Transgene reports business update and end Q3 2020 financial position

- *Promising clinical data for TG4001 – late breaker abstract at SITC 2020*
- *Advanced technological leadership with the* myvac® *platform: two clinical trials in patients with solid tumors initiated in January 2020*
- *Initial translational data confirm that I.V. TG6002 can induce the production of a chemotherapy agent (5-FU) in the tumor*
- *Invir.IO™ -based BT-001 on track to enter the clinic before the end of 2020*
- *€45.3 million in cash and cash equivalents as of September 30, 2020, following the partial sale of stake in Tasly BioPharmaceuticals*

Strasbourg, France, November 5, 2020, 5:45 p.m. CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, today announces its business update for the quarter ending September 30, 2020.

Promising data for TG4001 to be presented at SITC 2020

A late breaking abstract presenting the detailed results from the Phase 1b/2 trial combining TG4001, a HPV16-targeted therapeutic vaccine, with avelumab in advance HPV16-positive has been accepted at the SITC 35th Anniversary Annual Meeting (SITC 2020).

The combination of TG4001 and avelumab demonstrated anti-tumor activity (23.5% ORR) in patients with previously treated recurrent and/or metastatic HPV-related cancers.

The trial showed that the presence of liver metastases has a profound impact on outcome in terms of ORR and PFS. **In patients without liver metastases, an ORR of 34.8% and a median PFS of 5.6 months were achieved. These results compare favorably to single-agent immune checkpoint inhibitors.**

The treatment induced HPV-specific T-cell responses and was associated with increased levels of immune cell infiltration in the tumors and expression of genes associated with activation of the immune system.

A planned randomized controlled trial will allow for a larger scale confirmation of these promising results.

The poster, as well as an audio commentary by Prof. Christophe Le Tourneau, principal investigator of the trial, will be available on the congress website from November 9, 2020.

Philippe Archinard, Chairman and CEO of Transgene, and **Dr. Maud Brandely**, MD, PhD, Chief Medical Officer of Transgene, will provide some further background to the data. **An investor and analyst conference call/webcast in English is scheduled November 12, 2020, at 12:00 p.m. ET (6:00 p.m. CET). The webcast will be accessible via the following link:** https://channel.royalcast.com/transgene/#!/transgene/20201112_1.

Advanced technological leadership with the myvac® *platform*

Transgene is developing TG4050, an individualized immunotherapy, together with NEC. This individualized cancer vaccine is based on the *myvac*® platform, which integrates NEC's artificial intelligence capabilities.

Transgene's *myvac*® platform brings together a series of highly innovative technologies, to build an integrated framework for the clinical use of this revolutionary viral-based immunotherapeutic approach.

- ✓ Transgene, together with Hypertrust, has implemented the first block chain solution dedicated to the traceability of personalized treatment in clinical trials. This cloud-based solution monitors and orchestrates all of the processes related to the design and manufacturing of Transgene's TG4050, a therapeutic vaccine created for each individual patient
- ✓ BostonGene conducts genomic and transcriptomic analyses of tumors collected from patients enrolled in the clinical trials to identify predictors of response to TG4050. These include cancer cell-intrinsic and cell-extrinsic factors that may mediate each patient's response to the vaccine. This novel way of analyzing patient data is part of an ambitious translational program that supports the development of our *myvac*® platform with the aim of accelerating the development of TG4050 by identifying patients who should achieve the best possible clinical outcomes.

The first Phase 1 clinical trials assessing TG4050 in patients with ovarian and head and neck cancers started in January 2020 in Europe and in the United States. NEC is financing 50% of these studies.

The Company has set up an in-house production unit dedicated to the manufacturing of the individualized clinical batches of TG4050 needed for each patient. This unit is operational and complies with good manufacturing practice (GMP) norms. The manufacturing process and unit have been validated and the first clinical batches have been produced.

Initial translational data of TG6002 highlight the potential of the IV route – Invir.IO™ -based BT-001 on track to enter the clinic before the end of 2020

Initial data from the Phase 1 trial confirm the good tolerability of TG6002 in humans. The study also demonstrated that this *Vaccinia Virus* can reach the tumor and replicate within these cancer cells when administered intravenously. These data also showed that 5-FU (a chemotherapeutic agent) can be produced at therapeutic doses, resulting from the expression of the FCU1 gene, integrated into the TG6002 genome, as the virus replicates selectively in the tumor cells. In addition, these results support the development of the Invir.IO™ platform, which uses the same patented viral backbone.

BT-001 is the first oncolytic virus from the Invir.IO™ platform. A first-in-human trial is being prepared; the trial protocol has been filed in France and in Belgium. Transgene and its partner BioInvent expect to initiate a Phase I clinical trial with BT-001 before the end of 2020. Promising preclinical results for BT-001 will be presented at the SITC annual congress.

The collaboration with AstraZeneca continues, as planned, with the development of new innovative oncolytic viruses. AstraZeneca can exercise options to further develop each of these novel drug candidates.

Operating revenue

In millions of euros	*Q3*		First Nine Months	
	2020	***2019***	**2020**	**2019**
Revenue from collaborative and licensing agreements	*0.4*	*2.0*	2.7	3.4
Government financing for research expenditures	*1.5*	*1.5*	4.5	4.6
Other revenue	*0.1*	*0.1*	0.6	0.4
Operating revenue	***2.0***	***3.6***	**7.8**	**8.4**

During the first nine months of 2020, operating revenues amounted to €7.8 million compared to €8.4 million in the same period in 2019.

Revenue from collaborative and licensing agreements, amounted to €2.7 million in the first nine months of 2020, compared with €3.4 million in the same period in 2019. These revenues are mainly derived from Transgene's collaboration agreement with AstraZeneca on the Invir.IO™ program. This amount corresponds to €2.1 million recognized as the initial payment of €8.9 million ($10 million) received in 2019 and reflects the progress of the related activities; the remaining corresponds to the payment of contract-defined preclinical milestones.

During the first nine months of 2020, government financing for research expenditures mainly in the form of a research tax credit remained stable at €4.5 million.

Cash, cash equivalents and other financial assets

Cash, cash equivalents, and other current financial assets stood at €45.3 million as of September 30, 2020, compared to €43.3 million as of December 31, 2019. In the first nine months of 2020, Transgene's cash position increased by €2.0 million. This compares to a cash burn of €10.1 million (excluding the net proceeds from a rights issue) for the same period in 2019.

This increase is due to the receipt of a net amount of €18.2 million in July 2020, following the partial sale of Transgene's stake in Tasly BioPharmaceuticals. Following this share sale, Transgene holds 17.1 million shares in Tasly BioPharmaceuticals, equivalent to 1.58% of the Chinese company's capital. Transgene's remaining shareholding in Tasly BioPharmaceuticals is valued at approximately $36.9 million based on the price of the current share sale.

In addition, on October 20, 2020, the Company made an early repayment of the €10 million loan granted by the European Investment Bank (EIB). The loan was due to be repaid in June 2021. This early repayment resulted in interest savings of approximately €0.6 million.

Planned succession of the Chairman and Chief Executive Officer

In September 2020, Philippe Archinard, Chairman and Chief Executive Officer of Transgene, has informed the Board of Directors of his intention to leave his position at the end of 2020 and to take up new responsibilities within Institut Mérieux. His successor will be Hedi Ben Brahim, who will take office on January 1, 2021. Hedi Ben Brahim has been a Board member of Transgene since May 2019

Outlook

The Company confirms its financial visibility until 2022.

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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

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.