Transgene and BioInvent receive CTA approval for Phase 1/2a trial of oncolytic virus BT-001 in solid tumors

Strasbourg, France and Lund, Sweden – December 21, 2020 – 8:30 a.m. CET– **Transgene (Euronext Paris: TNG)**, a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer**, and BioInvent International AB ("BioInvent") (OMXS: BINV)**, a biotech company focused on the discovery and development of novel and first-in-class immune-modulatory antibodies for cancer immunotherapy, **today announced they have received regulatory approval in Belgium for a clinical trial application (CTA) for a Phase 1/2a study of the novel oncolytic *Vaccinia virus* BT-001.**

BT-001 is a best-in-class oncolytic *Vaccinia virus.* It has been 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-CTLA4 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. Delivering the anti-CTLA4 antibody directly to the tumor microenvironment will allow a local therapeutic activity and will thus greatly increase the safety and tolerability profile of the monoclonal antibody by reducing systemic exposure. BT-001 is being co-developed through a 50/50 collaboration between BioInvent and Transgene.

Philippe Archinard, PhD, Chairman and CEO of Transgene, said: *"We are pleased that we have received a first approval to initiate the Phase 1/2a trial of BT-001. This oncolytic virus has induced long-lasting antitumor immune responses and abscopal effects in several tumor models, and its activity is further enhanced through combination with an anti-PD-1 antibody treatment. Thanks to its unique mode of action and the results seen so far, we believe it has the potential to make a significant difference to cancer patients."*

"*This clinical trial approval sets the stage to further broaden BioInvent's promising clinical pipeline. BT-001 will soon be our fourth product in clinical development. We are very excited to move forward this unique oncolytic virus which combines multiple, clinically proven mechanisms of action into a single drug. This clinical study will allow us to test BT-001's potential to treat a range of solid cancer indications. Regulatory approval of this agent demonstrates the excellent performance of our teams.*" added **Martin Welschof, CEO of BioInvent**.

This multicenter, open-label, dose-escalation Phase 1/2a trial evaluating BT-001 alone or in combination with pembrolizumab will first be including patients in several countries in Europe and then in the USA. The Phase 1, which is expected to begin within the next few weeks, will be divided into two parts. Part A will enroll up to 36 patients with metastatic/advanced solid

tumors, who have already been pretreated, including with immunotherapies. Patients will receive single agent, intra-tumoral administrations of BT-001, in cutaneous or palpable subcutaneous lesions or easily injectable lymph nodes, to select the recommended dose and best regimen. Part B will explore the combination of intra-tumoral injections of BT-001 with pembrolizumab, an anti-PD1 targeting agent in 12 patients. The Phase 2a will evaluate the combination regiment in several patient cohorts with different tumors types. These expansion cohorts will offer the exciting possibility of exploring the activity of this approach to treat other malignancies not traditionally addressed with this type of treatment.

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For further information, please contact:

Transgene:

Lucie Larguier
Director Corporate Communications & IR
+33 (0)3 88 27 91 04
investorrelations@transgene.fr

Media: Citigate Dewe Rogerson
David Dible/Sylvie Berrebi
+ 44 (0)20 7638 9571
transgene@citigatedewerogerson.com

BioInvent:

Martin Welschof, CEO
+46 (0)46 286 85 50
martin.welschof@bioinvent.com

Mary-Ann Chang, LifeSci Advisors
+44 7483 284 853
mchang@lifesciadvisors.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 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
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About BioInvent

BioInvent International AB (OMXS: BINV) is a clinical stage company that discovers and develops novel and first-in-class immuno-modulatory antibodies for cancer therapies, with four programs in clinical development. 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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