PRESS RELEASE

Transgene reports business update and Q3 2022 financial position

- ***Positive result from interim analysis and reduction of the size of the Phase II trial evaluating TG4001 + avelumab vs avelumab*** *in HPV-positive anogenital cancers*
- ***Positive clinical data on TG4050*** *were presented during a R&D Day in Sept. 2022*
- ***€36.3 million in cash and cash equivalents*** *as of September 30, 2022*
- *Financial visibility until the end of 2023*

Strasbourg, France, November 7, 2022, 7:30 a.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 and its financial position for the quarter ending September 30, 2022.

Positive result from interim analysis of Phase II trial evaluating TG4001 + avelumab vs avelumab in HPV-positive anogenital cancers

On November 2, 2022, Transgene announced that following a prespecified interim analysis of its randomized, controlled Phase II clinical study comparing TG4001 in combination with avelumab to avelumab alone in patients with HPV16-positive anogenital tumors (NCT: 03260023), **the Independent Data Monitoring Committee (IDMC) has recommended the study continues**.

Based on progression-free survival (PFS) and positive efficacy signals observed in the interim analysis, the trial is now expected to enroll **a total of 120 patients** compared to the initial forecast of 150 patients. **Transgene anticipates the last patient to be randomized in the trial in H1 2024**. Final results will be communicated subsequently when they are available.

Final positive results from this trial would allow Transgene to launch a registration trial to further confirm the benefit of its therapeutic vaccine. TG4001 aims at bringing a new solution to patients who currently have very limited treatment options.

The positive interim analysis result highlights the potential of Transgene's platform of therapeutic vaccines based on the MVA viral vector. Alongside TG4001, Transgene is also developing TG4050, an individualized, MVA-based therapeutic vaccine. TG4050 is currently being evaluated in two Phase I trials and has also delivered initial positive data, including in a randomized trial (see below).

Key events of the third quarter 2022 and expected news flow

During an R&D day, held on September 27, 2022, Transgene's management team, leading clinicians and scientists from around the world, provided insights on TG4001, TG4050 and the progress of the Invir.IO™ platform.

TG4001: New positive clinical data from previous trial in HPV16+ cancer patients

In a previous single-arm Phase Ib/II, Transgene generated strong clinical data in advanced HPV16-positive cancer patients who received TG4001 + avelumab. The Company also identified a patient population that derived increased benefit from the treatment: metastatic patients with lesions located in organs other than the liver.
In these patients, an overall response rate (ORR) of 32%, a median PFS of 5.6 months and a median overall survival (OS) of 13.3 months were achieved in this earlier trial. These results compare favorably with checkpoint inhibitors administered alone.

The treatment induced HPV16-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.
The current randomized, controlled Phase II trial was launched based on these very encouraging data.

TG4050: New updates from the two ongoing Phase I trials confirm the strong potential of this individualized cancer vaccine

In the head and neck cancer trial, 20 of the 30 planned patients have been randomized at the end of August 2022. All 10 evaluable patients who immediately received vaccination with TG4050 (arm A) remain stable and in complete response at the cutoff date. Out of the 10 patients of the control arm, who are monitored and did not receive the vaccine (arm B), 3 have experienced relapse.

In the ovarian cancer trial (n=5), one patient treated after an elevation of CA-125 experienced a normalization of CA-125 without clinical progression for nine months until death from an unrelated chronic illness. Another patient was treated upon onset of radiological evidence of relapse and remained stable for 11.4 months.

To date, the vaccine has been well tolerated and no related Serious Adverse Events have been reported across the two studies.

In the two clinical studies, enrollment has been completed. Enrolled patients are being randomized or treated in line with study protocols. Overall, Transgene plans to treat 13 patients in the ovarian cancer trial and 30 patients in the head and neck cancer trial.

Transgene plans to communicate an update on these potentially landscape changing trials at a scientific conference in the first half of 2023.

Significant progress on oncolytic viruses, including data demonstrating the potential of the Invir.IO™ platform oncolytic viruses to be administered intravenously

Transgene presented a poster on TG6002 at the ESMO congress (September 11, 2022). The Company discussed **positive confirmatory data from the Phase I trial evaluating TG6002 administered intravenously (IV)** in combination with oral 5-FC in patients with advanced gastrointestinal carcinomas. These updated data generated on 37 patients treated at the highest dose levels of the Phase I demonstrated that the therapy is well tolerated and confirmed the mechanism of action of TG6002 administered IV.

These findings support the potential of IV administration of Invir.IO™-based oncolytic viruses, extending the use of these therapies to a broad range of solid tumors. Additional data will be produced from the Phase I program and will be presented at a scientific congress in the first half of 2023.

In June 2022, Transgene and BioInvent released positive progress and safety data in the ongoing Phase I/IIa trial evaluating BT-001 in patients with solid tumors. The initial data generated in the Phase I part A demonstrated that BT-001 alone is well tolerated, with first signs of anti-tumor activity in a hard-to-treat population and confirmed the mechanism of action of BT-001 as a single agent. A clinical collaboration and supply agreement for KEYTRUDA® (pembrolizumab) was signed with MSD (Merck & Co) at the end of June 2022. The Phase Ib part of the clinical trial (combination with pembrolizumab) is expected to start in the first half of 2023.

