BioInvent's BI-1206 Triplet Achieves 83% Response Rate in Refractory NHL with Improved Safety vs. SOC (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)

- 83% ORR across all evaluable patients in the total non-Hodgkin's lymphoma (NHL) population (n=23)
- 81% objective response rate (ORR) and 44% complete response rate (CRR) in relapsed /refractory follicular lymphoma (FL), on par with the recently approved tafasitamab+R2 (rituximab + Revlimid) combination
- Markedly lower rate of serious adverse events (14%) versus tafasitamab+R2 (34%), obinutuzumab+zanubrutinib (35%), rituximab+lenalidomide "R2" (29–32%), and epcoritamab+R2 (56%)
- Only 3% TEAE (treatment emergent adverse events)-related treatment discontinuation, compared to 7%–19% across R2-based standard-of-care regimens
- Acalabrutinib (Calquence®) with BI-1206 + rituximab boosted efficacy without increasing toxicity

Lund, Sweden – June 11, 2026 – BioInvent International AB ("BioInvent") (Nasdaq Stockholm: BINV), a leader in the discovery of novel immune-modulatory antibodies, today announced new clinical data from the BI-1206 triplet combination in relapsed/refractory (R/R) non-Hodgkin's lymphoma (NHL) to be presented in a poster at the 31st European Hematology Association (EHA2026) Congress, taking place June 11-14, 2026 in Stockholm, Sweden.

The poster summarizes key efficacy, safety, and mechanistic data from the ongoing Phase 1/2 study (NCT03571568) evaluating BI-1206 in combination with rituximab and Calquence® (acalabrutinib) in patients with relapsed or refractory NHL, including follicular lymphoma. BI-1206 directly targets FcγRIIB-mediated rituximab internalization, a major driver of resistance to CD20-directed therapy, while leveraging BTK inhibition with acalabrutinib to enhance anti-tumor activity.

"These EHA data reinforce our conviction that BI-1206 has the potential to meaningfully change the treatment landscape for patients with relapsed or refractory follicular lymphoma," said Martin Welschof, Chief Executive Officer of BioInvent. "An 81% response rate that matches or exceeds recently approved combinations – coupled with a safety profile that is markedly more favorable than the widely used R2-based regimens – is exactly the kind of differentiated clinical profile we set out to build. BI-1206 is now the cornerstone of our NHL strategy, and we look forward to advancing this program toward pivotal development as we work to bring a compelling new option to patients who urgently need it."

Overview of data included in the poster at EHA 2026

The BI-1206 triplet exhibits an ORR and safety profile consistent with established clinical benchmarks, including standard-of-care (SOC) R2 therapy and the recently approved tafasitamab+R2 combination, underscoring its potential as a highly competitive therapeutic option in R/R FL.

- As of data cut-off May 6, 2026, the triplet of BI-1206 + rituximab + acalabrutinib delivered an 83% objective response rate (ORR) in the total population (n=23 evaluable), with 11 complete responses (CR) and 8 partial responses (PR).
- In the follicular lymphoma (FL) subset (n=16), ORR was 81% and complete response rate (CRR) was 44%.
- All remaining patients exhibited stable disease as best response, giving a disease control rate (DCR) of 100%.
- The cohort has been completely enrolled, though response assessment has not yet occurred for all patients; as the majority of patients are still on treatment, any PFS (progression-free survival) calculation is yet premature.
- The regimen showed a very favorable tolerability profile, with treatment-related serious adverse events observed in only 4 (14%) patients and discontinuation due to a drug-related adverse event in 1 patient. Grade 3+ treatment-related adverse events observed in only 31% of patients, versus 54–84% for comparator regimens.

Poster presentation details

- **Title:** Targeting resistance to rituximab through FcγRIIB (CD32B) blockade: BI-1206 + rituximab + acalabrutinib shows powerful activity in R/R NHL
- **Presenter:** Dr. Laura Fogliatto, Hospital de Clínicas de Porto Alegre, Brazil
- **Session Date/Time:** Friday, June 12, 6:45 pm-7:45 pm CEST (12:45 pm-1:45 pm EDT)
- **Location:** EHA2026 Congress, Stockholm

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

About the BI-1206 Phase 2a part of the study

The triple combination arm in the ongoing Phase 2a part of the study (NCT03571568) combines the subcutaneous formulation of BI-1206 with rituximab and acalabrutinib in subjects with indolent B-cell non-Hodgkin's lymphoma (NHL) who have relapsed or are refractory to rituximab. Patient enrolment (approximately 30 patients) has been completed in Spain, Germany, USA, and Brazil. BioInvent has a clinical supply agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) providing Calquence® (acalabrutinib) for the combination arm.

About BI-1206

FcγRIIB is overexpressed in several forms of NHL and its overexpression has been associated with poor prognosis in difficult-to-treat subtypes, including mantle cell lymphoma. Fcγ RIIB-mediated internalization of rituximab is a well-established driver of resistance to CD20-directed therapy. By blocking this receptor on tumor cells, BI-1206 is designed to restore and enhance rituximab activity in combination regimens. The clinical rationale for the BI-1206 triplet is supported by the ROSEWOOD trial (Zinzani et al., JCO 2023), which showed that adding the BTK inhibitor zanubrutinib to the Fc-engineered anti-CD20 antibody obinutuzumab – which has reduced but not absent FcγRIIB-mediated internalization – increased ORR from 45% to 69% and median PFS from 10.4 to 28 months in R/R FL. By contrast, acalabrutinib added to standard rituximab yielded only 31% ORR and a median PFS of 8.3 months (Strati et al., Br J Haem 2024), despite similar BTK kinase profiles for the two inhibitors. These data point to improved CD20 targeting – not BTK inhibition per se – as the key driver of superior outcomes. Because BI-1206 directly targets FcγRIIB-mediated internalization, combining it with rituximab and acalabrutinib offers a mechanistically distinct approach to overcoming rituximab resistance. The 81% ORR observed in the EHA 2026 data, substantially exceeding the 31% seen with acalabrutinib plus rituximab alone, is consistent with this hypothesis. BI-1206 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 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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