PRESS RELEASE

Transgene and BioInvent have enrolled first patient in Phase I/IIa trial of novel oncolytic virus BT-001 in solid tumors

Strasbourg, France and Lund, Sweden – March 1, 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**, 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 announced that the first patient in a Phase I/IIa clinical trial of the novel dual mechanism-of-action oncolytic *Vaccinia virus* BT-001 has been enrolled at Institut Bergonié (Bordeaux, France).**

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

BT-001 has been generated using Transgene's Invir.IO™ platform and its patented large-capacity VVcopTK$^-$RR$^-$ oncolytic virus, which 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. In addition, delivering the anti-CTLA4 antibody directly to the tumor microenvironment aims to induce local Treg depletion and strong therapeutic activity. As a consequence, by reducing systemic exposure, the safety and tolerability profile of the anti-CTLA4 antibody will be greatly improved. BT-001 is being co-developed through a 50/50 collaboration between BioInvent and Transgene.

Hedi Ben Brahim, Chairman and CEO of Transgene, said: "*We are excited to start this clinical trial with BT-001, which is the result of a very productive collaboration between Transgene and BioInvent. This first Invir.IO™ based oncolytic virus entering the clinic has been shown to induce long-lasting antitumor immune responses and abscopal effects in several preclinical tumor models; in these experiments, the activity of BT-001 was further enhanced through combination with an anti-PD-1 antibody treatment. It has a unique mode of action and the outstanding results so far indicate it could make a significant difference to cancer patients.*"

"*The inclusion of the first patient in this Phase I/IIa trial marks a further broadening of our clinical pipeline, which now comprises three candidate products and four clinical studies. BT-001 is a unique oncolytic virus, combining multiple mechanisms-of-action, and has outstanding potential in a wide range of indications thanks to its combination of multiple anti-cancer properties,*" said **Martin Welschof, CEO of BioInvent**.

This multicenter, open label, dose escalation Phase I/IIa trial evaluating BT-001 as a single agent and in combination with pembrolizumab (anti-PD-1 treatment) will first be including patients in several countries in Europe. An IND submission will follow 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. Patients will receive single agent, intra-tumoral administrations of BT-001, in cutaneous or palpable subcutaneous lesions or easily injectable lymph nodes. Part B will explore the combination of intra-tumoral injections of BT-001 with pembrolizumab in 12 patients. The Phase IIa will evaluate the combination regimen in several patient cohorts with different 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.

The trial (NCT04725331) will first be conducted at the UCL Saint Luc (Brussels, Belgium), the Bergonié Institute (Bordeaux, France), the Gustave Roussy Institute (Paris area, France), the Centre Léon Bérard (Lyon, France) and the Hôpital Saint-Louis (Paris, France).

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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.
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
Follow us on Twitter: @TransgeneSA

About BioInvent

BioInvent International AB (Nasdaq Stockholm: BINV) is a clinical stage company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapies, with four programs in clinical development. The Company's validated, proprietary F.I.R.S.T™ technology platform simultaneously 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 or for additional licensing and partnering.
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.

Disclaimer Transgene

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.

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