

BioInvent Announces Publication of First-in-Human BI-1808 Data in Clinical Cancer Research

BI-1808 monotherapy demonstrated an excellent safety profile and evidence of single-agent anti-tumor activity, correlating with tumor-infiltrating CD8⁺ T cells and inducing antitumor immunity.

Translational data were consistent with BI-1808's preclinically characterized mechanism of action, which includes regulatory T cell depletion, myeloid reprogramming, tertiary lymphoid structure formation, and activation of T cell anti-tumor immunity.

- Phase 1 dose escalation in 24 patients with advanced solid tumors did not identify a maximum tolerated dose, with no dose-limiting toxicities and no deaths. All treatment-related AEs were limited to Grades 1 or 2.
- Durable partial response throughout the study duration (two years) in a GIST patient, a cold tumor type that responds poorly to checkpoint blockade. Tumor reduction was also observed in a non-small cell lung cancer patient. In the subsequent expansion phase, a complete response was observed in a patient with ovarian cancer (ASCO 2024, poster #2641).
- BI-1808-induced tumor regression was preceded by increased peripheral CX3CR1⁺ CD8⁺ T cells and tumor-infiltrating CD8⁺ T cells, consistent with activation of T cell antitumor immunity.
- Translational data were consistent with BI-1808's preclinically characterized mechanism of action, which involves macrophage reprogramming, Treg depletion, recruitment and activation of CD8⁺ T cells within tumors, and stimulation of tertiary lymphoid structure formation.
- The 1000 mg Q3W dose was safe and resulted in sustained receptor occupancy, supporting combination with immunotherapy, chemotherapy, and targeted modalities. This dose is being evaluated in Phase 2a cohorts focused on recurrent ovarian cancer and cutaneous T cell lymphoma.

Lund, Sweden – October 15, 2026 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a leader in discovering novel immune-modulatory antibodies, today announced the publication of results from the first-in-human Phase 1 study of the BI-1808 antibody in Clinical Cancer Research, a journal of the American Association for Cancer Research (AACR). BI-1808 binds to TNFR2 and is the first antibody in its class to be tested in patients. The publication, titled *"Anti-TNFR2 antibody BI-1808 induces tumor regression and antitumor T cell immunity through T reg*

and myeloid cell modulation in patients with solid tumors: a preclinical and phase 1 clinical study," presents clinical, translational, and preclinical data supporting BI-1808 as a differentiated immunotherapy approach with the potential to address patients who do not respond to current immune checkpoint inhibitors.

The publication reports results from the monotherapy dose-escalation portion of BioInvent's ongoing Phase 1/2a clinical trial ([NCT04752826](#)) of BI-1808 in patients with advanced solid tumors. BI-1808 is a fully human, ligand-blocking, Fcγ receptor-engaging anti-TNFR2 antibody designed to enhance anti-tumor immunity through multiple complementary mechanisms.

Patients with advanced solid tumors who progress after standard therapy have few remaining options, and checkpoint blockade leaves many tumor types, particularly non-inflamed or cold tumors, largely untreated. TNFR2 is highly upregulated in the tumor microenvironment and is expressed on the most immunosuppressive tumor-associated myeloid cells and Tregs. BI-1808 is a first-in-class, ligand-blocking, FcγR-engaging anti-TNFR2 antibody designed to deplete these Tregs, reprogram myeloid cells, and induce CD8⁺ T cell antitumor immunity.

The published data show that this mechanism, established in preclinical models, translates to treated patients. The mechanism itself was characterized in a recent complementary paper in AACR's sister journal, *Cancer Research*, titled "*Ligand-Blocking and Agonist Antibodies Targeting TNFR2 Employ Distinct Modes of Action to Induce Antitumor Immunity*." DOI: [10.1158/0008-5472.CAN-26-0274](#)

"Our findings provide the first clinical validation of TNFR2 as an immunotherapy target and demonstrate that BI-1808 can safely induce broad immune activation through mechanisms distinct from existing checkpoint inhibitors," said Andres McAllister, Chief Medical Officer at BioInvent and co-senior author of the publication. "Particularly encouraging is the evidence of anti-tumor activity in a patient with GIST, a tumor type that rarely responds to current immunotherapies, supporting the potential of BI-1808 to expand the reach of immunotherapy to patients with non-inflamed cancers."

