Transgene and BioInvent announce compelling preclinical data for BT-001 in solid tumors

- ✓ *BT-001 is a novel Invir.IO® based oncolytic virus expressing a Treg-depleting anti-CTLA4 antibody and the cytokine GM-CSF*
- ✓ *Broad antitumor activity shown in immunocompetent models sensitive or resistant to immune checkpoint blockade*
- ✓ *Regulatory submission for first clinical trial in Europe and US in H1 2020*

Strasbourg (France) and Lund (Sweden), December 11, 2019, 8:15 a.m. CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapeutics against cancer, and BioInvent International AB (OMXS: BINV), a biotech company focused on the discovery and development of novel and first-in-class immuno-modulatory antibodies for cancer immunotherapy, announce compelling results from extensive *in vitro* and *in vivo* preclinical studies with BT-001, an oncolytic virus (OV) expressing an anti-CTLA4 antibody and the cytokine GM-CSF.

BT-001 is a multifunctional OV being co-developed by Transgene and BioInvent. It was generated using Transgene's Invir.IO® platform and its patented large capacity VV_{cop}TK-RR- oncolytic virus, which has been designed to encode for a Treg-depleting anti-CTLA4 antibody derived from BioInvent's proprietary n-CoDeR®/F.I.R.S.T™ platforms as well as the cytokine GM-CSF.

The therapeutic activity was assessed in several immunocompetent preclinical models, showing outstanding antitumoral activity for BT-001 murine surrogate antibody-encoding viruses conferring cures in a majority of mice transplanted with different solid cancer tumors (> 70% in all tested models).

- The new preclinical data also confirmed that the anti-CTLA4 antibody expressed by BT-001 in mouse tumor cells retained biochemical integrity and folding, functionality, and biological activity.
- In addition, BT-001's biodistribution profile demonstrated higher concentration and prolonged activity of the anti-CTLA4 antibodies in tumors compared to intravenous anti-CTLA4 antibody therapy.

A comprehensive and detailed package of preclinical data on BT-001 will be presented at scientific meetings in the coming months.

BioInvent and Transgene confirm that they intend to submit a clinical trial application in the first half of 2020 to conduct a first-in-human trial with BT-001 in Europe and in the USA.

"*Thanks to the fruitful collaboration between Transgene and BioInvent, we have been able to generate these exciting preclinical data with BT-001. We have confirmed that BT-001 is able to replicate within cancer cells in immunocompetent models, and locally produce high and long-lasting concentrations of both anti-CTLA4 antibody and GM-CSF, leading to the destruction of the tumor. Based on these data, we are optimistic that upcoming clinical trials with BT-001 will deliver improved efficacy while minimizing the adverse events that have been associated with this class of immune checkpoint inhibitor,*" said **Éric Quéméneur, Pharm.D., Ph.D., Executive VP, Chief Scientific Officer of Transgene**.

"*With BT-001, we build on the success of three clinically validated axes of activating patients own immune defense to combat cancer - anti-CTLA-4, anti-PD-1/PD-L1, and oncoviral immunotherapy. We are excited to bring forward to clinical testing our antibody-encoding oncolytic virus, which has indicated synergistic activity and potential for significantly improved tolerability compared to available anti-PD-1/anti-CTLA-4 combination therapy*" said **Björn Frendéus, Ph.D., Chief Scientific Officer of BioInvent.**

***

Contacts

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

BioInvent:
Martin Welschof, CEO
+46 (0)46 286 85 50
martin.welschof@bioinvent.com

Hans Herklots, LifeSci Advisors
+41 79 598 71 49
hherklots@lifesciadvisors.com

BioInvent International AB (publ)
Co. Reg. No. Org nr: 556537-7263
Visiting address: Ideongatan 1
Mailing address: 223 70 LUND
Phone: +46 (0)46 286 85 50
www.bioinvent.com

About Transgene

Transgene (Euronext: TNG) is a publicly traded French biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer and infectious diseases. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing infected or cancerous cells. The Company's lead clinical-stage programs are: TG4010, a therapeutic vaccine against non-small cell lung cancer, TG4001, a therapeutic vaccine against HPV-positive cancers, and TG6002, an oncolytic virus for the treatment of solid tumors.

With its proprietary platform Invir.IO®, Transgene builds on its expertise in viral vectors engineering to design a new generation of multifunctional oncolytic viruses. *myvac*™, an individualized MVA-based immunotherapy platform designed to integrate neoantigens, completes this innovative research portfolio. TG4050, the first candidate selected from the *myvac*™ platform, will enter the clinic for the treatment of ovarian cancer and head and neck cancer.
Additional information about Transgene is available at: www.transgene.fr.
Follow us on Twitter: @TransgeneSA

About BioInvent

BioInvent International AB (publ) (OMXS: BINV) is a clinical stage company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapies, with two ongoing programs in Phase I/II clinical trials for the treatment of hematological cancer and solid tumors, respectively. Three preclinical programs in solid tumors are expected to have entered clinical trials by the end of 2020. 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. 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 Document de Référence, 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.

Disclaimer BioInvent

The press release contains statements about the future, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as the date they are made and are, by their very nature, in the same way as research and development work in the biotech segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios described in this press release.