PRESS RELEASE

Transgene and BioInvent to Present Promising Initial Phase I/IIa Data on Oncolytic Virus, BT-001, at ESMO 2024

BT-001 monotherapy showed stable disease and shrinkage of injected lesions in patients with advanced solid tumors.

BT-001 in combination with KEYTRUDA® (pembrolizumab) showed promising efficacy data with partial responses in patients with relapsed and refractory advanced melanoma and leiomyosarcoma.

BT-001 shows a favorable safety profile with minimal adverse events and no dose-limiting toxicities.

Strasbourg, France, and Lund, Sweden, September 9, 2024, 7:00 am CET– Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of 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, **announce initial promising clinical results from the Phase I part of the ongoing randomized Phase I/IIa trial evaluating BT-001** as a single agent and in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab)**. The Phase I data will be presented at the European Society of Medical Oncology (ESMO) Annual Meeting** to be held in Barcelona, Spain, from September 13 to 17, 2024.

Key findings of the abstract include:

- **In the monotherapy part, in terms of overall response, stable disease** was observed in 4 out of 18 patients with advanced solid tumors receiving BT-001. Additionally, **tumor shrinkage** was observed in 2 out of 20 injected lesions.
- **In the combination part, partial responses** were observed in 2 out of 6 heavily pretreated patients with advanced solid tumors receiving BT-001 in combination with pembrolizumab. This includes one patient with a PD(L)-1 resistant melanoma and one patient with a leiomyosarcoma after five lines of therapy. Patient response profiles and updated results will be presented at ESMO.
- **BT-001 was well-tolerated with no dose-limiting toxicities (DLTs) observed.** Two grade three adverse events related to BT-001 were reported (one skin ulcer and one lymphocyte count decrease). **No DLTs** were observed with repeated intratumoral injections of BT-001 alone (in 18 patients) or in combination with pembrolizumab (in six patients).
- **BT-001 was shown to replicate and express its anti-CTLA-4 monoclonal antibody (mAb) payload in tumor tissue with rare and sporadic shedding**, as shown by preliminary translational data.

Dr Stéphane Champiat, Medical Oncologist at Gustave Roussy, Head of the Inpatient Unit, Drug Development Department (DITEP) and Clinical Investigator of the study, added: "*Many cancer patients fail to respond to existing treatments, emphasizing the significant need for new approaches. BT-001 is a very promising potential new immunotherapy shown to elicit a strong immune response that is further enhanced by the local expression of the anti-immune checkpoint inhibitor CTLA-4 antibody and the cytokine GM-CSF. The initial clinical data from this study provide important proof of principle and demonstrate the relevance of this oncolytic virus. Alone or in combination with pembrolizumab, BT-001 offers the potential to improve therapeutic options with a better safety profile for patients in many types of cancer.*"

Dr Alessandro Riva, Chairman and CEO of Transgene, commented: "*The promising initial clinical results from the ongoing Phase I/IIa trial of BT-001 demonstrate its potential as a standout asset within Transgene's oncolytic virus pipeline, highlighting the ability of our invir.IO® platform to generate targeted tumor specific immunotherapies. BT-001 shows preliminary efficacy without dose limiting toxicities, both as monotherapy and in combination with pembrolizumab, with an ability to modulate the tumor microenvironment. We look forward to reporting further results as this study progresses.*"

Martin Welschof, CEO of BioInvent, stated: "*These are exciting data that further support BioInvent's belief that BT-001 has the potential to provide an important new treatment option for cancer patients. BT-001 is one of six programs utilizing five BioInvent-generated antibodies, illustrating the depth of our scientific understanding and the power of our approach to improve treatments for patients with unmet needs*."

The abstract #1024P titled "*Initial clinical results of BT-001, an oncolytic virus expressing an anti-CTLA4 mAb, administered as single agent and in combination with pembrolizumab in patients with advanced solid tumors"* is available on ESMO's and Transgene's websites.

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

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About BT-001

BT-001 is an oncolytic virus, from Transgene's invir.IO® platform, with enhanced replication selectivity in tumor cells and recombinantly armed to express an anti-CTLA4 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 designed to induce a strong and effective antitumor response and by limiting systemic exposure, this approach aims to significantly improve the safety and tolerability profile of the human anti-CTLA-4 antibody. The ongoing Phase I/IIa trial (NCT04725331) is a multi-center, open-label study, and aims to evaluate safety and antitumor activity of intratumoral BT-001 alone and in combination with pembrolizumab in patients with advanced solid tumors.

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

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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 cancers 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 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.

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Transgene disclaimer

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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.