BioInvent Presents Promising Early Phase 2a BI-1808 Monotherapy Data in CTCL at ASH 2025

- 46% objective response rate (6 of 13 evaluable patients) and a 92% disease control rate (12 of 13) in relapsed/refractory CTCL
- Immune activation confirmed by $CD8^+$ T cell infiltration and granzyme B elevation in skin biopsies
- BI-1808 plus pembrolizumab combination part of the trial in CTCL ongoing in parallel

Lund, Sweden – December 7, 2025 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a biotech company focused on the discovery and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, announced the presentation of updated data from the ongoing Phase 2a monotherapy of BI-1808, a first-in-class anti-TNFR2 antibody, in cutaneous T-cell lymphoma (CTCL) in a poster at the 2025 American Society of Hematology (ASH) Annual Meeting, taking place December 6-9, 2025, in Orlando, Florida.

Results are from the signal#seeking monotherapy portion of the ongoing Phase 2a trial (NCT04752826). Overall, treatment has been well#tolerated with encouraging monotherapy activity in patients with CTCL; n=14; (13 evaluable for efficacy) and peripheral T-cell lymphoma (PTCL; n=2). The monotherapy part of the study has proceeded to the dose optimization phase, which will inform the design of future pivotal trials. BioInvent is currently also evaluating BI-1808 in combination with pembrolizumab in a separate cohort for solid tumors.

"We're excited by the emerging clinical profile of BI-1808 in T-cell lymphomas, especially CTCL where treatment options are scarce," said Martin Welschof, Chief Executive Officer of BioInvent. "The strong disease control rate and immune activation validate TNFR2 as a powerful dual-action target—reducing regulatory T cells while boosting effector function. With Fast Track and Orphan Drug designations, we're well-positioned to accelerate development and tap into a significant market opportunity."

In April 2025, BI-1808 was granted Fast Track Designation for the treatment of CTCL from the U.S. Food and Drug Administration (FDA) and Orphan Drug Designation (ODD) was received in March 2025 for the treatment of T-cell lymphoma (TCL). In November 2025, a positive opinion was received from EMA regarding ODD for BI-1808 in CTCL.

Overview of data:

- As of October 6, 2025, 21 patients with TCL received BI-1808 as a 1000 mg single agent every 3 weeks (Q3W)
- All treatment related adverse events were classified as mild or moderate with no potentially related Gr3+ AE reported

- Disease “flares” characterized by increased skin peeling, erythema, and pruritis were observed during the first weeks of treatment in several cases, considered related to immune activation associated with depletion of T reg and influx of CD8+ T cells
- The CTCL cohort demonstrated a 46% (6/13) objective response rate and 92% disease control rate (12/13)
- Of 13 evaluable CTCL patients:
  - 1 Sézary syndrome (SS) patient exhibited complete response (CR)
  - 5 patients (four Mycosis Fungoides [MF], one SS) exhibited partial response (PR)
  - 6 patients showed stable disease (SD)
  - 1 MF patient had progressive disease (PD)
- Among 2 evaluable PTCL patients:
  - 1 PR, 1 SD
- Evidence of robust CD8+ T-cell infiltration observed in skin biopsies at 5 weeks, accompanied by elevated granzyme B levels—indicative of cytotoxic immune activation

Poster presentation details:
Title: BI-1808, a tumor necrosis factor receptor 2 (TNFR2) blocker/depleter, showing promising efficacy in T cell lymphoma patients
Date and Time: December 7, 6:00-8:00 pm ET
Session Name: 625. T Cell, NK Cell, or NK/T Cell Lymphomas: Clinical and Epidemiological: Poster II
Lead Author: Stefan K. Barta, University of Pennsylvania Hospital, Philadelphia, PA, USA
Publication Number: 3633

The poster will be posted to the Scientific Publications section of the company website (https://www.bioinvent.com/en/our-science/scientific-publications).

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 solid tumors and T-cell lymphoma.

Overall, BI-1808 monotherapy has demonstrated promising clinical activity and robust immune engagement. Additionally, BI-1808 has been well tolerated, with all treatment-related adverse events reported as mild or moderate (Grade 1-2). Notably, no Grade 3 or higher adverse events have been observed. The safety and preliminary efficacy of BI-1808 monotherapy and in combination with KEYTRUDA® (pembrolizumab) are currently being evaluated in sub-cohorts in the ongoing Phase 2a part of the study in patients with T-cell lymphomas, including CTCL. These cohorts will form the basis for the selection of monotherapy or combination for the subsequent pivotal Phase 2 study.

During the first part of the Phase 1/2a study (NCT04752826) the safety, tolerability, and potential signs of efficacy of BI-1808 as a single agent (part A) and in combination with the anti-PD-1 therapy pembrolizumab (part B) are evaluated in patients with advanced solid tumors and T-cell lymphoma.

Disease Context CTCL and PTCL

T-cell lymphomas (TCL) make up about 10-15% of all Non-Hodgkin's Lymphomas (NHLs), with cutaneous T-cell lymphoma (CTCL) and peripheral T-cell lymphoma (PTCL) being the main types. PTCLs are nodal or systemic T-cell lymphomas, whereas CTCL originates in the skin and includes mycosis fungoides (MF) and Sézary syndrome (SS). Survival is poor in PTCL, advanced MF as well in SS, with a 5-year survival range of 20–60%.

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 five drug candidates in six 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.

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 2025-12-07 14:00 CET.

Attachments

BioInvent Presents Promising Early Phase 2a BI-1808 Monotherapy Data in CTCL at ASH 2025