PRESS RELEASE

Transgene and BioInvent receive approval from ANSM to proceed with Phase I/IIa trial of anti-CTLA4-armed oncolytic virus BT-001 in solid tumors

Strasbourg, France – January 19, 2021 – 7:30 a.m. CET– **Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, today announced it has received approval from the French National Agency for the Safety of Medicines and Health Products (ANSM) to proceed with a Phase I/IIa study of the novel oncolytic *Vaccinia virus* BT-001.** This announcement follows the approval received in December 2020 from the Belgian health authorities. The first patient is expected to be enrolled in this trial in the upcoming weeks.

BT-001 IS AN ONCOLYTIC VIRUS GENERATED WITH TRANSGENE'S INNOVATIVE INVIR.IO™ PLATFORM

BT-001 is based on the patented Invir.IO™ oncolytic virus (VVcopTK-RR-), and has been engineered to encode both a Treg-depleting human recombinant 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 expected to elicit a much stronger and more effective antitumoral response and greatly increase the safety and tolerability profile of the anti-CTLA4 antibody. BT-001 is being co-developed through a 50/50 collaboration between Transgene and BioInvent.

IN FRANCE, FOUR CLINICAL CENTERS WILL ENROLL PATIENTS

"*The development of BT-001 is progressing well and we are pleased to start this clinical trial in France with patients being enrolled across the country in four reference clinical centers, and in other hospitals in Europe. BT-001 is a highly innovative oncolytic virus, that has been designed to achieve a strong anti-tumor response by combining multiple mechanisms of action. We would like to thank the investigators and the clinical teams for their support and look forward to treating the first patients with this first Invir.IO™ generated oncolytic virus candidate to enter clinical development*" said **Dr. Maud Brandely, MD, PhD, Chief Medical Officer of Transgene.**

In France, the BT-001 Phase I/IIa trial will be conducted in four clinical centers: the Bergonié Institute (Bordeaux), the Gustave Roussy Institute (Paris area), the Centre Léon Bérard (Lyon) and the Hôpital Saint-Louis (Paris).

This international study will enroll up to 48 patients with metastatic/advanced solid tumors in its Phase I part followed by expansion cohorts in its Phase IIa part. The trial will evaluate the administration of BT-001 as a single agent and in combination with pembrolizumab, an anti-PD1.

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For further information, please contact:

Transgene:

Lucie Larguier
Director Corporate Communications & IR
+33 (0)3 88 27 91 04
investorrelations@transgene.fr

Media: Citigate Dewe Rogerson
David Dible/Sylvie Berrebi
+ 44 (0)20 7638 9571
transgene@citigatedewerogerson.com

About the trial

The trial is a multicenter, open-label, dose-escalation Phase I/IIa trial evaluating BT-001 alone or in combination with pembrolizumab. The trial has been approved in Europe (France and Belgium) and will be next conducted in the USA. The Phase I will be divided into two parts. Part A will enroll up to 36 patients with metastatic/advanced solid tumors, who have already been pretreated, including with immunotherapies. Patients will receive single agent, intra-tumoral administrations of BT-001, in cutaneous or palpable subcutaneous lesions or easily injectable lymph nodes, to select the recommended dose and best regimen. Part B will explore the combination of intra-tumoral injections of BT-001 with pembrolizumab, an anti-PD1 targeting agent in 12 patients. The Phase IIa will evaluate the combination regimen in several patient cohorts with different tumors 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 a best-in-class oncolytic virus developed with Transgene's Invir.IO™ platform. Invir.IO™'s viruses are based on the patented large capacity *Vaccinia virus* Copenhagen strain genetically modified with the double deletion TK^- RR^-. This optimization enhances the safety profile of the virus. From this, BT-001 is engineered to encode both a highly differentiated Treg depleting anti-CTLA4 antibody and the human GM-CSF cytokine. The recombinant antibody recognizing human CTLA4 was generated by BioInvent's proprietary n-CoDeR®/F.I.R.S.T™ platforms. The use of an oncolytic virus to deliver the anti-CTLA4 locally and selectively in the tumor microenvironment allows high intratumoral concentrations of both transgenes eliciting a stronger and more effective antitumor response. By reducing systemic exposure to a very low level, this local therapeutic activity furthermore allows to increase the safety and tolerability profile of the anti-CTLA4 antibody. Preclinical data have shown that BT-001 has potential for broad single agent activity, and that selective tumor-localized delivery of anti-CTLA4 may allow for a better tolerated, sustained and more effective combination therapy with antibodies targeting the PD-1/PDL1 axis.

A multicenter, open-label, dose-escalation Phase I/IIa trial evaluating BT-001 alone or in combination with pembrolizumab has been approved in Europe (France and Belgium) and should be next conducted in the USA.

The scientific and clinical development of the oncolytic virus candidate BT-001 is a 50/50 collaboration between BioInvent and Transgene.

About Transgene

Transgene (Euronext: TNG) is a publicly traded French 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 two therapeutic vaccines (TG4001 for the treatment of HPV-positive cancers, and TG4050, the first individualized therapeutic vaccine based on the *myvac*® platform) as well as two oncolytic viruses (TG6002 for the treatment of solid tumors, and BT-001, the first oncolytic virus based on the Invir.IO™ platform).

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. Transgene has an ongoing Invir.IO™ collaboration with AstraZeneca.

Additional information about Transgene is available at: www.transgene.fr

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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. There can be no guarantee that (i) the results of pre-clinical work and prior clinical trials will be predictive of the results of the clinical trials currently underway, (ii) regulatory authorities will agree with the Company's further development plans for its therapies, or (iii) the Company will find development and commercialization partners for its therapies in a timely manner and on satisfactory terms and conditions, if at all. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results and development. 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 Risques") section of the Universal Registration Document, available on the AMF website (http://www.amf-france.org) or on Transgene's website (www.transgene.fr). 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.