BioInvent and Transgene to Present Promising Initial Phase 1/2a Data on Oncolytic Virus, BT-001, at ESMO 2024

- **BT-001 monotherapy showed stable disease and injected lesions shrinkage in advanced solid tumor patients.**
- **Promising efficacy data in combination with KEYTRUDA® (pembrolizumab) with partial responses in relapsed and refractory advanced melanoma and leiomyosarcoma patients.**
- **Favorable safety profile with minimal adverse events and no dose-limiting toxicities.**

Lund, Sweden and Strasbourg, France, September 9, 2024, 07:00 am CEST– 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, and **Transgene (Euronext Paris: TNG),** a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, announce initial promising clinical results from the Phase 1 part of the ongoing Phase 1/2a trial of BT-001 as a single agent and in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab), to 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 4/18 advanced solid tumor patients receiving BT-001 as single agent, while **tumor shrinkage** was observed in 2/20 **injected lesions**.
- **In the combination part, two patients with partial responses** were observed in a cohort of six heavily pretreated patients with advanced solid tumor receiving BT-001 in combination with pembrolizumab (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 to 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 6 patients).
- **Oncolytic virus BT-001 was shown to replicate and express its anti-CTLA-4 mAb payload in tumor tissue with rare and sporadic shedding**, as shown by preliminary translational data.

Alessandro Riva, Chairman and CEO of Transgene, commented: "*We are delighted to present these promising initial clinical results from part 1 of the ongoing Phase 1/2a trial of BT-001. We are also excited about the potential of BT-001 as a standout asset within Transgene's oncolytic virus pipeline, further demonstrating 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 and by modulating the tumor microenvironment. We look forward to reporting further results as this study progresses.*"

Stéphane Champiat, Medical Oncologist at Gustave Roussy, Head of the Inpatient Unit, Drug Development Department (DITEP) and a clinical investigatior for the study, added: "*Many cancer patients fail to respond to existing treatments, highlighting 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 immune checkpoint inhibitor and the cytokine. The initial clinical data from this study provide important proof of principle and demonstrate the relevance of this oncolytic virus approach. These promising data generated alone or in combination with pembrolizumab offer the chance to deliver better treatment outcomes with an improved safety profile for patients across multiple different cancer indications.*"

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 patients. BT-001 is one of six programs with five BioInvent generated antibodies, illustrating the power of our scientific understanding and approach to improve treatments for patients with a number of different cancer types."

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

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.

About BT-001
BT-001 is an oncolytic virus, from the Transgene's invir.IO® platform, with enhanced replication selectivity in tumor cells and recombinantly armed to express 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 aims to induce a strong and effective antitumor response. Consequently, 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 1/2a trial (NCT04725331) is a multi-center, open-label study, and aims at evaluating safety and antitumor activity of intratumoral BT-001 alone and in combination with pembrolizumab in patients with advanced solid tumors.

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, 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: X (previously Twitter): @BioInvent

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 (previously-Twitter): @TransgeneSA – LinkedIn: @Transgene

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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.

Attachments

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