Transgene and BioInvent present preclinical data demonstrating BT-001’s powerful activity against solid tumors

✓ AACR abstract outlines the broad therapeutic potential of BT-001, an oncolytic virus encoding an anti-CTLA4 antibody
✓ Activity demonstrated across a wide range of solid cancers
✓ BT-001 leverages the combined strengths of BioInvent’s n-CoDeR®/F.I.R.S.T™ platforms and Transgene’s Invir.IO™ platform
✓ First human trial with BT-001 expected to start before the end of 2020

Strasbourg (France) and Lund (Sweden), May 15, 2020, 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 BioInvent International AB (“BioInvent”) (OMXS: BINV), a biotech company focused on the discovery and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, today announce new highly promising preclinical data demonstrating the broad therapeutic potential of BT-001, an anti-CTLA4 antibody-encoding oncolytic virus, against solid tumors. These data will be presented at the AACR 2020 Virtual Annual Meeting II.

BT-001 is a multifunctional oncolytic virus being co-developed by Transgene and BioInvent. It has been engineered to encode a Treg-depleting, anti-CTLA4 antibody generated by BioInvent’s proprietary n-CoDeR®/F.I.R.S.T™ platforms, and GM-CSF. It uses Transgene’s Vaccinia-based Invir.IO™ viral vector platform to deliver this powerful immunotherapy directly into the tumor.

Key results:

- The new data demonstrate a powerful therapeutic effect, indicated by curative potential as a single agent in multiple syngeneic mouse models spanning solid tumor models (CT26, EMT6, C38, and A20).
- An improved therapeutic window relative to systemic anti-CTLA4 blockade was indicated by higher, receptor-saturating, anti-CTLA4 antibody intratumoral concentrations versus much lower levels in the blood compartments.
- BT-001’s activity was further enhanced when combined with anti-PD-1 antibody therapy – opening up the potential for powerful dual checkpoint blockade treatment regimens.

These promising findings will be presented at the American Association for Cancer Research (AACR) Virtual Annual Meeting II, taking place June 22-24. The abstract is posted online today.

The oncolytic virus, the anti-CTLA4 and the GM-CSF therapeutic strategies that underpin BT-001 have already demonstrated activity in humans based on their ability to induce a fundamental change in the tumor microenvironment and anti-tumor activity.
Looking at the clinical landscape, BioInvent and Transgene are confident that BT-001 could either be used as a monotherapy or be associated with standard of care immunotherapy options such as anti-PD1/anti-PD-L1 therapies in order to deliver improved clinical outcomes for patients with solid tumors.

Éric Quéméneur, Pharm.D., Ph.D., Executive VP, Chief Scientific Officer of Transgene, added: “The preclinical results generated with BT-001 have been remarkable and we remain extremely confident in its ability to change the treatment landscape for a significant number of solid tumors. We have submitted our first clinical trial application for BT-001 in March 2020 and are working hard to make sure we can take our first multifunctional Invir.IO™ oncolytic into the clinic before the end of 2020, despite uncertainties caused by the Covid-19 pandemic.”

Martin Welschof, CEO of BioInvent, says: “We are very pleased with these data on BT-001, which indicate the oncolytic virus has the potential to treat a broad range of cancers. This is a further demonstration of the power of BioInvent’s technology platform, multiplied by our strong cooperation with Transgene, and we look forward to further investigating the capabilities of this promising therapeutic option.”

• **Title of the poster:** “BT-001, an oncolytic Vaccinia virus armed with a Treg-depletion-optimized recombinant human anti-CTLA4 antibody and GM-CSF to target the tumor microenvironment.”
• **Authors:** Jean-Baptiste Marchand, Monika Semmrich, Laetitia Fend, Matilda Rehn, Nathalie Silvestre, Ingrid Teige, Johann Foloppe, Linda Mårtensson, Éric Quéméneur, Björn Frendefus
• **Abstract Number:** 2902
• **Session Date:** June 22-24, 2020
• **Poster Session Title:** Inflammation, Immunity, and Cancer / Modifiers of the Tumor Microenvironment 2
• **Poster number:** 5602

The abstract can be downloaded on the AACR website.

**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](http://www.transgene.fr).
Follow us on Twitter: [@TransgeneSA](https://twitter.com/TransgeneSA)

**About BioInvent**

BioInvent International AB (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. Two 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](http://www.bioinvent.com).
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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.