BioInvent Receives FDA Fast Track Designation for BI-1808 for the Treatment of Ovarian Cancer

- FDA Fast Track Designation granted for BI-1808, a first-in-class anti-TNFR2 antibody, for the treatment of ovarian cancer.
- BI-1808 in combination with pembrolizumab demonstrated a 24% confirmed ORR and 56% DCR in heavily pretreated patients with advanced platinum-resistant ovarian cancer, presented at ASCO 2026
- Cohort expansion is underway, focusing on high-grade serous and clear cell subtypes, with another data readout expected in H2 2026

Lund, Sweden – August 7, 2026 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a leader in the discovery of novel immune-modulatory antibodies, today announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation to BI-1808, a first-in-class anti-TNFR2 antibody, for the treatment of ovarian cancer in combination with pembrolizumab.

"Receiving FDA Fast Track Designation for BI-1808 in ovarian cancer is an important milestone that reflects the significant unmet medical need in this difficult-to-treat disease and the strength of the clinical signals we have generated to date," said Martin Welschof, Chief Executive Officer of BioInvent. "The data we have presented across both high-grade serous and clear cell subtypes underscore the potential of targeting TNFR2 to meaningfully enhance the activity of PD-1 inhibitors in tumors where these agents have historically shown limited benefit. This designation validates our development strategy and strengthens our commitment to advancing BI-1808 as a new treatment option for patients with ovarian cancer."

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 is a first-in-class antibody targeting TNFR2 that depletes immunosuppressive Tregs, activates myeloid cells and CD8+ T cells in the tumor microenvironment and synergizes with PD-1 blockade. The interim Phase 2a results presented at ASCO 2026 demonstrate that BI-1808 plus pembrolizumab (without chemotherapy) produced a 24% confirmed overall response rate (ORR) and 56% disease control rate (DCR) 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 and partial responses were observed in multiple patients, with several responses ongoing beyond 10 months. Preliminary analyses indicate a median progression free survival (mPFS) of 10.3 months.

The poster presentation showcasing the ASCO data is available on the company's website: https://www.bioinvent.com/en/our-science/scientific-publications. For further information, please see the KOL event: BioInvent Virtual KOL Event to Discuss BI-1808 for the Treatment of Ovarian Cancer - LifeSci Events

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 mechanism of action of BI-1808 (and BI-1910) is available on BioRxiv.com, an open-access online repository for unpublished research manuscripts (preprints). BI-1808 is a ligand-blocking FcgR-engaging antibody that depletes immunosuppressive Treg cells and reprograms myeloid cells. BI-1808 shows potent anti-tumor efficacy across multiple syngeneic mouse tumor models, can effectively be combined with anti-PD-1, and triggers effective CD8+ T cell antitumor immunity.

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.

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

BioInvent International AB (publ)
Co. Reg. No.: 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.

Attachments

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