BioInvent to Present Updated Phase 2a BI-1808 Monotherapy Data in CTCL at ASH 2025

Lund, Sweden – November 3, 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, today announced that it will present 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 upcoming 2025 American Society of Hematology (ASH) Annual Meeting, taking place December 6-9, 2025, in Orlando, Florida.

The results to be presented are from the signal-seeking monotherapy portion of the ongoing Phase 2a trial. The treatment has been well-tolerated, with no grade 3 or higher adverse events reported. A more comprehensive data package will be disclosed in the poster on December 7, 2025.

"We are excited to share the latest results from our BI-1808 program at ASH," said Martin Welschof, Chief Executive Officer of BioInvent. "Data from this signal-seeking cohort show efficacy associated with strong immune activation with a very high disease control rate (DCR), demonstrating the continued promise of BI-1808 to deliver meaningful clinical benefit. We look forward to sharing more comprehensive data at ASH and moving into the dose optimization phase as we advance BI-1808 for patients with serious unmet medical needs."

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 in March 2025, FDA Orphan Drug Designation was received for BI-1808 in T-cell lymphoma (TCL).

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

August 4, 2025, observations included the abstract:

- 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

- Out of nine CTCL evaluable cases, one Sézary Syndrome (SS) patient exhibited complete response (CR), four patients (three Mycosis Fungoides (MF), one SS) exhibited partial response (PR) as best clinical response; the remaining four patients showed stable disease (SD)
- Out of two evaluable PTCL patients (peripheral T-cell lymphoma, both stage IV), one patient showed SD as best clinical response, while the other patient exhibited a substantial PR at first assessment.

More complete data will be disclosed in the poster on December 7, 2025, at the ASH Annual Meeting.

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.

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 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.

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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.

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 2025-11-03 15:00 CET.

Attachments

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