

BioInvent Announces Updated Phase 2a Triple Combination Arm Data of BI-1206, rituximab, and Calquence for the treatment of non-Hodgkin's lymphoma

- Latest preliminary data show continued promising clinical activity in NHL patients, with two complete responses (CR), three partial responses (PR), and three stable disease (SD) as best clinical response in the first eight patients evaluated
- Results equate to an objective response rate (CRs and PRs) of 63%
- Data from an earlier cutoff date in February are included in an abstract published today by the European Hematology Association (EHA) 2025 conference

Lund, Sweden - May 14, 2025 - BioInvent International AB ("BioInvent") (Nasdag Stockholm: BINV), a biotech company focused on the discovery and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, today announces latest updated data from the ongoing Phase 2a study of BI-1206 in combination with rituximab and Calquence® (acalabrutinib) for the treatment of non-Hodgkin's lymphoma (NHL). Additionally today, an abstract containing data from an earlier February cutoff date has been published by the European Hematology Association (EHA) as part of its 2025 congress due to take place June 12-15 in Milan, Italy.

The data released today show the first eight patients in the triple combination arm of BioInvent's ongoing Phase 2a in non-Hodgkin's lymphoma. All patients exhibited disease control at first assessment (DCR 100%), and results show an overall objective response rate of 63% with two patients achieving a complete response (CR) and three patients with partial responses (PR). Stable disease (SD) was observed in the three remaining patients. The combination has been well tolerated in all patients treated at the cut-off-date. These data are further updated compared to the data included in the EHA abstract.

"We continue to be encouraged by the early data demonstrating robust clinical activity and manageable safety profile in the ongoing triple combination arm of the Phase 2a study of BI-1206 in combination with rituximab and Calquence in NHL patients who have relapsed after previous lines of treatment," said Martin Welschof, Chief Executive Officer of BioInvent. "The objective responses observed to date highlight the potential of the combination to improve outcomes and overcome resistance, a result we believe is driven by the mechanism of action of BI-1206. Previously we have demonstrated that BI-1206 can restore response to rituximab in relapsed/refractory patients. Now we demonstrate that a BTK inhibitor may be added to this combination without compromising safety. We look forward to advancing the clinical development of this promising and highly convenient treatment."



Details of the EHA abstract released today are below:

Title: BI-1206, an Antibody Targeting FcyRIIB, given in Combination with Rituximab and Acalabrutinib in Subjects with Indolent B-Cell Non-Hodgkin's Lymphoma

Lead Author: Laura Fogliatto, Hospital de Clínicas de Porto Alegre, Porto Alegre, Brazil

Abstract Number: PB3180

About the study

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

About BI-1206

BI-1206 is one of BioInvent's lead drug candidates and is developed to re-establish the clinical effect of existing cancer treatments such as pembrolizumab and rituximab. The drug candidate is evaluated in two separate clinical programs, one for the treatment of non-Hodgkin's lymphoma (NHL, a type of blood cancer) and one 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 currently five drug candidates in six 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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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 2025-05-14 15:30 CEST.

Attachments

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