BioInvent announces first patient enrolled in Phase 1b/2a study of BI-1607 in combination with ipilimumab and KEYTRUDA (pembrolizumab) in patients with unresectable or metastatic melanoma

- Study to evaluate safety and anti-tumoral activity of anti-FcgRIIB antibody BI-1607 with anti-CTLA-4: ipilimumab, in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA)(anti-PD-1 therapy, KEYTRUDA® (pembrolizumab); initial data expected in H2 2025
- Data from Phase 1 study in combination with trastuzumab previously demonstrated BI-1607 is safe, well tolerated and achieves full receptor occupancy during the treatment interval at several dose levels; preclinical data show BI-1607 enables lower anti-CTLA-4 dosing with improved survival
- Clinical supply agreement for KEYTRUDA® in place with MSD

Lund, Sweden – December 12, 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 announces it has enrolled the first patient in the Phase1b/2a study evaluating the safety and anti-tumoral activity of its second FcyRIIB-blocking antibody BI-1607 in combination with ipilimumab and KEYTRUDA® (pembrolizumab) in patients with unresectable or metastatic melanoma.

The study will incorporate four cohorts in which two different dose levels of BI-1607 will be tested with two different dose levels of the CTLA-4 antibody ipilimumab, 3 mg/kg, approved for the treatment of melanoma, and the lower dose 1 mg/kg, in combination with a 200 mg flat dose of pembrolizumab in patients with unresectable or metastatic melanoma previously treated with anti-PD-1/L1.

Approximately 35 patients will be enrolled in 10 to 12 sites located in the UK, Germany and Spain with first data expected in H2 2025. In July 2024, BioInvent signed a clinical supply agreement with MSD International Business GmbH, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA to provide KEYTRUDA for use in the study.

"The early data delivered so far by our BI-1607 program have been highly promising and we are very pleased to be advancing the asset's development with this new study," said Martin Welschof, Chief Executive Officer of BioInvent. "We have shown BI-1607 to be safe and well tolerated with signs of early clinical activity in Phase 1 evaluation in combination with trastuzumab. Additionally, our preclinical data also indicate that a regimen including BI-1607 could allow the use of lower doses of ipilimumab, potentially achieving increased tolerability and higher efficacy. We are looking forward to exploring the huge potential of this combination further and preliminary data from the study expected next year."

BI-1607 is an engineered antibody that can be viewed as a platform to enhance efficacy and overcome resistance to existing cancer treatments, such as targeted monoclonal antibodies and immune checkpoint inhibitors. In December 2023, BioInvent presented first clinical data from the Phase 1 dose escalation study evaluating BI-1607 in combination with trastuzumab in subjects with HER2+ advanced solid tumors. The data demonstrated that the treatment was well tolerated, and no serious adverse events related to BI-1607 were observed. Stabilization of the disease was observed in 7 patients. Previously in 2021, BioInvent announced preclinical proof-of-concept data showing the ability of BI-1607 to overcome resistance to CTLA-4-based therapy.

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 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 us on the social media platform X: @BioInvent.

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Attachments

BioInvent announces first patient enrolled in Phase 1b/2a study of BI-1607 in combination with ipilimumab and KEYTRUDA (pembrolizumab) in patients with unresectable or metastatic melanoma