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

- *Data from the cutaneous T-cell lymphoma (CTCL) cohort demonstrate promising clinical activity that correlates with strong immune activation*
- *One complete response (CR), three partial responses (PR), and four stable diseases (SD) achieved as of Feb 2025 in eight evaluable patients*
- *Study currently enrolling patients for signal-seeking. Dose optimization phase to follow*

Lund, Sweden – May 14, 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 additional data from the ongoing Phase 2a dose expansion study of BI-1808 monotherapy in Cutaneous T-cell Lymphoma (CTCL) will be presented in a poster at the European Hematology Association (EHA) 2025 congress to take place June 12-15 in Milan, Italy.

The submitted abstract data from the CTCL cohort include results from ten patients treated with BI-1808 with eight deemed evaluable. As of the cut-off date February 20, 2025, one patient had achieved a complete response (CR), three achieved partial response (PR), and four demonstrated stable disease (SD). The treatment was well tolerated with primarily mild to moderate adverse events with no grade 3 or higher events reported. Notably, immune activation was observed in the early weeks of treatment, specifically depletion of regulatory T cells and an influx of CD8+ T cells into the skin, suggesting that BI-1808 effectively stimulates the targeted response in CTCL. The upcoming poster presentation will include more detailed and recent data, including findings in patients with PTCL (Peripheral T-cell lymphoma).

"We look forward to presenting these positive data at EHA, which illustrate BI-1808's potential as an immunomodulatory treatment for CTCL patients, said Martin Welschof, Chief Executive Officer of BioInvent. "The emerging clinical responses, along with immune activation reflect the meaningful biological activity of BI-1808 and support further development in hematologic malignancies and solid tumor settings. We believe that BI-1808 could become a novel treatment option for CTCL patients, where innovative approaches are urgently needed – a belief further supported by the recent Fast Track and Orphan Drug Designation granted by the FDA."

Details of the presentation are below:

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 after the e-poster disclosure (https://www.bioinvent.com/en/our-science/scientific-publications) on June 12 at 9:00 am CEST.

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

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 Part B of the Phase 1 /2a study (ASCO 2024).

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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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 2025-05-14 15:30 CEST.

Attachments

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