BioInvent's BI-1206 to advance into expansion stage of Phase 1/2a study in NHL after a productive End-of-Phase 1 FDA meeting

- **BI-1206 moving into expansion phase as planned**
- **Data presented so far include early signs of efficacy**
- **Next steps to include planning potentially pivotal Phase 2 study**

Lund, Sweden – May 3, 2022 – 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 its novel anti-FcγRIIB antibody BI-1206 is progressing into the expansion phase of a Phase 1/2a trial for non-Hodgkin's lymphoma (NHL), following a positive End-of-Phase 1 meeting with the US FDA.

The Phase 1 data presented so far (December 2021) include early signs of efficacy in the form of three long-lasting complete responses, four partial responses and one stable disease in 13 patients with NHL evaluated for therapeutic benefit. Based on these data, the FDA has agreed the ongoing Phase 1/2a study may proceed into its expansion phase.

"*BI-1206 has the potential to significantly improve treatment for lymphoma and solid tumor patients, and we are pleased to continue our positive dialogue with regulatory agencies. We continue to evaluate BI-1206 as a game-changer for patients who relapse after rituximab or other anti-CD20 treatments. This represents a substantial unmet medical need and an important commercial opportunity for BioInvent. Our recent interaction with FDA has provided valuable guidance on the study design that should enable BioInvent to optimize clinical development and plan the most effective route to market for BI-1206, and we look forward to continuing our work to bring these potential benefits to patients,* said **Martin Welschof, CEO of BioInvent.**

The expansion Phase 2a part of the study will start dosing patients at 100 mg of BI-1206. Once the Phase 1/2a data package is completed, the plan is to move forward with a randomized, controlled, potentially pivotal Phase 2 study. The Phase 2 study is expected to start on schedule in H1 2023. The Phase 1 trial of the subcutaneous formulation of BI-1206 is on track to begin in H2 2022.

In the Phase 1/2a study, patients whose disease has previously worsened despite being treated with rituximab-containing therapy receive 1 cycle of induction therapy with BI-1206 in combination with rituximab. Those patients who show clinical benefit at week 6, continue onto maintenance therapy and receive BI-1206 and rituximab once every 8 weeks for up to 6 maintenance cycles, or up to 2 years from first dose of BI-1206.

About BI-1206
Recently published data (ASH 2021) showed that BI-1206 in combination with rituximab provided an objective response rate (ORR) of 54%, with three complete responses and four partial responses in 13 patients evaluated for therapeutic benefit for the three indications (Mantle cell lymphoma, Marginal zone lymphoma and Follicular lymphoma) enrolled in the clinical study. The treatment stabilized disease in one additional patient, giving a disease control rate of 62% (8 out of 13 patients).

When considered alone, the response rate for Follicular lymphoma is particularly impressive: of nine evaluable patients, three developed a CR, three developed a PR and one patient had SD at the cut-off date, giving a 67% ORR and 78% DCR. Previous rituximab treatments without BI-1206 had failed in these patients, prior to participation in the trial all patients had relapsed on earlier lines of rituximab-containing treatments.

At the time of the data release, all complete responses had been sustained for extended periods, with the longest complete response enduring beyond 36 months. In two additional patients, complete responses had lasted beyond 12 and 24 months after end of treatment.

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 three drug candidates in four ongoing clinical programs in Phase 1/2 trials for the treatment of hematological cancer and solid tumors, respectively and a fifth program just initiating clinical development. The Company's validated, proprietary F.I.R.S.T™ technology platform simultaneously identifies both targets and the antibodies that bind to them, generating many promising new drug candidates to fuel the Company's own clinical development pipeline or for additional licensing and partnering.

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 Twitter: @BioInvent.

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Attachments

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