

BioInvent's BI-1808 and KEYTRUDA® Induce Durable Responses in Heavily Pretreated Platinum-Resistant Ovarian Cancer

Updated efficacy data in 34 evaluable patients with a chemotherapy-free regimen; randomized Part C will add BI-1808 to the new standard of care

- 24% objective response rate (8 of 34 evaluable patients: 1 complete and 7 partial responses), including patients with high-grade serous and clear cell carcinoma
- 53% disease control rate, with several patients in stable disease beyond 10 months; 6 patients were still on treatment at data cutoff
- Median progression-free survival of 4.1 months per RECIST, compared with 2.1 months reported for pembrolizumab alone¹ (indirect comparison); 10.3 months per iRECIST
- Duration of response was not met at cutoff (median follow-up 11.6 months), suggesting that responses are durable
- Well tolerated: fewer than 5% treatment-related discontinuations among 81 solid tumor patients treated with the combination
- Part C will add BI-1808 to pembrolizumab plus weekly paclitaxel ± bevacizumab in a randomized design; first data expected in H2 2027

Lund, Sweden – October 24, 2026 – BioInvent International AB (“BioInvent”) (Nasdaq Stockholm: BINV), a leader in the discovery of novel immune-modulatory antibodies, today announced updated data from Part B of its ongoing clinical study of BI-1808, a first-in-class anti-TNFR2 antibody, combined with MSD’s (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced platinum-resistant recurrent ovarian cancer (PRROC) and a median of four prior lines of therapy.

The data are presented today in poster #2009P (12:00–12:45 CEST) at the ESMO Congress 2026 in Madrid. They update the 25-patient analysis reported at ASCO 2026, the ESMO abstract published on October 19 and now include 34 evaluable patients (cutoff September 14, 2026).

Checkpoint inhibitors alone have limited activity in PRROC because CD8+ T cells poorly infiltrate the tumor microenvironment, where immunosuppressive TNFR2-expressing cells such as regulatory T cells (Tregs) and tumor-associated myeloid cells are enriched and further suppress antitumor T-cell activity. BI-1808 is a ligand-blocking, FcγR-engaging TNFR2 antibody designed to deplete these Tregs and remodel the myeloid compartment, promoting activation, expansion and infiltration of anti-tumoral CD8+ T cells.

“Patients with platinum-resistant ovarian cancer have few therapeutic options, and checkpoint inhibitors alone have done little to change that,” said Martin Welschof, Chief Executive Officer at BioInvent. “With Part B complete, a 24% response rate and durable disease control in heavily pretreated patients suggest that targeting TNFR2 can add significant activity when combined with immune checkpoint inhibition. Our next step will be to evaluate BI-1808 as an add-on to the newly established pembrolizumab and paclitaxel backbone in a randomized Part C.”

Durable responses in heavily pretreated patients

The 34 evaluable patients (of 40 planned) had a median age of 62 years and had received a median of four prior lines of therapy; 88% had received three or more, and all had received platinum. Histology was high-grade serous adenocarcinoma (HGSA) in 59% and clear cell in 41%, and 24% had liver involvement at screening. They were treated with BI-1808 1000 mg plus pembrolizumab 200 mg every three weeks for up to two years.

- Responses were seen in both HGSA and clear cell ovarian cancer, including in patients with active liver metastases.
- In some patients, tumors grew before shrinking. This may reflect pseudoprogression (an apparent increase in size caused by immune cells entering the tumor) or a delay in CD8+ T-cell expansion, an observation previously made in preclinical models (ASCO#2605 poster).
- Most cases of progressive disease were not confirmed on a follow-up scan. These patients left the study with unconfirmed progressive disease under iRECIST, which explains the difference between PFS and iPFS.

What is iRECIST? iRECIST is an adaptation of the standard RECIST criteria for immunotherapies. It requires confirmation of progression before treatment is stopped, so it can capture responses that appear after initial apparent tumor growth. Median PFS by iRECIST may therefore be longer than by RECIST.

In KEYNOTE-100, pembrolizumab alone produced an objective response rate of 8% and a disease control rate of 37%. Median progression-free survival was 2.1 months by RECIST 1.1, and no iRECIST-based figure was reported.

Well tolerated, with fewer than 5% treatment-related discontinuations

- 81 patients with solid tumors have received BI-1808 plus pembrolizumab to date
- Immune-related adverse events were manageable, and the rate of Grade 3 or higher adverse events was low
- Treatment-related discontinuations in the combination arm occurred in 4 patients (fewer than 5%)

Immune data consistent with the mechanism of BI-1808

- Reduced Tregs in the blood of ovarian cancer patients, and a shift in the CD8+ T-cell over Treg ratio in tumor biopsies
- Induction of IL-12 and CXCL10, cytokines associated with myeloid reprogramming, proinflammatory activation, and effector T cell recruitment
- Induction of CCL19 and CXCL13, chemokines associated with tertiary lymphoid structure (TLS) formation
- Proinflammatory myeloid and TLS-stimulating cytokines were strongly potentiated when BI-1808 was combined with pembrolizumab²

Next step: adding BI-1808 to pembrolizumab and paclitaxel

The KEYNOTE-B96 study³ recently added an immunotherapy option to the standard weekly paclitaxel ± bevacizumab regimen in platinum-resistant ovarian cancer, improving median PFS (8.3 vs 7.2 months) and overall survival (17.7 vs 14.0 months) versus chemotherapy alone. This creates a backbone on which to test additional mechanisms.

