BioInvent Receives FDA Orphan Drug Designation for BI-1808 for the Treatment of T-cell Lymphoma

Lund, Sweden – March 20, 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 announces that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) for BI-1808, a first-in-class anti-TNFR2 antibody for the treatment of T-cell Lymphoma (TCL).

T-cell lymphomas include a number of subtypes of T cell-derived non-Hodgkins's lymphoma, including cutaneous T-cell lymphoma (CTCL). CTCL is a rare and aggressive form that originates in T-lymphocytes residing in the skin. It typically manifests with persistent skin lesions, itching, and potential systemic complications, significantly impacting patients' quality of life. Each year, approximately 3,000 new cases are diagnosed in the United States with limited effective treatment options available (1).

"We are excited to receive the FDA's Orphan Drug Designation for the treatment of TCL. This designation along with the recently announced positive Phase 2a data in CTCL reinforces our continued progress and commitment to developing BI-1808 as a potential novel class of immunomodulatory agents for TCL", said Martin Welschof, Chief Executive Officer of BioInvent. "We look forward to working closely with the regulatory agencies to accelerate the development of BI-1808 and bring this innovative treatment to patients who are in great need of new treatment options."

*

About Orphan Drug Designation

The FDA grants ODD status to drugs and biologics intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. Data should support the expectation that the drug would be a major contribution to patient care. ODD provides benefits to drug developers designed to support the development of drugs and biologics for small patient populations with unmet medical needs. These benefits include assistance in the drug development process, tax credits for qualified clinical costs, exemptions from certain FDA fees, and seven years of marketing exclusivity.

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 the Phase 1/2a 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. The efficacy of BI-1808 as single agent is currently explored in the Phase 2a part of the trial in a larger sample of patients. Expansion cohorts include ovarian cancer, all tumor types and T-cell lymphomas (including CTCL). The dose escalation in Phase 1 Part B has been completed and the Phase 2a dose expansion study for the combination is ongoing. The expansion cohorts are planned to include ovarian cancer, all tumor types and T-cell lymphoma (including CTCL).

To date, results from the single agent CTCL cohort show three patients with partial response (PR) and one with stable disease (SD) out of four evaluable patients. All these patients had previously deteriorated after standard treatment. These data support the single agent data disclosed earlier in 2024, showing one complete response (CR), one PR and nine patients with SD, presented at the American Society of Clinical Oncology conference (ASCO) in June 2024. Additional data from Phase 2a study of single agent BI-1808 are expected by mid-2025.

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.

(1) https://www.clfoundation.org/cutaneous-t-cell-lymphoma

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.

Attachments

BioInvent Receives FDA Orphan Drug Designation for BI-1808 for the Treatment of T-cell Lymphoma