NEWS RELEASE

Transgene and BioInvent - First Patient Treated in Part B of Phase I Trial Assessing the Novel Oncolytic Virus BT-001 in Combination With KEYTRUDA® (pembrolizumab)

10/10/2023

The Phase I Part B will evaluate the combination of BT-001 and pembrolizumab in solid tumors, including melanoma

STRASBOURG, France & LUND, Sweden--(BUSINESS WIRE)-- Regulatory News:

Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapeutics against cancer, and 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 announce that the first patient of the Phase I part B clinical trial evaluating the combination of BT-001 and MSD's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) has been dosed.

The Phase I Part B of the trial explores repeated intra-tumoral injections of BT-001 in combination with intravenous infusions of KEYTRUDA. Transgene and BioInvent plan to enroll a minimum of 12 patients with metastatic or advanced solid tumors, including melanoma. In accordance with our clinical trial and supply agreement, KEYTRUDA is being supplied by MSD (a tradename of Merck & Co., Inc., Rahway, NJ, USA). Trial endpoints include safety, evaluation of efficacy, and assessment of immune changes in the tumor microenvironment.

Transgene and BioInvent are co-developing BT-001, an oncolytic virus designed using Transgene's Invir.IO®

platform encoding BioInvent's differentiated anti-CTLA-4 antibody and human GM-CSF cytokine to elicit a strong and effective anti-tumoral response. The drug is currently being evaluated against solid tumors in a Phase I/IIa clinical trial as a single agent and in combination with the PD-1 checkpoint inhibitor KEYTRUDA.

The inclusion of the last patient in Part B of the study is expected in H1 2024.

Previously reported Phase I data confirmed the mechanism of action of BT-001 as a single agent and demonstrated first signs of anti-tumoral activity.

Dr. Martin Welschof, CEO of BioInvent and Dr. Alessandro Riva, Chairman and CEO of Transgene, added: "By combining BT-001 with pembrolizumab, we are building upon the promising data generated by BT-001 as a single agent. Targeting the PD1/PD-L1 pathway in addition to BT-001's mechanism of action is expected to further stimulate and restore the patient's immune system, which should result in improved antitumoral activity and patient outcome. We are thrilled to enter this new phase of the development of the novel oncolytic virus BT-001 and further demonstrate its potential in combination with a reference treatment."

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

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About the trial

The ongoing Phase I/IIa (NCT: 04725331) study is a multicenter, open label, dose-escalation trial evaluating BT-001 as a single agent and in combination with pembrolizumab (anti-PD-1 treatment). Patient inclusions are ongoing in Europe (France, Belgium) and the trial has been authorized in the US.
This Phase I is divided into two parts. In part A, patients with metastatic/advanced tumors received single agent, intra-tumoral administrations of BT-001. Part B is exploring intra-tumoral injections of BT-001 in combination with KEYTRUDA. In this part, KEYTRUDA is being provided to the trial by MSD (a tradename of Merck & Co., Inc., Rahway, NJ, USA).
The Phase IIa will evaluate the combination regimen in several patient cohorts with selected tumor types. These expansion cohorts will offer the possibility of exploring the activity of this approach to treat other malignancies not traditionally addressed with this type of treatment.

About BT-001

BT-001 is an oncolytic virus generated using Transgene's Invir.IO® platform and its patented large-capacity VVcopTK-RR- oncolytic virus, which has been engineered to encode both a Treg-depleting recombinant human anti-CTLA-4 antibody generated by BioInvent's proprietary n-CoDeR®/F.I.R.S.T™ platforms, and the human GM-CSF

cytokine. By selectively targeting the tumor microenvironment, BT-001 is expected to elicit a much stronger and more effective antitumoral response. Therefore, by reducing systemic exposure, the safety and tolerability profile of the anti-CTLA-4 antibody may be greatly improved.
BT-001 is being co-developed as part of a 50/50 collaboration on oncolytic viruses between Transgene and BioInvent. To know more on BT-001, watch our video **here**.

About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing cancer cells.
The Company's clinical-stage programs consist of a portfolio of therapeutic vaccines and oncolytic viruses: TG4050, the first individualized therapeutic vaccine based on the myvac® platform, TG4001 for the treatment of HPV-positive cancers, as well as BT-001 and TG6050, two oncolytic viruses based on the Invir.IO® viral backbone.
With Transgene's myvac® platform, therapeutic vaccination enters the field of precision medicine with a novel immunotherapy that is fully tailored to each individual. The myvac® approach allows the generation of a virus-based immunotherapy that encodes patient-specific mutations identified and selected by Artificial Intelligence capabilities provided by its partner NEC.
With its proprietary platform Invir.IO®, Transgene is building on its viral vector engineering expertise to design a new generation of multifunctional oncolytic viruses.
Additional information about Transgene is available at: **www.transgene.fr**
Follow us on social media: X (ex-Twitter): **@TransgeneSA**– LinkedIn:**@Transgene**

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 us on social media platform X: **@BioInvent**

Transgene disclaimer

This press release contains forward-looking statements, which are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results, regulatory authorities' agreement with development phases, and development. The Company's ability to commercialize its products depends on but is not limited to the following factors: positive pre-clinical data may not be predictive of human clinical results, the success of clinical studies, the ability to obtain financing and/or partnerships for product manufacturing, development and commercialization, and marketing approval by government regulatory authorities. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Universal Registration Document, available on the AMF website (**http://www.amf-france.org**) or on Transgene's website (**www.transgene.fr**). Forward-looking statements speak only as of the date on which they are made, and Transgene undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.

BioInvent 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.

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