

Transgene and BioInvent announce clinical trial collaboration and supply agreement with MSD to evaluate BT-001 in combination with KEYTRUDA®

Strasbourg, France, and Lund, Sweden, June 28, 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 immuno-modulatory antibodies for cancer immunotherapy, **today announced a clinical trial collaboration and supply agreement with MSD, a tradename of Merck & Co., Inc., Rahway, NJ., USA, to evaluate the oncolytic virus BT-001 in combination with MSD’s anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in a Phase I/IIa clinical trial for the treatment of patients with solid tumors.**

Under the terms of the supply agreement, MSD will provide pembrolizumab to be used in combination with BT-001 in the ongoing Phase I/IIa clinical trial.

“By combining BT-001 with the anti-PD-1 drug KEYTRUDA® we expect to optimize the patient’s immune response to induce a strong and effective anti-tumor response. This agreement will allow us to move further on the clinical development of our promising co-developed oncolytic candidate BT-001” said **Hedi Ben Brahim, CEO of Transgene.**

“We are very pleased to be signing another collaboration with MSD, supporting the expansion of the clinical trial program of BT-001, the oncolytic virus expressing our proprietary anti-CTLA-4 antibody, jointly developed by Transgene and BioInvent. It marks a further validation of our expanding and promising clinical pipeline of anti-cancer treatments, which currently encompasses three compounds in four ongoing clinical trials” added **Martin Welschhof, CEO of BioInvent.**

Recruitment in the clinical study ([NCT04725331](https://clinicaltrials.gov/ct2/show/study/NCT04725331)) is ongoing. The trial is a Phase I/IIa of BT-001, which is being co-developed as part of a 50/50 collaboration between Transgene and BioInvent, as a single agent and in combination with KEYTRUDA® for the treatment of solid tumors.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

Contacts

Transgene:

Lucie Larguier

Director Corporate Communications & IR

+33 (0)3 88 27 91 04

investorrelations@transgene.fr

Media Transgene:

MEDiSTRAVA Consulting

David Dible/Sylvie Berrebi

+44 (0)203 928 6900

transgene@medistrava.com

BioInvent:

Cecilia Hofvander

Senior Director Investor Relations

+46 (0)46 286 85 50

cecilia.hofvander@bioinvent.com

BioInvent International AB (publ):

Co. Reg. No. Org nr: 556537-7263

Visiting address: Ideongatan 1

Mailing address: 223 70 LUND

Phone: +46 (0)46 286 85 50

www.bioinvent.com

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 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.

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.

Follow us on Twitter: [@BioInvent](https://twitter.com/BioInvent)

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.

BioInvent disclaimer

The press release contains statements about the future, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as the date they are made and are, by their very nature, in the same way as research and development work in the biotech segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios described in this press release.