BioInvent to Present Additional Promising Phase 1/2a Data at EHA 2024 for BI-1206 with rituximab in NHL

- *First data for the **SC arm**: 1 complete response (CR), 2 partial response (PR), 1 stable disease (SD) out of 4 evaluable patients.*
- *Further updates from the **IV arm**; a fifth CR has been observed, adding to a total of 5 CR, 1 PR and 6 SD out of 17 evaluable patients.*
- *Data to be presented at the European Hematology Association, June 13-16, 2024.*
- *BI-1206 is developed to re-establish the clinical effect of existing cancer treatments such as rituximab and is evaluated as both intravenous (IV) and subcutaneous (SC) administration.*
- *Phase 2a trial plans to include a triple combination with BI-1206, rituximab and acalabrutinib.*

Lund, Sweden – May 14, 2024 – 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 that promising clinical data for BI-1206 in relapsed/refractory (R/R) non-Hodgkin lymphoma (NHL), dosed in combination with rituximab, will be presented in a poster at the European Hematology Association congress held in Madrid, Spain from June 13-16, 2024.

"We are pleased to share further validating Phase 1/2a data for BI-1206 in NHL during EHA. There is a high unmet need to develop treatments that can overcome resistance and improve the durability of responses to rituximab, an essential part of NHL treatment. We believe BI-1206 has the potential to meet this need," said Martin Welschof, Chief Executive Officer of BioInvent. " To identify the best options and meet the needs of clinicians and patients, we are evaluating BI-1206 administration as both IV and SC. IV dosing so far has produced response rates of a 35% ORR (overall response rate), 29% CRR (cumulative response rate) and 71% DCR (disease control rate), and we see promising early efficacy data from the subcutaneous dosing. In addition, we report an ORR of 56% in the subset of patients with follicular lymphoma (FL). Based on these encouraging results, we plan to initiate a Phase 2a study arm where the BTK inhibitor, acalabrutinib (Calquence®), will be added to the rituximab and BI-1206 combination, which should further increase response rates."

BI-1206 is also being developed for the treatment of solid tumors and data will be presented at ASCO 2024.

Abstract summary:

Title: Safety And Preliminary Efficacy Of BI-1206, An Antibody To CD32B (FcγRIIB), Given In Combination With Rituximab In Subjects With Indolent B-Cell Non-Hodgkin Lymphoma
Abstract#: P1135
Session: Indolent and mantle-cell non-Hodgkin lymphoma
Date: June 14, 2024
Time: 6 - 7 pm CEST

Overview: While anti-CD20 antibodies such as rituximab are a cornerstone of NHL care, approximately 15% of patients are refractory to treatment and 25% relapse within 3 years after treatment. The inhibitory Fc receptor CD32b (FcγRIIB) promotes resistance by triggering tumor cells to internalize and destroy rituximab. BI-1206 has been designed as an anti-FcγRIIB mAb to block rituximab internalization.

Methods: BioInvent conducted a Phase 1/2a trial in several R/R B-cell NHL subtypes to evaluate safety and tolerability of BI-1206 in combination with rituximab. Dose expansion is ongoing for the IV formulation since the recommended Phase 2 dose (RP2D) of IV BI-1206 has been established. Phase 1 dose escalation is still ongoing for the SC formulation.

Safety and Efficacy Results (May 2024):

- **Safety:** Thrombocytopenia and elevated transaminase levels were the most frequent treatment-emergent adverse events (TEAEs). The events resolved with a median duration of 4 days without any clinical complication. DLTs were not observed with intravenous (IV) dosing after pre-treatment with corticosteroids.
- **Efficacy**: In the **FL subset** of 16 evaluable patients (IV+SC), an ORR of 56% and CRR of 38% were observed.
- **SC administration:** In the **SC dosing** arm, in 4 evaluable patients, 1 complete response (CR), 2 partial response (PR) and 1 stable disease (SD) were observed.

The full poster will be posted to the company's website https://www.bioinvent.com/en/our-science/scientific-publications shortly after the presentation in June.

About BI-1206
The anti-FcγRIIB antibody BI-1206 is being evaluated in two separate tracks: for the treatment of NHL and solid tumors. It blocks a receptor class found on tumor cells as well as on certain immune cells, including macrophages. By selectively blocking this receptor, the aim is to improve the efficacy and/or overcome resistance from targeted therapies for hematologic cancers (including rituximab) and solid tumors (including agents that target PD-1/PD-L1).

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, or other anti-CD20 monoclonal antibodies, in the treatment of several forms of NHL. The combination of the two drugs could provide a new and important option for patients suffering from NHL and represents a substantial commercial opportunity.

An SC formulation is being developed in parallel to the IV and patient recruitment to the Phase 1 part with BI-1206 SC as well as to the Phase 2a expansion cohorts with BI-1206 IV is ongoing.

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 on the social media platform X: @BioInvent.

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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 2024-05-14 16:00 CEST.

Attachments

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