BioInvent announces 2024 strategic priorities and anticipated milestones

- **Data from seven different clinical studies expected throughout the year, including combination data for the two lead programs BI-1808 and BI-1206 in H1/mid-2024**
- **Well-financed with 1358 SEK million (~USD 132M), as of September 30, 2023**

Lund, Sweden – January 04, 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 highlighted the Company's strategic priorities and anticipated milestones for 2024.

The company expects multiple data readouts from different clinical studies during the year, including Phase 1 combination data from lead programs BI-1808 and BI-1206 in H1/mid-2024. Additionally, data from five other clinical studies are expected from programs BI-1206 in NHL, single agent BI-1808, BI-1607, BT-001 and BI-1910. The company is well financed with SEK 1358 million which supports current development plans.

"Going into 2024, we are eager to build on the momentum from a very successful 2023, where we made excellent progress with our six clinical programs. In particular, positive clinical data readouts from three of our programs (BI-1206, BI-1808 and BT-001) provided important validation of our proprietary F.I.R.S.T™ antibody generation platform and we look forward to continuing the development of these programs during 2024 and beyond. Likewise, the encouraging early clinical data from our BI-1607 program, which we believe could be used to increase response rates when used in combination with other antibody therapies, illustrated the ability of our state-of-the art platform to generate important novel antibody candidates. We were also very pleased to further bolster our clinical pipeline by announcing in December the first patient had been enrolled in our Phase 1/2a trial with BI-1910," said Dr. Martin Welschof, CEO of BioInvent. "We expect an equally busy 2024, with multiple value-inflection points including data sets for target engagement and initial Phase 2 clinical proof-of-concept results from our growing portfolio of novel, first/best-in-class immune-modulatory antibodies. We are well-funded with 1358 SEK million (~$120 million USD) in cash and combined with the expertise and hard work of our team I am looking forward to another productive year at BioInvent."

UPDATE & MILESTONES FOR LEAD PIPELINE PROGRAMS BI-1808 AND BI-1206

BI-1808: an anti-TNFR2 antibody targeting regulatory T cells (Treg) in solid tumors and lymphoma

The anti-TNFR2 antibody BI-1808 is a first-in-class drug candidate. TNFR2 has been shown to be important for tumor expansion and survival, representing a new and promising target for cancer immunotherapy. BI-1808 is being developed under the Leukemia & Lymphoma Society's Therapy Acceleration Program® (LLS TAP) aimed at supporting and accelerating the advancement of the most promising and innovative blood cancer therapeutics worldwide.

BI-1808 is currently evaluated as a single agent in Phase 2 and in combination with pembrolizumab in Phase 1. Positive interim results from the Phase 1 part presented at SITC in November 2023 showcased early signs of efficacy together with a strong safety profile.

BI-1808 administered as single agent induced a **robust partial response** (PR) in a patient with a gastrointestinal tumor (GIST) who had received 12 previous lines of treatment. This patient is still receiving BI-1808 treatment, and a recent scan showed a 59% reduced tumor burden. Another patient, with lung cancer, experienced a 20% reduction in the tumor size but had to be taken off study due to an unrelated reason.

There are a further **7 cases of stable disease** out of 21 evaluable patients and pharmacokinetic/ pharmacodynamic data has enabled identification of a wide dose range where complete target coverage can be achieved with a remarkable safety profile.

The efficacy of BI-1808 as single agent is further explored in an **ongoing Phase 2a trial** in a larger sample of patients. In addition to the originally planned expansion cohorts in lung cancer, ovarian cancer, and cutaneous T cell lymphoma (CTCL), BioInvent plans to enlarge the scope of the signal seeking cohorts to include new cohorts in melanoma and other forms of T cell lymphomas. This is driven by the exciting data observed so far.

Next milestones:
Mid-2024: Initial data from Phase 1 part of the combination study of BI-1808 and pembrolizumab.
YE 2024: Initial data from Phase 2a BI-1808 single-agent trial.

BI-1206 – an anti-FcyRIIB antibody for the treatment of NHL and solid tumors

BI-1206 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 product is being evaluated in two separate clinical trials, 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. An SC administration would provide an improvement in terms of convenience and flexibility to both patients and healthcare professionals.

BI-1206 in NHL: All patients in the ongoing Phase 1/2a study have previously been treated with one or more rituximab containing treatments. In the intravenous (IV) Phase 1 part, responses have been observed 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.

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. No maximum tolerated dose has been defined, and **Phase 2a dose IV expansion cohort** is currently enrolling patients.

BI-1206 in solid tumors: As reported in June 2023, the Phase 1 IV arm of the study has already generated early signs of efficacy, e.g., **two long-lasting partial responses** and **two patients displaying stable disease**, out of a total of 18 evaluable patients having received BI-1206 in combination with pembrolizumab. Both responding patients have melanoma, and both had previously been treated with immune checkpoint inhibitors. In September 2023, the first patient was recruited to the subcutaneous (SC) arm of the Phase 1/2a study.

Next milestones:
H1 2024: Data from the Phase 1 dose escalation segment evaluating BI-1206 SC dosing in combination with rituximab in NHL. Further data from the Phase 1 dose escalation of BI-1206 IV in combination with pembrolizumab for the treatment of solid tumors.
YE 2024: Initial Phase 2 data for BI-1206 in NHL.

Participation in the 13th Annual LifeSci Partners Corporate Access Event
Martin Welschof and part of the BioInvent Management Team will be in San Francisco during JPM week. The Company will be meeting with institutional investors on January 9th and 10th at the LifeSci Partners Corporate Access Event. Registration can be accessed through this link.

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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Attachments

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