BioInvent Reveals Solid Data with its TNFR2 Antibody BI-1808 and KEYTRUDA® (pembrolizumab) in Advanced Ovarian Cancer at ASCO

- 24% confirmed ORR (including complete response) in heavily pretreated patients (n=25) with advanced ovarian cancer who received BI-1808 and KEYTRUDA — multiplying by three the historical single agent activity of 8% in KEYNOTE-100 (2019)
- 56% disease control rate (DCR) in the combination arm, including multiple durable responses extending beyond 10 months with patients still on treatment
- The treatment exhibits a very favorable safety profile, and, in contrast to chemotherapy-based regimens, result in very low rates of safety-related treatment discontinuations
- A preliminary median progression-free survival (mPFS) of 10.3 months in the combination arm, based on early PFS analysis
- Activity observed across both high-grade serous and clear cell ovarian cancer subtypes
- Demonstrated robust Treg depletion, reprogramming of myeloid cells, and CD8+ T-cell activation, supporting BI-1808's differentiated mechanism and combination synergy with pembrolizumab
- Cohort expansion is underway, focusing on high-grade serous and clear cell subtypes, with another data readout expected in H2 2026

Lund, Sweden – May 21, 2026 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a leader in the discovery of novel immune-modulatory antibodies, today announced highly promising early data from its ongoing Phase 2a clinical trial evaluating BI-1808, its monoclonal antibody targeting TNFR2, in combination with MSD's (Merck & Co., Inc., Rahway, NJ., USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) for the treatment of heavily pretreated patients with advanced ovarian cancer. These data will be presented in a poster (#2605) as part of the Developmental Therapeutics - Immunotherapy track at the 2026 American Society of Clinical Oncology (ASCO) Annual Meeting.

"With a confirmed response rate of 24% and durable disease control in more than half of patients, this combination constitutes an important treatment benefit compared to historical benchmarks for PD-1 monotherapy. We are seeing compelling signals that BI-1808 may unlock a new therapeutic potential when combined with pembrolizumab," said Martin Welschof, CEO of BioInvent. "These emerging data represent continued clinical validation of TNFR2 targeting and demonstrate the powerful mechanistic synergy we envisioned, including meaningful immune activation in tumors where checkpoint inhibitors have historically shown limited benefit. This combination has the potential to redefine how PD-1 inhibitors are used in difficult-to-treat cancers."

Patients with recurrent ovarian cancer progressing after platinum therapy (PROC) face a major unmet need, with pembrolizumab monotherapy historically achieving only an 8% response rate. BI-1808, a first-in-class antibody that depletes immunosuppressive Tregs and activates CD8+ T cells by targeting TNFR2, is designed to synergize with PD-1 blockade. In interim Phase 2a results released today, BI-1808 plus pembrolizumab (without chemotherapy) demonstrates a 24% confirmed ORR and 56% disease control rate in this heavily pretreated population, with durable benefit across both high-grade serous and clear cell subtypes, highlighting the potential for a meaningful new option where existing approaches have largely failed. Importantly, prolonged stable disease was observed in multiple patients, with several responses ongoing beyond 10 months, and early analyses indicate a median progression-free survival (mPFS) of 10.3 months.

Poster data overview: robust clinical and translational signals in patients with advanced ovarian cancer

As of April 20, 2026, 25 patients with recurrent, heavily pretreated advanced ovarian cancer who had progressed following platinum-based chemotherapy (predominantly high-grade serous adenocarcinoma (n=16), with the remaining cases comprising clear cell ovarian carcinoma, n=9) received BI-1808 (1000 mg Q3W) in combination with pembrolizumab (200 mg Q3W).

Among 25 response-evaluable patients, the chemotherapy-free combination demonstrated promising antitumor activity, achieving a confirmed objective response rate (ORR) of 24%, driven by one complete response (CR) and five partial responses (PR). An additional eight patients achieved stable disease, resulting in a disease control rate (DCR) of 56%. Importantly, prolonged stable disease was observed in multiple patients, with several responses ongoing beyond 10 months, and early analyses indicate a median progression-free survival (mPFS) of 10.3 months. Clinical activity was observed across both high-grade serous and clear cell histology, two subtypes associated with particularly poor outcomes in the recurrent setting.

Pembrolizumab monotherapy in KEYNOTE-100 showed an ORR of 8% and mPFS of 2.1 months in ovarian cancer, and BI-1808 monotherapy exhibited similar limited activity in this study with one CR and a mPFS of 3.6 months.

Treatment was generally safe and well tolerated, with immune-related adverse events consistent with expectations for immunotherapy and effectively managed using standard clinical practice, and a low rate of treatment related discontinuations (<5%).

Translational analyses further supported BI-1808’s differentiated mechanism of action, demonstrating robust depletion of regulatory T cells and reprogramming of myeloid cells, as evidenced by induction of IL-12, along with activation of circulating CD8+ T cells. When BI-1808 was administered in combination with pembrolizumab, increased CD8+ T-cell activation was observed together with elevated cytokines associated with the formation of tertiary lymphoid structures (TLS) - organized immune cell aggregates within the tumor microenvironment that support sustained antitumor immune responses - providing pharmacodynamic evidence of active immune remodeling and enhanced antitumor engagement.

BioInvent is preparing for opening of Part C of the study, evaluating the triplet combination of BI-1808, pembrolizumab and paclitaxel in H2 2026.

The poster presentation showcasing the above data will be available on the company's website on May 30, at 8 am EDT/2 pm CEST: https://www.bioinvent.com/en/our-science/scientific-publications.

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 BI-1808 Phase 2a Study

This Phase 2a trial (NCT04752826) is designed to assess the safety and tolerability of BI-1808 as a single agent (Part A), in combination with pembrolizumab (Part B) and in a triple combination with pembrolizumab and paclitaxel (Part C). The study aims to characterize safety, pharmacokinetics 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 and T-cell lymphomas.

A manuscript detailing the mechanisms of action of the BI-1808 and differentiated BI-1910 anti-TNFR2 antibodies is available on 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 2026-05-21 23:00 CEST.

Attachments

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