BioInvent and Transgene receive IND approval from the U.S. FDA for BT-001, a novel oncolytic virus for the treatment of solid tumors

Lund, Sweden and Strasbourg, France – May 27, 2021 – **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, and **Transgene** (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, announce that their Investigational New Drug (IND) application for BT-001 has been granted by the U.S. Food and Drug Administration (FDA). This IND will allow patients in the U.S. to be enrolled into the ongoing Phase 1/2a clinical trial of this novel oncolytic virus BT-001. BT-001 is armed with both a differentiated Treg-depleting human recombinant anti-CTLA4 antibody and GM-CSF.

The ongoing Phase 1/2a (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). The Phase 1 part of the trial has already been initiated in Europe, where it is enrolling patients in several countries.

BT-001 is expected to elicit a strong and effective antitumoral response by selectively targeting and modulating the tumor microenvironment. In addition, delivering the anti-CTLA4 antibody directly to the tumor aims to induce local Treg depletion and strong therapeutic activity. As a consequence, the safety and tolerability profile of the anti-CTLA4 antibody is expected to be greatly improved due to reduced systemic exposure.

BT-001 is being codeveloped through a 50/50 collaboration between BioInvent and Transgene.

"We are pleased to receive IND approval for this Phase 1/2a clinical trial of BT-001, which is BioInvent's fourth clinical program. This unique oncolytic virus has very exciting potential as it combines multiple mechanisms of action and anti-cancer properties, and we are looking forward to developing it further with our partners at Transgene," said **Martin Welschof, CEO of BioInvent.**

Hedi Ben Brahim, Chairman and CEO of Transgene, said: "We have designed BT-001 to significantly improve treatment for patients with solid tumors by restoring their immune response against cancer. Its capacity to induce long-lasting antitumor immune responses and abscopal effects has been demonstrated in several tumor models. Patient accrual in the ongoing Phase 1 clinical trial is in line with our plan and highlight clinicians' interest in this novel and promising immunotherapy approach. We are pleased to prepare the next step in its clinical development with this IND clearance which will allow us to enroll U.S. patients in this exciting clinical trial."

The Phase 1 trial is divided into two parts. Part A will enroll up to 36 patients with metastatic/advanced solid tumors. Patients will receive single agent, intra-tumoral administrations of BT-001. Part B will explore the combination of intra-tumoral injections of BT-001 with the standard treatment regimen of pembrolizumab in 12 patients. The Phase 2a part of the trial will evaluate BT-001-based 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.

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About BT-001

BT-001 is a novel oncolytic virus developed with Transgene's Invir.IO™ platform. Invir.IO™'s viruses are based on the patented large capacity *Vaccinia virus* Copenhagen strain genetically modified with the double deletion TK^-RR^-. This optimization enhances the safety profile of the virus.

BT-001 is engineered to encode both a highly differentiated Treg depleting anti-CTLA4 antibody and the human GM-CSF cytokine. The recombinant antibody recognizing human CTLA4 was generated by BioInvent's proprietary n-CoDeR®/F.I.R.S.T™ platforms. The use of an oncolytic virus to deliver the anti-CTLA4 locally and selectively in the tumor microenvironment allows high intratumoral concentrations of

both transgenes eliciting a stronger and more effective antitumor response, by reducing systemic exposure to a very low level.

Preclinical data have shown that BT-001 has potential for broad single agent activity, and that selective tumor-localized delivery of anti-CTLA4 may allow for a better tolerated, sustained and more effective combination therapy with antibodies targeting the PD-1/PDL1 axis.

The scientific and clinical development of the oncolytic virus candidate BT-001 is a 50/50 collaboration between BioInvent and Transgene.

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 1/2 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.

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.
Follow us on Twitter: @TransgeneSA

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