

Transgene and BioInvent announce positive progress for BT-001

The oncolytic virus BT-001 replicates in the tumor for several days and expresses the anti-CTLA-4 monoclonal antibody

Strasbourg, France, and Lund, Sweden, June 27, 2022, 8:00 am CEST – **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 immune-modulatory antibodies for cancer immunotherapy, **today jointly announced positive progress and safety data of the ongoing Phase I/IIa trial evaluating BT-001 in patients with solid tumors**, including melanoma.

The initial data generated in Phase I part A demonstrated that BT-001 alone is well tolerated, with first signs of anti-tumor activity in a hard-to-treat population and confirmed the mechanism of action of BT-001 as a single agent. The initial findings are as follows:

- After administration, the virus was found in the tumors after several days. **This suggests that BT-001 is able to persist and replicates within tumors;**
- This finding is consistent with the **expression of the anti-CTLA-4 observed in the tumor** with no detectable systemic exposure;
- No spreading in blood or biological fluids has been detected, **suggesting high tumor specificity;**
- Tumor shrinkage was observed in one patient in the first cohort.

The part A of the Phase I trial aims to establish the tolerability of BT-001 and to determine the dose and administration schedule for further development. Repeated (every 3 weeks) and ascending doses of intratumoral administration of BT-001, as a single agent, will be administered to up to 18 patients with metastatic/advanced tumors.

The first two dose levels have been successfully completed, with 12 patients dosed to date. The Safety Review Committee (SRC) has stated that the safety profile supports escalation to the highest dose level of Phase I part A.

The Phase I part B is planned to start in H2 2022. This part will assess the combination of intratumoral injections of BT-001 with intravenous administrations of the anti-PD1 antibody pembrolizumab.

BT-001 is based on Transgene’s patented oncolytic vector and is encoding BioInvent’s proprietary anti-CTLA-4 antibody; it is codeveloped by the two biotechnology companies.

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About the trial

The ongoing Phase I/IIa (NCT04725331) study is a multicenter, open label, dose-escalation trial evaluating BT-001 as a single agent and in combination with pembrolizumab (anti-PD-1 treatment). Patient inclusions are ongoing in Europe (France, Belgium) and the trial has been authorized in the US.

This Phase I is divided into two parts. In part A, patients with metastatic/advanced tumors receive single agent, intra-tumoral administrations of BT-001. Part B will explore the combination of intra-tumoral injections of BT-001 with pembrolizumab. The Phase IIa will evaluate the combination regimen in several patient cohorts with different tumor types. These expansion cohorts will offer the possibility of exploring the activity of this approach to treat other malignancies not traditionally addressed with this type of treatment.

About BT-001

BT-001 is an oncolytic virus generated using Transgene's Invir.IO™ platform and its patented large-capacity VV_{copTK} 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 may 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. Follow us on Twitter: [@TransgeneSA](https://twitter.com/TransgeneSA)

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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Transgene disclaimer

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 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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