BioInvent to evaluate BI-1206 in combination with rituximab and Calquence

- **Clinical supply agreement with AstraZeneca to support Phase 1/2a BI-1206 combination study**
- **BI-1206 to be evaluated in combination with Calquence® and rituximab in Phase 1/2a trial in non-Hodgkin's lymphoma**
- **The ongoing rituximab combination trial will be expanded to include the triplet arm**

Lund, Sweden – February 9, 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 a clinical supply agreement with AstraZeneca (LSE/STO/Nasdaq: AZN) to evaluate BioInvent's anti-FcyRIIB antibody, BI-1206, in combination with rituximab and Calquence® (acalabrutinib), in a Phase 1 /2a study in non-Hodgkin's lymphoma (NHL).

Under the terms of the supply agreement, AstraZeneca will provide Calquence, a selective inhibitor of Bruton's tyrosine kinase (BTK), for use in combination with BI-1206 and rituximab in the ongoing Phase 1/2a clinical study (NCT03571568) for the treatment of patients with follicular lymphoma who have progressed or are refractory to rituximab.

"Having already shown the benefits of combining BI-1206 with rituximab, we believe the addition of Calquence for a triplet combination could further improve clinical outcomes for patients with non-Hodgkin's lymphoma, including follicular lymphoma and mantle cell lymphoma, " said Dr. Martin Welschof, CEO of BioInvent. "We are extremely pleased to be entering into this supply agreement with AstraZeneca that allows us to explore a potential new, chemo-free, treatment option for these patients. "

The Phase 1 part - intravenously (IV) administered BI-1206 - has been completed with impressive early signs of clinical efficacy. The Phase 2a IV dose expansion cohort is currently enrolling patients, and it will look to enroll patients to be treated with the triplet. A subcutaneous (SC) formulation is being developed in parallel to the IV and it is expected to bring a great deal of convenience to the treatment. The Calquence expansion cohort is expected to enroll approximately 30 patients at sites in Sweden, Spain, the US, and Brazil.

About BI-1206

BI-1206 is one of BioInvent's most advanced drug candidates and is developed to re-establish the clinical effect of existing cancer treatments such as pembrolizumab and rituximab, drugs with combined global sales of approximately USD 23 billion annually.

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. Two delivery formulations (intravenous (IV) and (subcutaneous (SC) of BI-1206 are being evaluated in parallel.

BI-1206 in NHL
All patients in the ongoing Phase 1/2a study have previously been treated with one or more rituximab containing treatments. Results from the intravenous (IV) Phase 1 part (dose escalation) showcase responses across the dose range of 30-100 mg, including 4 complete responders (CR), 3 partial responders (PR) and 4 cases of stable disease (SD) out of 15 evaluable patients. No maximum tolerated dose has been defined, and Phase 2a dose IV expansion cohort is currently enrolling patients.

Among the CR population, responses have been long-lasting, three of them lasting years after end of treatment, while the 4th is still on treatment. As of June 2023, the median duration of complete response was 2.5 years, with three patients still ongoing.

In January 2023, BioInvent was selected as partner of The Leukemia & Lymphoma Society's Therapy Acceleration Program® (LLS TAP) aimed to support and accelerate the development of the most promising and innovative blood cancer therapeutics worldwide.

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.

For further information, please contact:
Cecilia Hofvander, Senior Director Investor Relations
Phone: +46 (0)46 286 85 50
Email: cecilia.hofvander@bioinvent.com

BioInvent International AB (publ)
Co. Reg. No. Org nr: 556537-7263
Visiting address: Ideongatan 1
Mailing address: 223 70 LUND
Phone: +46 (0)46 286 85 50

www.bioinvent.com

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Attachments

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