

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

- BT-001 is a novel Invir.IO<sup>®</sup> 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

**Lund, Sweden and Strasbourg, France – December 11, 2019** – BioInvent International AB (publ) (OMXS: BINV), a biotech company focused on the discovery and development of novel and first-inclass immuno-modulatory antibodies for cancer immunotherapy, and Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapeutics against cancer, 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<sub>cop</sub>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<sup>TM</sup> 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-CTLA-4 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.

"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.

"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.

#### 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<sup>TM</sup> 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 <a href="https://www.bioinvent.com">www.bioinvent.com</a>.

## **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.  $myvac^{TM}$ , an individualized MVA-based immunotherapy platform designed to integrate neoantigens, completes this innovative research portfolio. TG4050, the first candidate selected from the  $myvac^{TM}$  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.

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