BioInvent Presents Promising Phase 2a Monotherapy Data for BI-1808 in CTCL at EHA 2025

- *Data from the ongoing Phase 2a study shows a 100% disease control rate with 45% of patients with advanced cutaneous T-cell lymphoma achieving an objective response:*
  - *One complete response, three partial responses, and five stable diseases in nine evaluable patients so far*
  - *Robust immune activation supporting clinical activity observed*
- *Study continues to enroll patients; dose optimization phase to follow.*

Lund, Sweden – June 12, 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 updated positive data from the ongoing Phase 2a dose expansion study of BI-1808 monotherapy in cutaneous T-cell lymphoma (CTCL). The data will be presented in a poster at the European Hematology Association (EHA) 2025 congress, June 12-15 in Milan, Italy.

As of the cut-off date May 15, 2025, data showed a 100% disease control rate in nine evaluable patients with CTCL. Forty-five percent of these patients achieved an objective response, with one patient achieving a complete response (CR), three achieving a partial response (PR), and five exhibiting stable disease (SD). Additionally, two patients with peripheral T-cell lymphoma (PTCL) were evaluable, of which one showed a PR, while the other showed SD. Overall, BI-1808 monotherapy demonstrates promising clinical activity and robust immune engagement.

Additionally, BI-1808 was well tolerated, with all treatment-related adverse events reported as mild or moderate (Grade 1-2). Notably, no Grade 3 or higher adverse events were observed. Transient disease flares, including skin peeling, erythema, and pruritus during the first weeks of treatment, were observed and shown to be associated with the BI-1808 immunologic mechanism. These flares coincide with regulatory T cell depletion and influx of CD8+ T cells into the skin, indicating on-target immune activation. Immunofluorescence multiplexing, starting at week 5, further confirmed increased CD8+ T cell infiltration and elevated granzyme B, supporting the drug candidate's mechanism of action.

"These results reinforce the potential of BI-1808 as a novel immune-modulating therapy for CTCL," said Martin Welschof, Chief Executive Officer of BioInvent. "The early and sustained immune activation observed, combined with a favorable safety profile and 100% disease control rate, support the value of our anti-Tumor Necrosis Factor Receptor 2 (TNFR2) approach. We believe that these early Phase 2a data represent a meaningful milestone in our mission to deliver transformative therapies for difficult-to-treat patients, and we look forward to advancing BI-1808 into later-stage studies."

Details of the poster:
Title: Robust Single Agent Activity of BI-1808, a Tumor Necrosis Factor Receptor 2 (TNFR2) Blocker /Depleter, in Cutaneous T Cell Lymphoma (CTCL) Patients
Session Date and Time: June 13, 2025, 6:30-7:30 pm CEST
Session Title: Poster Session 1
Lead Author: Stefan K. Barta, University of Pennsylvania Hospital, Philadelphia, PA, USA
Abstract Number: PF961

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

The safety and preliminary efficacy of BI-1808 monotherapy are currently being evaluated in a sub-cohort (Part A) of the ongoing Phase 2a (NCT04752826) study in patients with T-cell lymphomas, including CTCL. The study is expected to enroll 20 patients at a signal-seeking dose, after which a dose optimization phase is planned to be initiated.

In April 2025, BioInvent received Fast Track Designation from the U.S. Food and Drug Administration (FDA) for BI-1808 for the treatment of CTCL and in March 2025, Orphan Drug Designation was received from the same agency for BI-1808 in T-cell lymphoma (TCL).

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 blood cancer. BI-1808 has shown single agent activity and excellent tolerability in an ongoing Phase 2a study and signs of efficacy and favorable safety profile in combination with pembrolizumab in the ongoing Phase 1/2a study.

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.

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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 2025-06-12 09:00 CEST.

Attachments

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