BioInvent initiates subcutaneous arm of Phase 1/2 trial with BI-1206 in solid tumors

- **First patient has been enrolled for treatment with subcutaneous BI-1206 in solid tumors**
- **Subcutaneous formulation will significantly improve convenience of dosing regimen**

Lund, Sweden – September 8, 2023 – **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 the enrollment of the first patient in a Phase 1/2 trial (NCT04219254; KEYNOTE-A04) in combination with KEYTRUDA® (pembrolizumab), MSD's (Merck & Co., Inc., Rahway, NJ., USA) anti-PD-1 therapy, investigating a subcutaneous (SC) formulation of its lead drug candidate, the novel anti-FcγRIIB antibody BI-1206, in solid tumors.

SC administration provides a significant improvement in terms of convenience and flexibility to both patients and healthcare professionals when compared to intravenous (IV) administration. In the ongoing Phase 1/2 trial of BI-1206, in combination with rituximab in non-Hodgkin's lymphoma (NHL), pharmacokinetically equivalent doses to IV have already been administered improving exposure and receptor engagement as had been predicted. Furthermore, there have been no safety or tolerability concerns.

The trial is recruiting patients with advanced solid tumors who had progressed after prior treatments including PD-1/PD-L1 immune checkpoint inhibitors. Patients will receive three-week cycles of BI-1206 in combination with pembrolizumab for up to two years, or until disease progression. As reported on June 7, 2023, the IV part of the study has already generated early signs of efficacy, e.g., two partial responses and two patients displaying stable disease, out of a total of 18 evaluable patients having received BI-1206+pembrolizumab.

"We are very pleased to continue to advance BI-1206 through clinical development with the possibility of using the simpler subcutaneous method of administration. The results generated so far further in this heavily pre-treated population reinforce our belief that BI-1206 has the potential to significantly improve the treatment of patients with non-Hodgkin lymphoma and solid tumors. We look forward to the continued development with the ultimate goal of improving the treatment and quality of life of patients with cancer," said Martin Welschof, CEO of BioInvent.

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

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 four drug candidates in five ongoing clinical programs in Phase 1/2 trials for the treatment of hematological cancer and solid tumors, respectively. 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 drug 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

Disclaimer
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.

Attachments

BioInvent initiates subcutaneous arm of Phase 1/2 trial with BI-1206 in solid tumors