BioInvent Announces Additional Positive Efficacy Data with Single Agent BI-1808 from the Phase 2a anti-TNFR2 program

- Three partial responses (PR) and one stable disease (SD) out of four evaluable patients with Cutaneous T-cell Lymphoma (CTCL) have been observed in the single agent part of the Phase 2a study. Three other patients in the cohort were considered non-evaluable.
- All patients had progressed after standard therapy. The three responding patients had received 9, 3 and 3 previous lines of treatment respectively, and one of them included previous anti-PD1 treatment.
- Today's news supports earlier data showing one complete response (CR), one PR and nine patients with stable disease (SD) presented at the American Society of Clinical Oncology conference in June 2024.
- BI-1808 continues to be impressively safe and well tolerated.
- In addition, an abstract for a trial in progress poster presentation on BI-1910, BioInvent's second anti-TNFR2 program was published today by the European Society for Medical Oncology. The poster is due to be presented at the ESMO conference on September 14, 2024, in Barcelona.

Lund, Sweden – September 9, 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 additional positive preliminary efficacy data from its ongoing Phase 2a dose expansion study of BI-1808 as a single agent.

Three out of four evaluable patients achieved a partial response (PR) in the CTCL cohort of patients who had progressed after standard therapy. The patients are still on treatment.

These data add to the results presented in June at ASCO 2024 from the same trial (Phase 2a dose expansion) where one complete response (CR), one PR and nine patients with stable disease (SD) were observed in 26 evaluable patients treated with single agent BI-1808.

"We are thrilled by the observation of these partial responses in the CTCL cohort, which, together with the previously reported data, support the potential of BI-1808 to become a new class of immunomodulatory treatment option for patients with different kinds of cancers," said Martin Welschof, Chief Executive Officer at BioInvent. "CTCL is an important indication where there is a high unmet need for new safe and effective solutions for patients, and we are now evaluating the next possible steps to accelerate the development of BI-1808 in this disease. We look forward to the emerging data from this trial from the CTCL cohorts as well as the ovarian cancer, and additional cohorts".

Additionally, today BioInvent announces the publication of the abstract for the company's second anti-TNFR2 antibody, BI-1910. The abstract covers the Trial in Progress (TiP) poster of the Phase 1 dose escalation study to be presented on September 14th, 2024, at the European Society for Medical Oncology Congress being held in Barcelona, Spain.

Details of the abstract to be presented:
Title: A Phase 1/2a First-in-Human Phase 1 Study of BI-1910, a Monoclonal Antibody Agonistic to TNFR2, as a Single Agent and in Combination with Pembrolizumab in Subjects with Advanced Solid Tumors
Authors: T. Hernandez Guerrero, B. Doger de Spéville, J. Yachnin, K. Rohrberg, M. Borggren, P. Holmkvist, I. Karlsson, M. Meller, L. Mårtensson, J.-A. Nilsson, M. Vaapil, M. Chisamore, J. Wallin, I. Teige, B. Frendeus, A. McAllister
Poster#: 1073TiP
Session: Investigational immunotherapy
Date: September 14, 2024

The abstract is available on the ESMO website.

The poster will be posted to the Scientific Publications section of the company website after the presentation (https://www.bioinvent.com/en/our-science/scientific-publications).

About BI-1808
BioInvent's lead anti-TNFR2 antibody BI-1808 is a first-in-class drug candidate in clinical development for the treatment of solid tumors, and for blood cancer under the Leukemia & Lymphoma Society's Therapy Acceleration Program® (LLS TAP). In May 2024, promising early signs of BI-1808 single agent efficacy and a robust safety profile were announced. The data was presented in a poster at the 2024 ASCO Annual Meeting (ASCO 2024) in the US. Data showed one complete response (CR), one partial response (PR) and nine patients with stable disease (SD) out of 26 evaluable patients.

The CR was observed in the ongoing Phase 2a part of the study, in an ovarian cancer patient with disease progression after three previous lines of treatments. One PR has been observed in a heavily pre-treated patient with metastatic GIST (12 prior lines of treatment).

Promising signs of efficacy and favorable safety profile in the Phase 1 dose escalation part studying BI-1808 in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab) was also presented at ASCO.

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

About BI-1910

BI-1910 second anti-TNFR antibody is a TNFR2 agonist, currently enrolling patients in the monotherapy cohort of the Phase 1/2a study in patients with advanced solid tumors.

Phase 1 dose escalation of single agent BI-1910 is ongoing and has reached the fifth planned dose level without any notable adverse events observed. The prespecified target dose range with robust target occupancy has been reached, and evidence of immune activation has been observed.

Dose escalation will continue for exploration of a wide range of dose-safety/tolerability margin, and is expected to complete before year-end 2024, leading to opening Phase 2a with BI-1910 monotherapy in NSCLC in first half of 2025. Phase 1 Part B dose escalation of BI-1910 in combination with pembrolizumab is expected to commence Q4 2024.

The Phase 1/2a study aims to establish the safety/tolerability profile, pharmacokinetics, pharmacodynamics and preliminary efficacy of BI-1910 as monotherapy and in combination with pembrolizumab. Phase 2a will be performed in advanced/metastatic NSCLC and HCC patients in parallel cohorts. Safety and efficacy of BI-1910 as monotherapy and in combination will be evaluated at two separate dose levels for dose optimization.

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.

This information is information that BioInvent International is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-09-09 07:15 CEST.

Attachments

BioInvent Announces Additional Positive Efficacy Data with Single Agent BI-1808 from the Phase 2a anti-TNFR2 program