BioInvent announces promising initial efficacy data from triple combination arm of BI-1206, rituximab and Calquence for the treatment of non-Hodgkin's lymphoma

- The first two patients enrolled in the Phase 2a study triplet arm combining BI-1206 with rituximab and Calquence® responded to treatment
    - One complete response (CR) and one partial response (PR)
    - The treatment has been well-tolerated with no safety or tolerability concerns
- Study now expanding to additional clinical investigational sites and patient enrollment on track with further Phase 2a results expected by mid-2025

Lund, Sweden – January 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 announces promising initial clinical response data from the two enrolled patients in the triple combination arm of the Phase 1/2a study of its anti-FcγRIIB antibody, BI-1206, combined with rituximab and AstraZeneca's Bruton's tyrosine kinase (BTK) inhibitor Calquence® (acalabrutinib), in non-Hodgkin's lymphoma (NHL).

The preliminary data demonstrates that the combination treatment is well tolerated with the two enrolled patients already showing clinical responses. One patient has obtained a complete response (CR), and one patient shows a partial response (PR). Patient enrollment remains on schedule. Further Phase 2a data are expected by mid-2025.

The triplet arm in the Phase 2a study is combining the subcutaneous formulation of BI-1206 and rituximab with Calquence® (acalabrutinib). 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/Nasdaq: AZN) to provide Calquence® for the combination arm.

"It is highly encouraging to see that the move to subcutaneous administration of BI-1206 has led to the improved safety profile we had predicted and hoped for, while also continuing to deliver on the promising efficacy signals already observed. We are also very pleased with the initial data from the Phase 2a triple combination study showing that the first two patients enrolled at the lower dose in the safety run-in are showing responses". said **Martin Welschof, Chief Executive Officer of BioInvent.** "The treatment is so far well-tolerated and with increasing interest in the study driven by the triplet arm, we are confident that we can remain on track with enrollment and provide further data next year."

In addition, the Phase 1/2a study of BI-1206 in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in heavily pre-treated patients with solid tumors continues to progress. The subcutaneous administration of BI-1206 has been well-tolerated with no notable injection reactions. Given the beneficial safety and tolerability profile observed to date, an additional dose cohort with increased dose frequency has been added to the Phase 1 part to further characterize the dose-response/safety of BI-1206 SC in order to maximize the likelihood of success in the subsequent Phase 2a part of the study.

The complete response (CR) in solid tumors previously reported in May 2024 at this year's ASCO Annual Meeting for a patient with metastatic melanoma is nearing the two-year milestone, with the response maintained.

"With BI-1206, we are continuing to produce compelling clinical data in both non-Hodgkin's lymphoma and solid tumors that demonstrate the potential of targeting FcyRIIB to restore the activity of existing cancer treatments which could lead to life-transforming therapies for patients," said Martin Welschof, Chief Executive Officer of BioInvent. "We look forward to further data from both studies next year and continue to believe that BI-1206 can play an important part in future treatment options for patients with different types of cancers."

Calquence® is a registered trademark of the AstraZeneca group of companies. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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.

BI-1206 in NHL

All patients in the ongoing Phase 1/2a study (NCT03571568) have previously been treated with one or more rituximab containing treatments. Latest results for the combination of BI-1206 and rituximab were presented in connection with EHA (European Hematology Association) congress in June 2024: the intravenous (IV) Phase 1 part (dose escalation) showcased responses across the dose range of 30-100 mg, including 5 patients with complete response (CR), 1 with partial response (PR) and 6 patients with stable disease (SD) out of 17 evaluable patients. Data from the subcutaneous (SC) Phase 1 part (dose escalation) with BI-1206 + rituximab has showed 2 CR, 3 PR and 3 SD out of 9 evaluable patients.
In February 2024 BioInvent signed a clinical supply agreement with AstraZeneca (LSE/STO /Nasdaq: AZN) to provide Calquence® for the triple combination arm of BI-1206 + rituximab + Calquence®.

BI-1206 in solid tumors
Clinical Phase 1/2a study with BI-1206 in combination with pembrolizumab (NCT04219254) ongoing. In May 2024, the company announced promising Phase 1 data for BI-1206 in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in heavily pre-treated patients with solid tumors. The data showed encouraging and durable responses in patients who previously had failed on anti-PD-1/L1 therapy. The combination was well-tolerated in this heavily pre-treated population of patients. Out of 28 evaluable patients (as of Oct 14th, 2024), the results included one complete response (CR) in metastatic melanoma, one partial response (PR) in uveal melanoma and eight patients with stable disease (SD) as best response, whereof one long-lasting metastatic melanoma patient who had previously progressed on nivolumab treatment that remained a stable disease throughout the two-year study duration. The ongoing study is recruiting patients with advanced solid tumors who had progressed on prior treatments including PD-1/PD-L1 immune checkpoint inhibitors. Patients receive a three-week cycle of BI-1206 in combination with pembrolizumab for up to two years, or until disease progression.

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. Follow us on the social media platform X: @BioInvent.

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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 2025-01-08 08:00 CET.

Attachments

BioInvent announces promising initial efficacy data from triple combination arm of BI-1206, rituximab and Calquence for the treatment of non-Hodgkin's lymphoma