Transgene’s and BioInvent’s BT-001 achieves outstanding tumor cure rates in preclinical models

✓ Proof of concept for novel oncolytic virus with differentiated anti-CTLA4 antibody
✓ Significant antitumor activity of BT-001 seen in several immunocompetent models
✓ Treatment with BT-001 also induced a specific and long-lasting immune memory, which is thought to act on distant tumors and to prevent potential relapse
✓ Phase I clinical trial with BT-001 expected to start before the end of 2020
✓ Data presented at AACR Virtual Session II

Strasbourg (France) and Lund (Sweden), June 22, 2020, 3:15 p.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 present preclinical data demonstrating high cure rates in solid tumors of BT-001, an anti-CTLA4 antibody-encoding oncolytic virus.

Cure rates exceeding 70% were seen in multiple mouse models, demonstrating the powerful therapeutic effect of BT-001 when used as a single agent, providing a solid basis for BT-001’s upcoming clinical development, with a Phase 1 clinical trial expected to start before the end of 2020.

BT-001 is a next-generation oncolytic virus (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 engineered to encode a Treg-depleting, anti-CTLA4 antibody generated by BioInvent’s proprietary n-CoDeR™/F.I.R.S.T™ platforms, as well as the cytokine GM-CSF.

BT-001 has multiple mechanisms of action. It has been designed to combine the killing of cancer cells (oncolysis), and the production of the anti-CTLA4 antibody and GM-CSF directly in the tumor site, while also generating an immune response against tumor cells.

These data indicate that BT-001 has the potential to make a significant difference in the treatment of solid tumors and as such, underpin the effectiveness of both Transgene’s and BioInvent’s technology platforms.

Main points from the presentation included:

• The anti-CTLA4 antibody and GM-CSF accumulate in tumors with low systemic exposure. Concentrations of the anti-CTLA4 antibody in the tumor after intratumoral injection of BT-001 is more than 10-fold higher than after intraperitoneal injection of 3 mg/kg of the recombinant antibody in a xenograft tumor model.

• When tumor cells were re-implanted in mice that had been cured after a first BT-001 treatment, a strong tumor-specific response and long-lasting immune memory were developed by these mice.

• BT-001, even at sub-optimal dose, reinforced the therapeutic activity of an anti-PD-1 antibody – opening up potential combinations for powerful dual checkpoint blockade treatment regimens.
These promising findings are available in a poster being presented at the American Association for Cancer Research (AACR) Virtual Annual Meeting II, on June 22-24, 2020. It can be downloaded from the AACR website and from both Transgene’s and BioInvent’s websites.

- **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, Eric Quéméneur, Björn Frendeus
- **Session Date:** June 22-24, 2020
- **Poster Session Title:** Inflammation, Immunity, and Cancer / Modifiers of the Tumor Microenvironment 2
- **Poster Number:** 5602 // **Abstract Number:** 2902

**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).

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**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 enter clinical trials by the end of 2020. The Company’s validated, proprietary F.I.R.S.TTM 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.

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