BioInvent Presents Poster Highlighting Model-Informed Early Clinical Development of anti-TNFR2 agent BI-1808 at PAGE 2024

- *Model-informed approach supporting dose selection and optimization of clinical development*
- *Confirming wide potential dose-range of BI-1808 in the continued clinical evaluation which already has shown promising single agent safety and efficacy*
- *Poster to be presented at PAGE 2024 to be held in Rome, Italy, June 26 to 28, 2024*

Lund, Sweden – June 26, 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 the presentation of a poster highlighting the model-informed early clinical development of the company's anti-TNFR2 program BI-1808 at the Population Approach Group in Europe (PAGE) 2024 meeting, being held in Rome, Italy from June 26 to 28, 2024.

"The data presented in this poster demonstrate our effective leveraging of a model-informed approach to support dose selection and optimization in the development of our immunomodulatory agent BI-1808," said Martin Welschof, Chief Executive Officer of BioInvent. "The model confirms the wide potential dose range of BI-1808 and will be beneficial in the selection of doses as our clinical evaluation of the asset continues in the ongoing Phase 1/2a study, which has already produced promising initial safety and efficacy results."

BI-1808 could represent a new class of immunomodulatory agent with the potential to improve efficacy of cancer therapy. As earlier communicated, initial efficacy and safety data from the ongoing Phase 1/2a study show so far:
- One complete response (CR), one partial response (PR) that is still improving, and nine patients with stable disease (SD) of 26 evaluable patients in the single agent arm of BI-1808
- Promising signs of efficacy and favorable safety profile in the Phase 1 dose escalation part studying BI-1808 in combination with KEYTRUDA® (pembrolizumab).

Poster summary

The objective was to characterize the population pharmacokinetics (PK), receptor occupancy (RO), and concentrations of the target engagement biomarker soluble tumor necrosis factor receptor 2 (sTNFR2) at different BI-1808 doses, to support the dose selection for the dose expansion trial.

Data and methods

Data was available from patients in the ongoing Phase 1/2a dose escalation trial. Model building and application proceeded in a sequential manner:

- Development of a joint PK-RO model to simultaneously characterize BI-1808 concentrations and TNFR2 receptor occupancy.

- Extension of the PK-RO model with a sTNFR2 PD model.
- Typical value simulations for RO as well as PK and sTNFR2 (not shown) considering different doses and dosing frequencies.

Conclusions

A simultaneous model of the BI-1808 PK, RO, and sTNFR2 successfully explained the observed profiles across a wide dose range. Simulations provided insights into the expected PK, RO, and sTNFR2 levels across potential dose levels and dosing frequencies and will support the selection of doses for further exploration.

Poster Title: Model-informed early clinical development of BI-1808, a novel monoclonal antibody to tumor necrosis factor receptor 2
Abstract Number: 10786
Session: Drug/Disease Modelling - Oncology
Date: June 27, 2024
Time: 9:50 – 11:20 AM CEST

The full poster will be posted to the company's website https://www.bioinvent.com/en/our-science/scientific-publications shortly after the presentation.

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

About BI-1808

The anti-TNFR2 antibody BI-1808 is part of BioInvent's tumor-associated regulatory T cells (Treg)-targeting program. TNFR2 is particularly upregulated on Tregs of the tumor microenvironment and has been shown to be important for tumor expansion and survival, representing a new and promising target for cancer immunotherapy. BI-1808 is being studied as both a single agent and in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in patients with advanced solid tumors or T-cell lymphomas, including CTCL. The Phase 2a single agent part is in the dose expansion phase evaluating the activity in four different tumor types: ovarian cancer (OC), melanoma, non-small cell lung cancer (NSCLC) and other tumor types (e.g., gastrointestinal stromal tumors (GIST)), and TCL/CTCL. The ongoing Phase 1 combination part is in the final stage of the dose escalation phase.

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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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

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