

Transgene and BioInvent to Present Translational Data and Updated Clinical Results on Armed Oncolytic Virus BT-001, at ESMO 2025

- Updated clinical data on BT-001 in combination with pembrolizumab to be presented in a poster

- Tumor shrinkage observed in both injected and non-injected lesions

Lund, Sweden and Strasbourg, France, October 13, 2025 – 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, Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, will jointly present a poster on translational data and updated clinical results from the Phase 1 study of BT-001 at the European Society for Medical Oncology (ESMO) Annual Meeting. ESMO will take place in Berlin, Germany, from October 17 to 21, 2025.

Key findings of the abstract include:

- Intra-tumoral BT-001 injection in combination with IV pembrolizumab was well tolerated with a manageable safety profile.
- The data showed encouraging and sustained anti-tumor activity in patients with advanced refractory tumors. One patient with PD(L)-1 resistant melanoma and one patient with heavily pretreated but ICI-naïve leiomyosarcoma showed partial response (iPR) lasting 6 and 16 months respectively, among the 13 patients who received the combination of intra-tumoral BT-001 (at 10^7 pfu/mL and 10^8 pfu/mL) and pembrolizumab.
- Tumor shrinkage was observed in both injected and non-injected lesions.
- BT-001 could be an effective option to improve the response to ICI in refractory patients.

The abstract is available on the ESMO website ([here](#)).

BT-001 is an oncolytic virus generated using Transgene's Invir.IO® platform and its patented large-capacity VVcopTK-RR- oncolytic virus, which has been engineered to encode both a Treg-depleting recombinant human anti-CTLA-4 antibody generated by BioInvent's proprietary n-CoDeR®/F.I.R.S.T.™ platforms, and the human GM-CSF cytokine.

BT-001 is being co-developed as part of a 50/50 collaboration on oncolytic viruses between Transgene and BioInvent. In the Phase 1 part of this study, BT-001 has been shown to be well tolerated as monotherapy and in combination with MSD's (Merck & Co., Inc., Rahway, NJ, USA) anti-PD-1 therapy KEYTRUDA® (pembrolizumab)*.

BT-001 showed first signs of efficacy with clinical response in two out of thirteen patients evaluated, when given in combination with pembrolizumab, with shrinkage of injected and non-injected lesions. Treatment with BT-001 converted “cold” tumors into “hot” ones, and induced T-cell infiltration, as well as PD(L)-1 expression in the tumor microenvironment (ESMO 2024, access press release [here](#)).

The Phase 1/2a study ([NCT04725331](#)) is a multicenter, open label, dose-escalation study evaluating BT-001 as a single agent and in combination with pembrolizumab. The last patient in the Phase 1 part was enrolled in August 2024.

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

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About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. The Company's clinical-stage programs consist of a portfolio of viral vector-based immunotherapeutics. TG4050, the first individualized therapeutic vaccine based on the *myvac*® platform is the Company's lead asset, with

demonstrated proof of principle in patients in the adjuvant treatment of head and neck cancers. The Company has other viral vector-based assets, including BT-001, an oncolytic virus based on the Invir.IO® viral backbone, which is in clinical development. The Company also conducts innovative discovery and preclinical work, aimed at developing novel viral vector-based modalities. 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.

Additional information about Transgene is available at: www.transgene.com

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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 several drug candidates in ongoing clinical programs in Phase 1/2 studies for the treatment of hematological cancer and solid tumors, respectively. The Company's validated, proprietary F.I.R.S.T.™ technology platform 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 and providing licensing and partnering opportunities.

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 <http://www.bioinvent.com/>

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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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Attachments

[Transgene and BioInvent to Present Translational Data and Updated Clinical Results on Armed Oncolytic Virus BT-001, at ESMO 2025](#)