EMA Positive Opinion for Orphan Drug Designation to BioInvent's BI#1808 for the Treatment of Cutaneous T-cell Lymphoma

Lund, Sweden – November 17, 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 the Committee for Orphan Medicinal Products (COMP) at the European Medicines Agency (EMA) has adopted a positive opinion for Orphan Drug Designation (ODD) to the company's investigational medicinal product BI-1808, a first-in-class anti-TNFR2 antibody, for the treatment of Cutaneous T-cell Lymphoma (CTCL). The European Commission is now assessing the opinion and is expected to grant the designation within 30 days.

T-cell lymphomas include a number of subtypes of T cell-derived non-Hodgkins's lymphoma, including 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. CTCL meets the EMA's criteria for orphan designation, affecting fewer than 5 in 10,000 individuals in the EU. Although specific European incidence data are limited, CTCL is globally recognized as a rare disease, with approximately 3,700 new cases diagnosed annually in the 27 European member states, plus Norway and Iceland.[1]

"The positive opinion by the EMA which underscores the potential of our anti-TNFR2 approach to address serious and underserved hematologic malignancies", said Martin Welschof, Chief Executive Officer of BioInvent. "This designation, along with encouraging clinical data, supports our commitment to advancing BI-1808 as a novel immunotherapy for CTCL patients."

The EMA's Orphan Drug Designation is intended to promote the development of drugs for rare diseases and provides incentives such as protocol assistance, reduced regulatory fees, and ten years of market exclusivity upon approval[2].

BI-1808 has demonstrated promising clinical activity in an ongoing Phase 2a trial with 100% disease control rate and a majority of patients with advanced CTCL achieving an objective response: one complete response, four partial responses, and four stable diseases in nine evaluable patients (ASH 2025 abstract[3]). Additionally, BI-1808 was well tolerated, with primarily mild to moderate adverse events (Grade 1-2). This study continues to enrol patients and additional data for BI#1808 are anticipated in the poster presentation at ASH (American Society of Hematology) Annual Meeting 2025 on December 7.

BI-1808 has previously been granted Fast Track Designation for the treatment of adults with relapsed or refractory Mycosis fungoides and Sézary syndrome, subtypes of CTCL by the US Food and Drug Administration (FDA)[4]. BI-1808 was also previously granted a US ODD for the treatment of T#cell lymphoma (TCL)[5].

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 T-cell lymphoma and solid tumors. 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 an ongoing Phase 1/2a study for the treatment of solid tumors.

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 drug candidates in 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.

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.

[1] Globocan Population Fact Sheets' 2022; Eurostat Data Browser - Population on 1 January' 2024
[2] For more information about EMA's ODD program, visit: https://www.ema.europa.eu/en/human-regulatory/research-development/orphan-designation-research-development
[3] BioInvent to Present Updated Phase 2a BI-1808 Monotherapy Data in CTCL at ASH 2025
[4] BioInvent Receives FDA Fast Track Designation for BI-1808 for the Treatment of Cutaneous T-cell Lymphoma
[5] BioInvent Receives FDA Orphan Drug Designation for BI-1808 for the Treatment of T-cell Lymphoma

Attachments

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