Björn Frenhéus, Chief Scientific Officer at BioInvent and co-senior author, added: "The translational data demonstrate remarkable consistency between our preclinical findings and the observations in patients. The combination of strong biological activity, preliminary clinical responses and an excellent safety profile reinforce our belief that BI-1808 is well positioned for development both as a monotherapy and in combination with checkpoint inhibitors, antibody-drug conjugates, targeted therapies and other treatment modalities."

Publication Details

Title: Anti-TNFR2 antibody BI-1808 induces tumor regression and antitumor T cell immunity through T reg and myeloid cell modulation in patients with solid tumors: a preclinical and phase 1 clinical study

Lead Author: Ingrid Teige, PhD, BioInvent International AB

Journal: *Clinical Cancer Research*, <https://aacrjournals.org/clincancerres/article/doi/10.1158/1078-0432.CCR-26-2049>

The publication presents the first clinical evidence that targeting TNFR2 can generate anti-tumor immunity by coordinately modulating regulatory T cells and myeloid cells, leading to intratumoral CD8+ T cell infiltration and activation. Alongside evidence of stimulation of tertiary lymphoid structure formation and of safe, well-tolerated administration at pharmacologically optimal doses, these observations support continued development of BI-1808 across solid tumors and T-cell malignancies.

Study Design and Patients

- 24 patients treated across five cohorts (25, 75, 225, 675, and 1000 mg every three weeks), enrolled January 2021 to April 2023; 21 evaluable for efficacy
- Median 3 prior lines of therapy (range 0 to 12); all patients progressed on prior treatment; 8 patients (33%) had received prior immunotherapy

Evidence of Clinical Activity

- Tumor regression in 2 of 21 evaluable patients
- GIST patient: partial response lasting more than two years, continuing through compassionate use; biopsies at weeks 16 and 82 contained no tumor cells
- NSCLC patient: all three target lesions reduced at week 16; withdrawn per protocol following detection of an unrelated prostate cancer lesion; best response recorded as stable disease
- Neither patient with tumor regression had received prior anti-PD-1 or anti-CTLA-4
- Stable disease best response in six additional patients

Favorable Safety and Tolerability

- No maximum tolerated dose reached
- No deaths, no dose-limiting toxicities, no immune-related adverse reactions above Grade 2
- All treatment-related adverse events Grade 1 or Grade 2
- No discontinuations or dose reductions due to drug-related adverse events
- Infusion-related reactions in 2 patients at 1000 mg (Grade 1 chest pain, Grade 2 chills), both resolved the same day
- No confirmed anti-drug antibody-positive samples across 24 patients

Mechanistic Validation of BI-1808 and TNFR2 Targeting

- Dose-dependent Treg depletion at all dose levels, sustained at 1000 mg
- Increased monocyte CD16 expression
- Dose-dependent serum increases in CCL22, CXCL10, IL-12p40, and CCL19
- Cytokine kinetics in patients matched those in murine BI-1808 surrogate (3F10)-treated tumor-bearing mice
- GIST patient: circulating CX3CR1+ CD8+ T cells rose at day 50, before imaging showed regression; paired biopsies showed an increased CD8+ T cell to Treg ratio

- No baseline difference in TNFR2 expression or tumor inflammation between the two regressing patients and the rest

Pharmacokinetics and Dose

- Mean estimated half-life approximately 9 days
- Sustained TNFR2 receptor occupancy at doses of 675 mg and above
- 1000 mg every three weeks selected as recommended Phase 2 dose

About the trial

The BI-1808 study ([NCT04752826](#)) is an ongoing open-label, dose-escalation Phase 1/2a study evaluating BI-1808 as a single agent and in combination with pembrolizumab. The publication reports on the monotherapy Phase 1 dose-escalation portion, where patients were enrolled at nine study locations in Europe.

About BI-1808

BI-1808 is a first-in-class drug candidate targeting TNFR2. TNFR2 is upregulated on both immunosuppressive and inflammatory tumor-infiltrating lymphocytes (TILs) and on myeloid cells in the tumor microenvironment, making it a dynamic, promising new target for cancer immunotherapy. BI-1808 is in clinical development for 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.

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 a positive opinion from the European Medicines Agency for Orphan Drug Designation in cutaneous T-cell lymphoma.

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 on the [Company's website](#).

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Attachments

[BioInvent Announces Publication of First-in-Human BI-1808 Data in Clinical Cancer Research](#)