PRESS RELEASE

# Transgene and BioInvent report positive Phase Ia data on oncolytic virus BT-001 in solid tumors

## Treatment of all Phase Ia cohorts in monotherapy completed with no safety concerns

## Stabilization of injected lesions in 11/18 patients

## An independent Safety Review Committee has approved initiation of the combination trial with pembrolizumab

Strasbourg, France, and Lund, Sweden, May 25, 2023, 7:30 am CEST – **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 positive Phase Ia data on the oncolytic virus BT-001 for the treatment of solid tumors**.

Treatment with single agent BT-001 in 18 patients has now been completed with no safety concerns reported. Patients had at least one accessible superficial lesion and were studied in three dose-escalating cohorts. BT-001 stabilized the injected lesions in eleven patients in total: two at the $10^6$ pfu dose (n=6), five at $10^7$ pfu (n=6) and four at $10^8$ pfu (n=6). Furthermore, objective antitumor activity, defined as decrease of injected lesion size of 50% or more, was observed in one patient in the $10^6$ pfu cohort (n=6) and one patient in the $10^7$ pfu cohort (n=6).

Transgene and BioInvent are co-developing BT-001, an oncolytic virus developed using Transgene's Invir.IO® platform encoding BioInvent's anti-CTLA-4 antibody to elicit a strong and effective anti-tumoral response. The drug is currently being evaluated in a Phase I/IIa clinical trial as a single agent and in combination with the PD-1 checkpoint inhibitor KEYTRUDA® (pembrolizumab) against solid tumors.

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

Based on these results, the independent Safety Review Committee (SRC) has now approved initiation of the combination part of the trial with pembrolizumab. The first patient in this Phase I part B is expected to be enrolled in H2 2023.

*"These data are a further positive indication of the efficacy of BT-001 against solid tumors. While the advanced disease setting of this first in human trial did not allow long-term monitoring of patients, the effect on injected lesions has the potential to translate into the induction of a systemic immune response, antitumor effect and ultimately clinical benefit in combination with pembrolizumab. There were no safety concerns and antitumor activity was observed even at the lowest dose. We are looking forward to investigating BT-001 further in combination with pembrolizumab,"* commented Martin Welschof, CEO of BioInvent and Dr. Alessandro Riva, Chairman of Transgene.

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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 receive single agent, intra-tumoral administrations of BT-001. Part B will explore the combination of intra-tumoral injections of BT-001 with pembrolizumab. In this part, KEYTRUDA® (pembrolizumab) will be provided to the trial by MSD (Merck & Co).
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 $VV_{cop}TK^{-}RR^{-}$ oncolytic virus, which has been engineered to encode both a Treg-depleting human recombinant 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. As a consequence, 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 TG6002, BT-001 and TG6050, three 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: 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 on Twitter: @BioInvent.

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***Transgene disclaimer***

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***BioInvent disclaimer***

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