BioInvent's TNFR2 Antibody BI-1808 Shows Strong Activity and Immune Activation as Single Agent and in Combination with KEYTRUDA® (pembrolizumab) in Advanced CTCL (EHA 2026)

- *40%* objective response rate (*ORR) as single agent in heavily pre-treated patients with advanced Cutaneous T-Cell Lymphoma (CTCL)*
- *Durable responses observed, including a complete response lasting over two years and ongoing*
- *50% ORR in combination with KEYTRUDA® (pembrolizumab)*
- *Targeting TNFR2 drove robust immune activation, with depletion of regulatory T cells and increased CD8+ T cell infiltration in skin lesions*
- *Early immune-related skin reactions - "flares"- correlated with biological activity and immune remodeling*
- *Favorable safety profile with mostly mild to moderate treatment-related adverse events*

Lund, Sweden – May 12, 2026 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a leader in the discovery of novel immune-modulatory antibodies, today announced that new clinical data from its ongoing Phase 2a trial evaluating BI-1808, its novel anti-TNFR2 monoclonal antibody, in patients with advanced CTCL will be presented at the upcoming European Hematology Association (EHA) 2026 Congress in Stockholm, Sweden. The data underscore BI-1808's potential as both a single agent and combination therapy in this difficult-to-treat cancer with limited therapeutic options.

Poster Presentation

- **Title:** Targeting TNFR2 with BI-1808 with or without pembrolizumab: Immune activation and promising responses in advanced cutaneous T-cell lymphomas (CTCLs)
- **Presenter:** Stefan K. Barta, MD, MS, Associate Professor of Medicine (Hematology-Oncology) at the Hospital of the University of Pennsylvania
- **Session Date/Time: on Friday, June 12, 18:45 - 19:45 CEST (12:45 pm-1:45 pm EDT)**
- **Location:** EHA2026 Congress, Stockholm, Sweden

The poster will highlight emerging translational, efficacy and safety findings from the Phase 2a cohort in patients with advanced CTCL, including mycosis fungoides and Sézary syndrome. Patients in these cohorts received BI-1808 either as monotherapy or in combination with MSD's (Merck & Co., Inc., Rahway, NJ., USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab).

Advanced cutaneous T-cell lymphomas are associated with poor long-term outcomes, and patients who relapse after multiple lines of systemic therapy face limited and often short-lived treatment options. Durable responses remain uncommon, underscoring the need for novel therapeutic approaches. TNFR2 is highly upregulated in the tumor microenvironment. With its differentiated mechanism of action, depleting immunosuppressive Treg cells and reprogramming myeloid cells to unleash CD8+ T cell antitumor immunity, BI-1808 offers a promising new approach to cancer immunotherapy. Against this backdrop, the BI-1808 data are particularly significant, demonstrating meaningful and durable clinical activity alongside strong immune activation in a heavily pretreated CTCL population. By selectively targeting TNFR2 and reshaping the tumor immune microenvironment, BI-1808 has the potential to translate immune activation into sustained clinical benefit, both as monotherapy and in combination with pembrolizumab.

“The data to be presented at EHA underscore the significant progress we are making with BI-1808 and its potential to address meaningful unmet needs for people with CTCL,” said Martin Welschof, Chief Executive Officer of BioInvent. “The Phase 2a monotherapy arm has already advanced into dose optimization to help inform the pivotal development path. With FDA Fast Track and Orphan Drug Designations (TCL), as well as Orphan Drug Designation in CTCL in Europe, BI-1808 is well-positioned for accelerated development for T-cell lymphomas.”

BioInvent will host a KOL event at GT30, Grev Turegatan 30 in Stockholm on June 11, more information to follow within short.

Abstract overview
Data from the signal-seeking cohort of BioInvent’s ongoing Phase 2a study of BI-1808 as monotherapy or in combination with pembrolizumab demonstrate promising clinical activity and strong immune activation in patients with advanced CTCL, including mycosis fungoides (MF) and Sézary syndrome (SS).

