PRESS RELEASE

First Patient Dosed in Phase 1 Trial Evaluating Transgene's and BioInvent's BT-001 in Patients with Rectal Cancer

Transgene and University of Copenhagen are collaborating on the investigator-sponsored OV-PRIME-R trial evaluating armed oncolytic virus BT-001 combined with an anti-PD1 in patients with localized rectal cancer with proficient mismatch repair status[1]

Strasbourg, France, November 5, 2026, 8:00 a.m. CET – **Transgene (Euronext Paris: TNG)**, a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer and **Bispebjerg and Frederiksberg Hospital, University of Copenhagen, Denmark**, today announce that **the first patient** with proficient mismatch repair (pMMR) rectal cancer **has successfully been dosed in the Phase 1 OV-PRIME-R[2] trial.** The investigator-sponsored trial is evaluating BT-001, an armed oncolytic virus administered via intratumoral injection which will be followed by intravenous pembrolizumab[3]. This population, which represents approximately 95% of rectal cancer cases, has to date shown poor response to immunotherapy alone.

Henry G. Smith, PhD, Associate Professor and consultant surgeon at Abdominal Center K, Bispebjerg and Frederiksberg Hospital University of Copenhagen and Principal Investigator, commented: "*We are excited to launch this investigator-sponsored trial, which explores an innovative approach to treating rectal cancer in patients with proficient mismatch repair status. By combining BT-001, an armed oncolytic virus, with anti-PD-1 therapy, in patients with localized disease, we aim to enhance the immune response and potentially improve outcomes for patients by reducing the risks of relapse or even reducing the number who need surgery at all. This study represents an important step toward more effective and less toxic treatment strategies for this underserved population.*"

"We are proud to support this investigator-sponsored trial in collaboration with the University of Copenhagen, evaluating BT-001 in patients with rectal cancer at high risk of relapse and severe toxicities from standard of care," added **Emmanuelle Dochy, MD, Chief Medical Officer of Transgene**. "*BT-001 has already demonstrated excellent tolerability and the ability to transform "cold" tumors into biologically active ones. This study aims to further validate its potential to improve outcomes and quality of life for cancer patients.*"

---

[1] *pMMR proficient mismatch repair*

[2] *Oncolytic Virotherapy to enhance PReoperative IMmunotherapy Efficacy in pMMR Rectal cancer - OV-PRIME-R - EUCT number: 2025-524375-23-00*

[3] *anti PD-1 KEYTRUDA® therapy, registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA*

While neoadjuvant (chemo)-radiotherapy can reduce recurrence and enable organ preservation in some patients with rectal cancer, fewer than 30% achieve a complete response and some patients still develop distant recurrences. Current adjuvant options are also limited, highlighting the need for effective, well-tolerated treatments that can prevent relapse without compromising quality of life.

The aim of this study is to investigate the safety, tolerability, and efficacy of neoadjuvant treatment with BT-001 combined with an anti-PD-1 antibody prior to standard surgery in patients with primary, localized rectal cancer.

Transgene and BioInvent are co-developing BT-001, developed using Transgene's Invir.IO® platform armed to express GM-CSF and BioInvent's full-length anti-CTLA-4 monoclonal antibody, to trigger a strong anti-tumor immunity while minimizing systemic exposure.

With the ability to induce both local and systemic anti-tumor immune responses (see press release), BT-001 is a prime candidate to remodel the pMMR rectal cancer tumor microenvironment and enhance immune checkpoint inhibition without adding significant treatment-related toxicity, as evidenced by early clinical trials of BT-001 in patients with treatment-resistant metastatic cancers.

***

Contacts

Transgene:
Media:
Caroline Tosch-Pourchot
Corporate and Scientific Communications Manager
+33 (0)3 68 33 27 38
communication@transgene.fr

Investors & Analysts:
Lucie Larguier
Chief Financial Officer (CFO)
+33 (0)3 88 27 91 00/21
investorrelations@transgene.fr

MEDiSTRAVA
Frazer Hall/Sylvie Berrebi
+ 44 (0)203 928 6900
transgene@medistrava.com

About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing virus-based targeted immunotherapies and vaccines. The Company's clinical-stage programs consist of a portfolio of viral vector-based immunotherapeutics. Transgene's *myvac*® platform is designed to develop individualized neoantigen therapeutic vaccines (INTVs), with potential across multiple solid tumor types.

TG4050, the first INTV based on the *myvac*® platform is the Company's lead asset, with demonstrated clinical proof of principle in the adjuvant treatment of head and neck cancer. TG4070, the second *myvac*®-based INTV introduces Transgene's proprietary AI-driven neoantigen selection and scalable cell-line manufacturing capabilities and is in Phase 1 clinical development in combination with nivolumab in the adjuvant treatment of non-small cell lung cancer (NSCLC). The Company's other viral vector-based assets include BT-001, an oncolytic virus based on the Invir.IO® viral backbone, which is in clinical development. Transgene also conducts innovative discovery and preclinical work, aimed at developing novel viral vector-based modalities.

With Transgene's *myvac*® platform, therapeutic vaccination enters the field of precision medicine with an immunotherapy tailored to each individual patient. The *myvac*® approach enables the generation of virus-based immunotherapies encoding patient-specific neoantigens. Transgene has further expanded the platform's capabilities with its own proprietary AI-driven neoantigen selection and scalable cell-line manufacturing.

Leveraging its MVA and cell-line manufacturing expertise, Transgene is developing TG-MVA™, a next-generation prophylactic vaccine candidate against mpox and smallpox designed to address key manufacturing and supply challenges.
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.com
Follow us on social media: LinkedIn: @Transgene — X: @TransgeneSA — Bluesky: @Transgene

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 anti-tumor 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.

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.com). 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.