PRESS RELEASE

# Transgene and BioInvent's Oncolytic Virus BT-001 Shows Promising Antitumor Activity in Ongoing Phase I/IIa Trial in Solid Tumors that Failed Previous Treatments

Preliminary data presented at ESMO 2024 demonstrate that BT-001 induces tumor regression in patients who failed previous anti-PD(L)-1 treatment

In a patient with a heavily pretreated leiomyosarcoma, BT-001 was able to modulate the tumor microenvironment, turning a "cold" tumor to "hot", enhancing the potential of T cell infiltration and a shift to PD(L)-1 positivity

Early signs of efficacy with clinical responses observed with BT-001 in combination with KEYTRUDA® (pembrolizumab), in 2 of 6 patients who failed previous treatment

**Strasbourg, France, and Lund, Sweden, September 14, 2024, 9:05 a.m. 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, **today announce new initial data from their ongoing Phase I/IIa study on the multifunctional oncolytic virus BT-001, demonstrating antitumor activity in patients who failed previous treatments**.

The data presented today at the 2024 European Society for Medical Oncology **(ESMO)** Annual Meeting, show that **BT-001 induced tumor regression in patients unresponsive to prior anti PD(L)-1 treatment,** both as a monotherapy and in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab).

Preliminary translational data suggest that **BT-001 replicates in the tumor** where the **payloads are expressed with undetectable systemic exposure**. BT-001 alone or in combination with pembrolizumab was well tolerated and showed **first signs of efficacy** with clinical responses in 2 of 6 patients who failed previous treatments, when given in combination with pembrolizumab. BT-001 treatment **turned "cold" tumors to "hot"** inducing **T cell infiltration**, a **higher M1/M2 ratio**, and a **shift to PD(L)-1 positivity in the tumor microenvironment**.

**Dr. Stéphane Champiat, Medical Oncologist, Head of the Inpatient Unit, Drug Development Department (DITEP) at Institut Gustave Roussy**, commented: *"The immunological data generated by BT-001 suggest that, as hoped, BT-001 is replicating in the tumor and its payload of transgenes is expressed with very limited exposure outside of the tumor thereby limiting systemic toxicity. I look forward to additional results*

*from this ongoing study which will provide further evidence of the safety and clinical activity of BT-001 and its potential role as a new therapy for cancer patients with solid tumors."*

**Transgene and BioInvent are co-developing BT-001, an oncolytic virus developed using Transgene's Invir.IO® platform armed to express GM-CSF and BioInvent's full-length anti-CTLA-4 monoclonal antibody, to elicit a strong and effective anti-tumoral response in solid tumors.**

**Dr. Alessandro Riva, Chairman and CEO of Transgene**, said: *"We are pleased to present the first promising clinical data on BT-001 at ESMO 2024, which confirm its mechanism of action as a single agent injected intratumorally and importantly demonstrate first signs of anti-tumor activity. Added to its good safety profile alone and in combination with pembrolizumab, BT-001 has the potential to shrink lesions and induce stable disease in refractory patients who may have few other treatment options. We will further explore the safety and efficacy of BT-001 in this development program with our partner BioInvent, and report additional data when it becomes available."*

**Andres McAllister, MD, PhD, Chief Medical Officer at BioInvent International AB,** concluded: *"We are encouraged by the early clinical results presented at ESMO for BT-001, which encodes a potent Treg-depleting recombinant human anti-CTLA-4 antibody generated by our proprietary n-CoDeR®* and *F.I.R.S.T™ platforms. This clinical proof of concept confirms our ability to identify antibodies that bind to a selected target but exhibit a differentiated activity, allowing the development of promising new drug candidates such as BT-001."*

**The abstract and poster 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."**, can be accessed on the ESMO and Transgene 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 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 explores the combination of intra-tumoral injections of BT-001 with pembrolizumab. In this part, KEYTRUDA® (pembrolizumab) is 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 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 (formerly 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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