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

BioInvent will host an in-person KOL lunch briefing (11:45 a.m. - 2:00 p.m. CEST / 5:45 - 8:00 a.m. EDT) in conjunction with EHA 2026 Congress today (virtual event link here)

- *BI-1808 monotherapy achieves 40% objective response rate (ORR), including a complete response ongoing at two years, and a 93 % disease control rate (DCR)*
- *50% ORR and 75% DCR in combination with KEYTRUDA® (pembrolizumab)*
- *BI-1808's Treg-depleting mechanism drives measurable immune activation in patients, confirmed by induction of IL-12, CXCL11 and CCL19 and increased CD8+ T-cell infiltration*
- *Selectively targeting TNFR2 to deplete Tregs and reactivate anti-tumor immunity, BI-1808 holds FDA Fast Track and Orphan Drug designations in CTCL.*

Lund, Sweden – June 11, 2026 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a leader in the discovery of novel immune-modulatory antibodies, today announced that clinical data from its ongoing Phase 2a trial evaluating BI-1808, its novel anti-TNFR2 monoclonal antibody, in patients with advanced CTCL is being presented at the European Hematology Association (EHA) 2026 Congress in Stockholm, Sweden in a poster titled "Targeting TNFR2 with BI-1808 with or without pembrolizumab: Immune activation and promising responses in advanced cutaneous T-cell lymphomas (CTCLs)." The poster is being presented by Stefan K. Barta, MD, MS, Associate Professor of Medicine (Hematology-Oncology) and Director of the T-Cell Lymphoma Program at the Abramson Cancer Center, Perelman School of Medicine at the University of Pennsylvania in Philadelphia, US, and these data underscore BI-1808's potential as both a single agent and combination therapy in this difficult-to-treat cancer with limited therapeutic options.

The poster highlights 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. BI-1808 has received FDA Orphan Drug Designation for T-cell lymphoma and FDA Fast Track Designation for relapsed or refractory MF and SS, as well as a positive opinion from the European Medicines Agency (EMA) for Orphan Drug Designation in CTCL, collectively underscoring the significant unmet medical need and supporting an accelerated path to approval.

“These results reinforce our conviction that TNFR2 blockade with BI-1808 represents a genuinely differentiated approach in CTCL,” said Martin Welschof, Chief Executive Officer of BioInvent. “A 40% objective response rate as monotherapy, including a complete response now sustained at close to two years, is a meaningful outcome in a disease where durable responses remain rare. What is equally compelling is the combination data demonstrating a 50% ORR in patients who had received a median of six prior lines of therapy and no prior anti-PD-1 treatment. These results demonstrate the potential of BI-1808 to sensitize the tumor microenvironment to checkpoint blockade. Together with the translational evidence of deep immune activation, we have a coherent and increasingly well-supported picture of how BI-1808 works and why it matters. We look forward to advancing the program.”

“Patients with advanced CTCL often experience limited and short-lived responses to available therapies,” said Stefan K. Barta, MD, MS, Associate Professor of Medicine (Hematology-Oncology) and Director of the T-Cell Lymphoma Program at the Abramson Cancer Center, Perelman School of Medicine at the University of Pennsylvania in Philadelphia, USA. “In this heavily pretreated population, BI-1808 demonstrated meaningful and durable clinical activity alongside clear biologic evidence of immune activation, including increased CD8-positive T-cell infiltration. These results highlight the therapeutic potential of targeting TNFR2 in CTCL.”

Overview of Data

BI-1808 Single Agent Cohort Fully Enrolled with Responses Across Both MF and SS Subtypes

The signal-seeking portion of the Phase 2a study has been fully enrolled. Twenty patients with advanced-stage CTCL received BI-1808 1000 mg Q3W as monotherapy (12 mycosis fungoides (MF), 8 Sézary syndrome (SS)). Nine patients received BI-1808 in combination with pembrolizumab 200 mg Q3W (6 MF, 3 SS), representing a heavily pretreated population with a median of 6 prior systemic lines of therapy (range 1–18), no prior anti-PD-1 exposure, and 4 patients having received prior mogamulizumab.

BI-1808 Monotherapy Achieves 40% ORR Including a Complete Response Ongoing at Two Years

Of 15 patients evaluable by the modified Severity Weighted Assessment Tool (mSWAT), the standard measure of skin disease burden in CTCL, BI-1808 achieved an ORR of 40%, with 5 confirmed partial responses across both MF and SS subtypes, and one Sézary syndrome patient achieving a complete response that remains ongoing at approximately two years. Eight additional patients achieved stable disease as best response, corresponding to a disease control rate (DCR) of 93%. Two patients with peripheral T-cell lymphoma (PTCL), an aggressive type of lymphoma, were also evaluable, with one achieving a partial response and one stable disease.

Combination with Pembrolizumab Delivers 50% ORR in Patients with No Prior Anti-PD-1 Exposure

Of 8 evaluable patients in the combination arm, 4 achieved a partial response at first assessment and 2 achieved stable disease, resulting in an ORR of 50% and a DCR of 75%. The lower DCR of 75% in the combination arm compared to 93% in the monotherapy arm is consistent with the smaller, more heavily pretreated patient population evaluated to date.

Translational Data Confirm Immune Activation and Provide a Mechanistic Basis for Durable Responses

Translational data from the study provides important mechanistic support for BI-1808's activity. Sustained depletion of CD4+ T cells in blood was observed in patients with disease control during the first treatment cycle, consistent with the drug's FcγR-mediated depletion of regulatory T cells. Elevated serum levels of IL-12, CXCL11, and CCL19 were observed in responders compared to non-responders, indicating an important myeloid reprogramming, CD8+ T cell activation, and the formation of tertiary lymphoid structures which are biomarker signals associated with durable and sustained anti-tumor immune responses.

Low Rate of Severe Side Effects Allows Patients to Remain on Treatment Long-Term

BI-1808 was very well tolerated as a single agent. The most commonly reported treatment-related adverse events (TRAEs) included fatigue, flares (a transient worsening of cutaneous symptoms such as erythema and pruritus shortly after the first dose that is recognized in this patient population), and hypertension. The combination with pembrolizumab was generally well tolerated in this heavily pretreated population, with the most frequently reported TRAEs including fatigue, chills, pyrexia, and infusion-related reactions, consistent with the known profiles of both agents.

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, non-Hodgkin 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 Phase 2a study

The aim of Phase 2a (NCT04752826) is to further 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) for CTCL.

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.

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 FcyR-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 FcyR-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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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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