BioInvent Presents Impressive Response Data from Ongoing Phase 2a Trial of Triple Combination BI-1206, Rituximab, and Calquence in r/r NHL at ASH 2025

- **Early data indicate that BI-1206 has the potential to reset one of the main resistance mechanisms to rituximab**
- **47% of patients exhibited complete responses (CR), with an overall response rate of 80%**
- **Favorable safety profile with most (87%) adverse events being mild or moderate and no treatment-related discontinuations**
- **The safety run-in portion is complete with no apparent differences in safety or efficacy between the two dose levels; the signal-seeking expansion phase of the study is ongoing**

Lund, Sweden – December 8, 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 the presentation of new data from the safety run-in portion of its ongoing trial evaluating BI-1206, an anti-FcγRIIB antibody, in combination with rituximab and Calquence® (acalabrutinib) for the treatment of non-Hodgkin's lymphoma (NHL) at the 2025 American Society of Hematology (ASH) Annual Meeting in Orlando, Florida.

Anti-CD20 antibodies like rituximab are essential for treating NHL. However, 15% of patients do not respond to treatment, and 25% relapse within 3 years. Resistance to rituximab is often driven by FcγRIIB-mediated internalization. BI-1206 blocks this mechanism, restoring rituximab activity, and the doublet rituximab+BI-1206 combination has previously demonstrated a highly encouraging response rate in relapsed/refractory NHL. The early data presented at ASH this year indicate that combining BI-1206 with rituximab and Bruton's tyrosine kinase (BTK) inhibitor acalabrutinib may offer a synergistic approach to overcoming resistance and improving outcomes.

"These results demonstrate that BI-1206, in combination with rituximab and acalabrutinib, could represent a promising new option for patients with indolent NHL who have limited treatment alternatives," said Martin Welschof, Chief Executive Officer of BioInvent. "These impressive early signs of efficacy, along with a remarkable safety profile provide a strong rationale for advancing BI-1206 for the treatment of CD20 expressing blood cancers."

The Phase 2a study (NCT03571568) combines the subcutaneous formulation of BI-1206 and rituximab with Calquence® (acalabrutinib) in subjects with indolent B-cell non#Hodgkin's lymphoma (NHL) who have relapsed or are refractory to rituximab.

Summary of data:
Among 15 evaluable patients in the safety run-in (data cut off December 1, 2025), the overall response rate was 80% (7 CR, 5 partial responses, PR), with 47% achieving complete responses. Disease control rate was 100%, and the majority of subjects were still on treatment as of the data cut off.

The treatment regimen was remarkably well-tolerated and most (87%) treatment-related adverse events were mild or moderate. Seven subjects had Grade 3 events considered related or possibly related to at least one of the study drugs, including neutropenia and lymphopenia. Two serious adverse events were recorded: grade 2 pain in extremity, grade 3 neutropenia. There were no discontinuations due to adverse events. Notably, no cytokine release syndrome, neurologic toxicity or serious infections related to treatment have been observed.

The safety run-in portion of the trial is complete with no apparent differences in safety or efficacy between the two dose levels. Results support continued enrollment into the expansion phase and suggest that the triplet regimen may offer a valuable therapeutic option for patients with indolent NHL who are refractory to rituximab.

Poster presentation details:
Title: Promising efficacy of BI-1206, an antibody targeting FcγRIIB in combination with rituximab and acalabrutinib in R/R NHL patients
Date and Time: December 8, 2025, 6:00 PM - 8:00 PM ET
Session name: 623. Mantle Cell, Follicular, Waldenstrom's, and Other Indolent B Cell Lymphomas: Clinical and Epidemiological: Poster III
Lead Author: Laura Fogliatto, Hospital de Clínicas de Porto Alegre, Porto Alegre, Brazil
Publication Number: 5349

The poster will be posted to the Scientific Publications section of the company website (https://www.bioinvent.com/en/our-science/scientific-publications).

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About the Phase 2a Study
The triple combination arm in the ongoing Phase 2a study (NCT03571568) combines the subcutaneous formulation of BI-1206 and rituximab with Calquence® (acalabrutinib) in subjects with indolent B-cell non#Hodgkin's lymphoma (NHL) who have relapsed or are refractory to rituximab. Approximately 30 patients are expected to be enrolled in Spain, Germany, USA, and Brazil. In February 2024, BioInvent signed a clinical supply agreement with AstraZeneca (LSE/STO /Nasdaq: AZN) to provide Calquence® for the combination arm.

About BI-1206

FcγRIIB is overexpressed in several forms of NHL and overexpression has been associated with poor prognosis in difficult-to-treat forms of NHL, such as mantle cell lymphoma. By blocking the receptor FcγRIIB on tumor cells, BI-1206 is expected to recover and enhance the activity of rituximab and acalabrutinib in the treatment of several forms of NHL. The drug candidate is evaluated in two separate clinical Phase 1/2a programs, one for the treatment of solid tumors and one for the treatment of non-Hodgkin's lymphoma (NHL), a type of blood cancer. Both programs show encouraging clinical activity along with good tolerability.

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 current 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.

This information is information that BioInvent International is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-12-08 14:00 CET.

Attachments

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