

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

Lund, Sweden – June 28, 2022 – Biolnvent International AB ("Biolnvent") (Nasdaq Stockholm: BINV), a biotech company focused on the discovery and development of novel and first-in-class immuno-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, 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 1/2a 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 1/2a clinical trial.

"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," said **Martin Welschof, CEO of BioInvent**.

"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," added **Hedi Ben Brahim, CEO of Transgene**.

Recruitment in the clinical study (<u>NCT04725331</u>) is ongoing. The trial is a phase 1/2a of BT-001, which is being co-developed as part of a 50/50 collaboration between BioInvent and Transgene, as a single agent and in combination with KEYTRUDA® for the treatment of solid tumors. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About the trial

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). Patient inclusions are ongoing in Europe (France, Belgium) and the trial has been authorized in the US.

This Phase 1 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 intratumoral injections of BT-001 with pembrolizumab. The Phase 2a 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 VVcopTK-RR- oncolytic virus, which has been engineered to encode both a Tregdepleting 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 between Transgene and BioInvent. To learn more about BT-001, watch our video <u>here</u>.

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 and a fifth program just initiating 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. Follow us on Twitter: @BioInvent.

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 (AI) 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: <u>www.transgene.fr</u>. Follow us on Twitter: @TransgeneSA

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Disclaimer Transgene

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. There can be no guarantee that (i) the results of pre-clinical work and prior clinical trials will be predictive of the results of the clinical trials currently underway, (ii) regulatory authorities will agree with the Company's further development plans for its therapies, or (iii) the Company will find development and commercialization partners for its therapies in a timely manner and on satisfactory terms and



conditions, if at all. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results and development. 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 Risques") 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.

Attachments

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