

Transgene and BioInvent present preclinical data highlighting the robust anti-tumoral activity of BT-001 oncolytic virus at SITC 2021

Data support BT-001's unique dual mode of action

Strasbourg, France, and Lund, Sweden, November 9, 2021, 2:00 pm CET – **Transgene (Euronext Paris: TNG)**, a biotech company that designs and develops virus-based immunotherapeutics against cancer, and **BioInvent International AB (“BioInvent”) (Nasdaq Stockholm: BINV)**, a biotech company focused on the discovery and development of novel and first-in-class immunomodulatory antibodies for cancer immunotherapy, today announce preclinical data supporting the mode of action of BT-001, their novel dual mechanism-of-action oncolytic *Vaccinia virus*. The data demonstrate high intratumoral expression of an immune checkpoint-inhibiting antibody and robust anti-tumoral activity in several tumor models.

BT-001, developed by BioInvent and Transgene, is a clinical phase oncolytic virus engineered to deliver an anti-CTLA-4 antibody and human GM-CSF in a tumor-specific vehicle (the VV_{cop}TK^{RR} virus backbone) for the treatment of solid tumors.

The companies' poster at the 36th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2021) shows that BT-001 selectively replicates in tumor cells. The murine surrogate of BT-001 delivered sustained and high intratumoral levels of antibody accompanied by low systemic exposure. These differential expression levels were associated with high depletion of intratumoral regulatory T cells (T_{reg}) but the absence of systemic T_{reg} depletion. Similar effects in humans would allow BT-001 to deliver powerful antitumor immunity.

Patient inclusion into the ongoing Phase I/IIa clinical study of BT-001 ([NCT04725331](https://clinicaltrials.gov/ct2/show/study/NCT04725331)) is progressing well. The multicenter trial, authorized in Europe and in the U.S., is assessing BT-001 as single agent and in combination with the PD-1 checkpoint inhibitor pembrolizumab for the treatment of solid tumors. Initial Phase I data are expected in the first half of 2022.

Other data highlighted in the SITC poster show improved survival in several syngeneic tumor models following treatment with a murine version of BT-001. There is also evidence of a positive synergistic effect between the murine 'BT-001' oncolytic virus expressing the CTLA-4 antibody and a systemic PD-1 checkpoint inhibitor.

“These impressive data, demonstrating the multiple mechanisms of action and anti-cancer properties of BT-001, played a key role in our decision to take this unique oncolytic virus into the clinic. We are pleased to be able to share them with our scientific and clinical peers at SITC” said **Martin Welschhof, CEO of BioInvent and Hedi Ben Brahim, Chairman and CEO of Transgene.**

SITC 2021 will take place on November 10–14, 2021, at the Walter E. Washington Convention Center in Washington, D.C. and virtually. **The poster**, entitled *“Vectorized Treg-depleting aCTLA-4 elicits antigen cross-presentation and CD8+ T cell immunity to reject “cold” tumors”*, **will be presented on the Virtual ePoster Hall and presented in the Poster Hall (Hall E) on Saturday, November 13, 2021.**

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About BT-001

BT-001 is an oncolytic virus generated using Transgene’s Invir.IO™ platform and its patented large-capacity VV_{cop}TK^{RR} oncolytic virus, which has been engineered to encode both a Treg-depleting human recombinant anti-CTLA-4 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. As a consequence, by reducing systemic exposure, the safety and tolerability profile of the anti-CTLA-4 antibody will be greatly improved.

BT-001 is being co-developed as part of a 50/50 collaboration on oncolytic viruses between Transgene and BioInvent. To know more on BT-001, watch our video [here](#).

About Transgene

Transgene (Euronext: TNG) is a 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.

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About BioInvent

BioInvent International AB (Nasdaq Stockholm: BINV) is a clinical-stage biotech company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapy, with currently three drug candidates in four ongoing clinical programs in Phase I/II trials for the treatment of hematological cancer and solid tumors, respectively. 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.

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BioInvent disclaimer

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