In a mouse model of ovarian cancer (ID8), the combination of a BI-1808 surrogate antibody, paclitaxel and anti-PD-1 improved survival, with increases in serum cytokines indicating myeloid reprogramming and TLS formation.

Part C of the study will randomize 20 patients to each of three arms: BI-1808 1000 mg, BI-1808 500 mg, or control, each with pembrolizumab and weekly paclitaxel +/- bevacizumab. Part C is expected to start in Q1 2027, with first data in H2 2027, subject to enrollment.

Poster details

Title: From Modest to Meaningful: Targeting TNFR2 with BI-1808 to Unlock Checkpoint Inhibitor Efficacy in Platinum-Resistant Recurrent Ovarian Cancer (PRROC)

Poster number: 2009P | Session: Investigational immunotherapy

Date and time: October 24, 12:00–12:45 CEST

First author: Rebecca Kristeleit, Guy's and St Thomas' NHS Foundation Trust, United Kingdom

The poster will be available on the publications tab of the BioInvent website: <https://www.bioinvent.com/en/our-science/scientific-publications>

About the trial

The BI-1808 study (NCT04752826, KEYNOTE-D20) is an ongoing open-label Phase 1/2a study evaluating BI-1808 as a single agent (Part A), in combination with pembrolizumab (Part B) and in combination with pembrolizumab and paclitaxel ± bevacizumab (Part C). Patients were enrolled at 14 study locations in Europe and the United States.

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 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 ovarian cancer

Ovarian cancer is a serious and life-threatening disease, affecting more than 320,000 women worldwide each year.⁴ It is frequently diagnosed at an advanced stage because its symptoms are often difficult to recognize, and is the eighth most common cancer and the eighth leading cause of cancer-related death among women globally.⁵ Recurrence affects an estimated 70–90% of patients with advanced disease after initial treatment.⁶ Five-year survival rate is estimated at 50%, across all stages, types and regions.^{7,8}

About BI-1808

BI-1808 is a first-in-class drug candidate targeting TNFR2, which is upregulated on both immunosuppressive and inflammatory tumor-infiltrating lymphocytes and on myeloid cells in the tumor microenvironment. BI-1808 is in clinical development for T-cell lymphoma and solid tumors, and has shown single-agent activity and excellent tolerability, and efficacy and a favorable safety profile in combination with pembrolizumab.

BI-1808 has received FDA Fast Track Designation for the treatment of ovarian cancer and for relapsed or refractory mycosis fungoides and Sézary syndrome, FDA Orphan Drug Designation for T-cell lymphoma, and Orphan Drug Designation in cutaneous T-cell lymphoma from the European Medicines Agency.

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 solid tumors and hematological cancer. 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.

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- 1 Matulonis UA, et al. Antitumor activity and safety of pembrolizumab in patients with advanced recurrent ovarian cancer: results from the phase II KEYNOTE-100 study. *Ann Oncol.* 2019;30(7):1080–1087.
 - 2 Mårtensson et al. *Cancer Research* 2026. <https://doi.org/10.1158/0008-5472.CAN-26-0274>
 - 3 Colombo-Zsiros et al. Pembrolizumab plus weekly paclitaxel in platinum-resistant recurrent ovarian cancer (ENGOT-ov65/KEYNOTE-B96): a multicentre, randomised, double-blind, phase 3 study. *Lancet* 2026 (KEYNOTE-B96).
 - 4 World Cancer Research Fund International. <https://www.wcrf.org/cancer-trends/ovarian-cancer-statistics/>
 - 5 World Ovarian Cancer Coalition. <https://worldovariancancercoalition.org/about-ovarian-cancer/key-stats/>
 - 6 Ovarian Cancer Research Alliance. <https://ocrahope.org/patients/diagnosis-and-treatment/recurrence/>
 - 7 European Institute of Women's Health. Policy brief: Women and ovarian cancer in the EU, 2018.
 - 8 American Cancer Society. Survival rates for ovarian cancer. <https://www.cancer.org/cancer/types/ovarian-cancer/detection-diagnosis-staging/survival-rates.html>

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 2026-10-24 09:00 CEST.

Press Release
24 October 2026 09:00:00 CEST



Attachments

[BioInvent's BI-1808 and KEYTRUDA® Induce Durable Responses in Heavily Pretreated Platinum-Resistant Ovarian Cancer](#)