The data in the EHA abstract has a cut-off date February 19, 2026. The signal-seeking portion of the study has been fully enrolled and 20 patients with advanced CTCL received BI-1808 as monotherapy and 9 patients received BI-1808 in combination with pembrolizumab. The MF patients enrolled in this trial had received a median of five (range 2-13) prior systemic treatments, and SS patients a median of three (range 1-14), underscoring the refractory nature of the study population.

Across evaluable patients (n=15), BI-1808 treatment resulted in objective clinical responses, including 1 durable complete response in a patient with Sézary syndrome, ongoing at two years, and multiple confirmed partial responses in both MF and SS. Overall, objective response rates (ORR) were 40% with BI-1808 monotherapy and 50% with the BI-1808 plus pembrolizumab combination, with additional patients achieving stable disease.

Correlative analyses provided strong mechanistic support for BI-1808's mode of action. Treatment was associated with early and sustained immune activation, including depletion of regulatory T cells and a significant increase in intratumoral CD8+ T cell infiltration and granzyme B expression in responding patients. Serum biomarker analysis showed rapid and sustained induction of IL-12, consistent with a shift from a pro-tumor Th2 environment toward a Th1-driven anti-tumor immune response.

Transient "flares", characterized by increased erythema, pruritus, or skin peeling, were observed early in treatment in some patients and were shown to correlate with immune activation and CD8+ T-cell influx, supporting the notion that they correspond to a pharmacodynamic on-target effect rather than disease progression.

BI-1808 was generally well-tolerated, with most treatment-related adverse events reported as mild to moderate in severity. Limited Grade 3 events were observed, and no new safety signals were identified.

Taken together, these data support TNFR2 as a compelling therapeutic target in CTCL and highlight BI-1808's potential as a novel immunotherapeutic approach, both as monotherapy and in combination with immune checkpoint inhibition.

Clinical trial collaboration and supply agreement

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. Since August 2021, BioInvent has had a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the combination of BI-1808 and MSD's anti-PD-1 therapy, KEYTRUDA (pembrolizumab).

About CTCL and the Unmet Medical Need

Cutaneous T-Cell Lymphomas (CTCL) are rare lymphomas arising from malignant skin-homing T cells. The two most common subtypes are mycosis fungoides (MF), typically an indolent skin-limited disease, and Sézary syndrome (SS), an aggressive leukemic variant. Outcomes for advanced CTCL remain poor, with five-year survival rates of approximately 20%–60%, and patients frequently exhaust multiple lines of treatment.

About the BI-1808 Phase 2a Study

This Phase 2a trial (NCT04752826) is designed to assess the safety and tolerability of BI-1808 as a single agent (Part A) and in combination with pembrolizumab (Part B), characterize its pharmacokinetics and pharmacodynamics, and assess preliminary antitumor activity by ORR, DoR (duration of response), and progression-free survival (PFS). The modified Severity-Weighted Assessment Tool (mSWAT) was used to assess disease activity.

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 efficacy and a favorable safety profile in combination with pembrolizumab in an ongoing Phase 1/2a study for the treatment of solid tumors and T-cell lymphoma.

A manuscript detailing the mechanisms of action of the BI-1808 and differentiated BI-1910 anti-TNFR2 antibodies is available on BioRxiv.com, an open-access online repository for yet unpublished research manuscripts (preprints). Both anti-TNFR antibodies show potent anti-tumor efficacy across multiple syngeneic mouse tumor models, can effectively be combined with anti-PD-1, and trigger CD8+ T cell antitumor immunity, albeit by different mechanisms; BI-1808 is a ligand-blocking FcgR-engaging antibody that depletes immunosuppressive Treg cells and reprograms myeloid cells. BI-1910 is a pure agonist antibody that directly co-stimulates T and NK cells through partially FcgR-independent mechanisms.

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.

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Attachments

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