several months of treatment, suggesting that additional responses with potentially important impact on PFS (Progression Free Survival) may be observed.

The combination was generally safe and well-tolerated, and all adverse events were manageable with standard medical treatments.

Exploratory analyses indicate strong activity in both high-grade serous and clear cell ovarian cancer subtypes. The Phase 2a expansion will enroll an additional 20 patients focusing on these subtypes to validate and quantify the signal with an expected readout in H2 2026.

Clinical trial collaboration and supply agreement

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. Since August 2021, BioInvent has had a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the combination of BI-1808 and MSD's anti-PD-1 therapy, KEYTRUDA (pembrolizumab).

About the Phase 2a Study

This Phase 2a trial (NCT04752826) is designed to assess BI-1808 administered as a single agent (Part A) and in combination with pembrolizumab (Part B) at the respective recommended Phase 2 dose (RP2D) determined in Phase 1. Phase 2a expansion is being conducted in indication specific cohorts of subjects. The aim of the Phase 2a is to further assess the safety and tolerability of BI-1808 as a single agent (Part A) and in combination with pembrolizumab (Part B), characterize its PK and pharmacodynamics, and assess preliminary antitumor activity by ORR, DoR (duration of response), and progression-free survival (PFS), as measured by RECIST v1.1 and iRECIST.

About BI-1808

The anti-TNFR2 antibody BI-1808 is 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 important for tumor expansion and survival, representing a new and promising target for cancer immunotherapy. BI-1808 is a first-in-class drug candidate in clinical

development for the treatment of T-cell lymphoma and solid tumors. BI-1808 has shown single-agent activity and excellent tolerability in an ongoing Phase 2a study and efficacy and a favorable safety profile in combination with pembrolizumab in an ongoing Phase 1/2a study for the treatment of solid tumors.

A manuscript detailing the mechanisms of action of the BI-1808 and differentiated BI-1910 anti-TNFR2 antibodies has been uploaded to BioRxiv.com, an open-access online repository for yet unpublished research manuscripts (preprints). Both anti-TNFR antibodies show potent anti-tumor efficacy across multiple syngeneic mouse tumor models, can effectively be combined with anti-PD-1, and trigger CD8+ T cell antitumor immunity, albeit by different mechanisms; BI-1808 is a ligand-blocking FcgR-engaging antibody that depletes immunosuppressive Treg cells and reprograms myeloid cells. BI-1910 is a pure agonist antibody that directly co-stimulates T and NK cells through partially FcgR-independent mechanisms.

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 drug candidates in 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.

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 2026-01-05 07:30 CET.

Attachments

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