At the R&D day, **Transgene introduced a novel oncolytic virus** vectorizing human IL-12 that has been designed to be administered intravenously. This Invir.IO™ candidate is expected to enter clinical development in 2023.

AstraZeneca will present a poster at SITC 2022 (November 8–12, 2022), on a construct that was designed within the frame of its collaboration with Transgene. The preclinical data that will be presented highlight oncolysis and tumor-specific immunity induced by the oncolytic virus.

Summary of key ongoing clinical trials

TG4001
+ avelumab
Phase II
NCT03260023

Targets: HPV16 E6 and E7 oncoproteins

Recurrent/metastatic anogenital HPV16-positive — 1st (patients ineligible for chemotherapy) and 2nd lines

- ✓ Randomized Phase II trial comparing the combination of TG4001 with avelumab versus avelumab alone
- ✓ Active patient enrollment in Europe (France and Spain) and in the USA
- ✓ Positive result of interim analysis, allowing trial to continue. Total number of patients to be randomized reduced from 150 to 120
- ➲ **Last patient expected to be randomized in H1 2024**

myvac®

TG4050
Phase I
NCT03839524

Targets: tumor neoantigens

- ✓ Codeveloped with NEC
- ✓ Positive initial data demonstrating the immunogenicity of the vaccine as well as first signs of clinical activity
- ➲ **Additional data on the 2 trials expected in H1 2023**

Ovarian cancer — after surgery and first-line chemotherapy

- ✓ Trial ongoing in the USA and in France
- ✓ Patient enrollment completed

TG4050
Phase I
NCT04183166

HPV-negative head and neck cancer — after surgery and adjuvant therapy

- ✓ Trial ongoing in the UK and in France
- ✓ Patient enrollment completed

TG6002 Phase I/IIa NCT03724071	**Payload: FCU1 for the local production of a 5-FU chemotherapy** ➲ **Additional data to be presented in H1 2023** *Advanced gastro-intestinal cancer (colorectal cancer for Phase II) — Intravenous (IV) administration* ✓ Multicenter trial ongoing in France, Belgium and Spain ✓ **Data confirming the potential of the IV administration presented at ESMO 2022 (Sept. 2022)** Patient enrollment completed in Phase I part
TG6002 Phase I/IIa NCT04194034	*Colorectal cancer with liver metastasis — Intrahepatic artery (IHA) administration* ✓ Multicenter trial ongoing in the UK and in France ✓ Patient enrollment completed in Phase I part
Invir.IO™ **BT-001** Phase I/IIa NCT04725331	**Payload: anti-CTLA4 antibody and GM-CSF cytokine** *Solid tumors* ✓ Co-development with BioInvent ✓ Collaboration agreement with MSD, supplying pembrolizumab for the trial ✓ Trial ongoing in France, Belgium and approved in the USA ✓ Initial data showing safety and first signs of clinical activity ➲ **Start of part B of the Phase I trial in H1 2023**

Operating income

	Q3		First Nine Months	
In millions of euros	**2022**	**2021**	**2022**	**2021**
Revenue from collaborative and licensing agreements	0.7	0.2	3.0	1.6
Government financing for research expenditures	1.5	1.4	5.2	4.9
Other income	0.1	0.2	0.2	0.3
Operating income	**2.3**	**1.8**	**8.4**	**6.8**

During the first nine months of 2022, operating income amounted to €8.4 million compared to €6.8 million in the same period in 2021.

Revenue from collaborative and licensing agreements amounted to €3 million in the first nine months of 2022, compared with €1.6 million in the same period in 2021. These revenues are mainly derived from Transgene's collaboration agreement with AstraZeneca on the Invir.IO™ program, whose recognized income represents €3 million as of September 30, 2022. Of this amount, €0.5 million reflects recognition of the initial payment for work done during the period and €2.5 million in respect of the supply of candidates and the performance of R&D services.

During the first nine months of 2022, government financing for research expenditures, mainly in the form of a research tax credit, amounted to €5.2 million, compared to €4.9 million for the same period in 2021.

Cash, cash equivalents and other financial assets

Cash, cash equivalents and other financial assets stood at €36.3 million as of September 30, 2022, compared to €49.6 million as of December 31, 2021. In the first nine months of 2022, Transgene's cash burn amounted to €13.3 million (including the receipt of an $8 million payment for the first license option exercised by AstraZeneca end of 2021) compared to a cash burn of €18.7 million for the same period in 2021 (excluding capital increase).

Transgene has financial visibility until the end of 2023.

Post-closing event

On October 11, 2022, Transgene notified Tasly Holding Group and its subsidiary Tianjin Fuhade Technology Development Co. the exercise of its option under the Tasly BioPharmaceuticals Shareholder Agreement, requiring them to repurchase Transgene's stake in Tasly BioPharmaceuticals.

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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. 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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