BioInvent announces new clinical trial collaboration and supply agreement with MSD to evaluate BI-1607 in combination with KEYTRUDA (pembrolizumab) and ipilimumab

- Agreement to support expansion of BI-1607 program with new Phase 2 triplet combination study in metastatic melanoma
- The study will evaluate anti-FcγRIIB antibody BI-1607 with low-dose anti-CTLA-4, ipilimumab, plus KEYTRUDA®
- Phase 1 data previously demonstrated BI-1607 is safe and 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

Lund, Sweden – July 17, 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 trial collaboration and supply agreement with MSD International Business GmbH, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA, to evaluate its second FcγRIIB-blocking antibody BI-1607 in combination with ipilimumab, and KEYTRUDA® (pembrolizumab) in a Phase 2 study in patients with metastatic melanoma.

Under the terms of the supply agreement, MSD will provide its anti-PD-1 therapy KEYTRUDA to be used in combination with BI-1607 and the CTLA-4 antibody ipilimumab. The open-label Phase 2 study will incorporate several dosing levels of BI-1607 and lower dosing levels of ipilimumab in patients with unresectable or metastatic melanoma.

"This clinical trial collaboration and supply agreement with MSD allows us to build on the promising Phase 1 and preclinical data by expanding our BI-1607 program with a Phase 2 study in a new triplet combination," said **Martin Welschof, CEO of BioInvent.** "While anti-PD-1 therapy and/or anti-CTLA-4 therapy is the standard of care in metastatic melanoma, many patients cannot tolerate the treatment due to ipilimumab's toxicity. Our preclinical studies indicate that a triple combination regimen including BI-1607 could allow the use of lower doses of ipilimumab, potentially achieving increased tolerability and higher efficacy. In our recent Phase 1 study, BI-1607 was safe and well-tolerated and showed early signs of clinical activity when administered in combination with trastuzumab. We look forward to broadening the clinical evaluation of this promising antibody in a combination that has the potential to make a major impact on cancer care."

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 the treatment was well tolerated and no serious adverse events related to BI-1607 were observed. Stable disease was observed in 6/11 evaluable patients. Previously in 2021, BioInvent announced proof-of-concept data showing the ability of BI-1607 to overcome resistance to CTLA-4-based therapy. BioInvent is currently running 6 clinical programs testing the use of five proprietary antibodies across different cancer indications and has multiple data readouts anticipated in the next six months.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merk & 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 on the social media platform X: @BioInvent.

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Attachments

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