

# BioInvent's BI-1910 Data Validates TNFR2 as a Novel Immunotherapy Approach in Advanced Solid Tumors: Phase 1 Data at SITC 2025

- Twelve patients achieved stable disease, whereof five with disease control lasting over six months; this correlates with strong CD4# and CD8# memory T-cell expansion
- As previously reported, the single agent dose escalation of BI-1910 in the Phase 1 study was completed without any notable adverse events
- Company remains focused on BI-1808, its lead anti-TNFR2 antibody, and the BI-1910 program is currently paused

Lund, Sweden - November 7, 2025 - BioInvent International AB ("BioInvent") (Nasdag 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 the presentation of Phase 1 clinical data for BI#1910, a TNFR2 agonist antibody, at the Society for Immunotherapy of Cancer (SITC) 2025 Annual Meeting. The data, presented in the poster titled "Preliminary Phase 1 results of clinical trial investigating BI-1910, a Tumor Necrosis Factor Receptor 2 (TNFR2) agonist in solid cancer tumor patients" highlight BI-1910's ability to activate immune responses and induce disease control in patients with advanced solid tumors.

BI-1910 has been developed as part of BioInvent's tumor-associated regulatory T cells (Treg)targeting program, but as announced in August of this year, BioInvent decided after a comprehensive strategic review to focus on its most advanced program BI-1808 (as well as BI-1206, an FcyRIIB-blocking antibody). As a result of this review, BioInvent has temporarily paused the development of BI-1910.

"The Phase 1 data for BI-1910 provide compelling validation of TNFR2 as a mechanism for immune activation and disease control in advanced solid tumors," said Martin Welschof, CEO of BioInvent. "These results reinforce the therapeutic relevance of the TNFR2 pathway and support our continued focus on BI-1808, our lead ligand-blocking TNFR2 antibody, which is progressing in Phase 2 clinical development."

## Poster summary:

As of September 6, 2025, the single agent BI-1910 Phase 1 study had enrolled and treated 26 patients with advanced/metastatic solid tumors who had progressed after standard therapy. BI-1910 was administered intravenously every three weeks across dose levels ranging from 4 mg to 900 mg.



Stable disease was the best clinical response in 12 patients out of 26 treated, of whom five patients (diagnosed with neuroendocrine, salivary gland, endometrial, and ovarian tumors) are currently experiencing disease control for more than six months. Durable response was associated with strong T-cell activation, and reduction in one or several sub lesions.

The treatment was well tolerated, with no dose-limiting toxicities observed. Fatigue was the most common adverse event.

#### Poster details:

Title: Preliminary Phase 1 results of clinical trial investigating BI-1910, a Tumor Necrosis Factor Receptor 2 (TNFR2) agonist in solid cancer tumor patients

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Authors: Hernandez T., Doger B., Yachnin J., Staahl Rorberg K., Moreno I., Carneiro A., Falcon

Gonzalez A., Holmkvist P., Karlsson I., Lindahl D., Meller M., Mårtensson L.,

Schoenborn-Kellenberger O., Sundstedt A., Teige I., Piliuhin D., Vaapil M., Wallin J., Frendéus B.,

McAllister A.

The abstract was published in the Journal for ImmunoTherapy of Cancer (JITC) Abstract Supplement and the poster is available on the company's website: https://www.bioinvent.com /en/our-science/scientific-publications.

# BI-1910 Phase 1/2a Clinical Trial (NCT06205706)

During this part of the Phase 1/2a study the safety, tolerability, and potential signs of efficacy of BI-1910 as a single agent were evaluated in patients with advanced solid tumors. As previously reported in January of this year, the single agent dose escalation of BI-1910 in the Phase 1 study has successfully been completed without any notable adverse events. Early results indicated favorable pharmacokinetic data and robust target engagement, with patients in the target dose range showing evidence of induction of T cell proliferation. However, as a result of a strategic priority review, BioInvent is currently pausing the ongoing trial.

#### About BI-1910

BI-1910 offers a differentiated, agonist approach to cancer treatment compared to BI-1808, BioInvent's first-in-class anti-TNFR2 antibody currently in a Phase 1/2a development. Both monoclonal antibodies were chosen as potential best-in-class, from a large family of binders generated through BioInvent's proprietary F.I.R.S.T™ technology platform. BI-1910 is an agonistic human IgG2 mAb targeting TNFR2.

## **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 currently 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

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## **Attachments**

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