BioInvent Receives FDA Fast Track Designation for BI-1808 for the Treatment of Cutaneous T-cell Lymphoma

Lund, Sweden – April 29, 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 Fast Track Designation to BI-1808, a first-in-class anti-TNFR2 antibody, for the treatment of adults with relapsed or refractory mycosis fungoides and Sézary syndrome, subtypes of cutaneous T-cell lymphoma (CTCL). Fast Track Designation (FTD) is intended to facilitate the development and review of drugs that treat serious conditions.

"Receiving FDA's Fast Track Designation following the recent Orphan Drug Designation underscores the potential of this novel immunomodulatory agent and reflects the urgent need for new, safe and durable treatment options for patients with CTCL", said Martin Welschof, Chief Executive Officer of BioInvent. "It's very encouraging that the FDA confirms that the presented BI-1808 data meet expectations to address this important unmet medical need". To date, BI-1808 demonstrated early clinical efficacy in heavily pretreated patients with an excellent safety and tolerability profile. We are committed to continue advancing the development of BI-1808 and look forward to providing an update from the ongoing Phase 2a by mid-2025."

CTCL is a rare and aggressive form of non-Hodgkin's lymphoma that originates in T-lymphocytes residing in the skin, with the most prevalent and advanced subtypes mycosis fungoides and Sézary syndrome. It typically manifests with persistent skin lesions, itching, and potential systemic complications, significantly impacting patients' quality of life and life expectancy. Each year, approximately 3,000 new cases are diagnosed in the United States with limited effective treatment options available.[1]

The FDA's Fast Track Designation is designed to facilitate the development and expedite the review of drugs that treat serious conditions and address important unmet medical needs. The aim is to accelerate the development of urgently needed new drugs for patients. Drugs granted FTD are eligible for more frequent meetings with the FDA to discuss the drug development plan and ensure the collection of appropriate data needed to support approval, as well as eligibility for Accelerated Approval, Priority Review and Rolling Review if relevant criteria are met.[2]

About 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 is ongoing and include ovarian cancer, all tumor types and T-cell lymphoma (including CTCL).

Results from the single agent CTCL cohort disclosed in the autumn of 2024 showed 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 corroborate the antitumoral activity observed with BI-1808 as single agent in the treatment of solid tumors 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 single agent data 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

2. https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

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

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