

## Transgene reports business update and end Q1 2021 financial position

- *TG4001 - Regulatory clearance received for randomized Phase II trial – First patient expected to be enrolled in 2Q 2021*
- *TG6002 - Initial Phase I data provides clinical proof of concept for the intravenous administration of Transgene's double deleted VV<sub>cop</sub>TK-RR- patented virus backbone, the basis of the Invir.IO™ oncolytic virus backbone*
- *€19.1 million in cash and cash equivalents as of March 31, 2021 – Financial visibility until the second half of 2022*

Strasbourg, France, April 27, 2021, 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 March 31, 2021, and provides an update on the progress of its portfolio of clinical trials.

### **SIGNIFICANT PROGRESS ON ALL CANDIDATES**

Since January 2021, Transgene has achieved significant milestones on all candidates of its clinical portfolio, with:

- ✓ **the first patients dosed with TG4050**, the individualized therapeutic vaccine against cancer based on Transgene's *myvac*® technology – the first data from the two ongoing Phase I clinical trials are expected in 4Q 2021;
- ✓ **regulatory clearance received in the United States, in France and in Spain**, which are expected to allow enrolment of patients with HPV-positive anogenital cancers in the **randomized Phase II trial of TG4001 + avelumab** versus avelumab alone in 2Q 2021;
- ✓ **first patients dosed in the Phase I trial evaluating BT-001**, an **oncolytic virus based on the Invir.IO™ platform** – first data are expected in 1H 2022;
- ✓ **TG6002 initial data, presented at AACR, providing the clinical proof of concept of the intravenous administration of an oncolytic virus**. After intravenous administration, TG6002 reached the tumor, multiplied within tumor cells, and induced the local expression of its payload (the FCU1 gene). These data also suggest that candidates derived from Transgene's unique Invir.IO™ platform could also be given intravenously, extending the use of these therapies to a broad range of solid tumors – **Next data with TG6002** are expected in 2H 2021 (intra-hepatic artery route).

# SUMMARY OF KEY ONGOING CLINICAL TRIALS AND EXPECTED MILESTONES

myvac®

## TG4050

Phase I

NCT03839524

### Targets: tumor neoantigens

Ovarian cancer – after surgery and first-line chemotherapy

- ✓ Trial ongoing in the United States and in France
- ✓ Inclusions and patient dosing progressing in line with forecast
- ➔ **First data expected in 4Q 2021**

myvac®

## TG4050

Phase I

NCT04183166

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

- ✓ Trial ongoing in the United Kingdom and in France
- ✓ First patient treated in Jan. 2021 – Inclusions and patient dosing progressing in line with forecast
- ➔ **First data expected in 4Q 2021**

## TG4001

+ avelumab

Phase II

NCT03260023

### Targets: HPV16 E6 and E7 oncoproteins

Recurrent/metastatic anoagenital HPV-positive – 1<sup>st</sup> and 2<sup>nd</sup> line

- ✓ **A Phase II randomized trial** comparing the efficacy of TG4001 + avelumab versus avelumab single-agent benefits from the extended clinical collaboration with Merck KGaA and Pfizer, for the supply of avelumab
- ✓ Regulatory authorizations received in the United States, Spain, and France
- ➔ **Patient enrollment in the randomized trial expected to start in 2Q 2021**
- ➔ **First data from the randomized trial are expected around the end of 2022.** This timeline is based on patient enrollment starting in 2Q 2021 and there being no major impact on recruitment from the Covid-19 pandemic.

Invir.IO™

## BT-001

Phase I/IIa

NCT04725331

### Payload: anti-CTLA4 antibody and GM-CSF cytokine

Solid tumors

- ✓ Co-development with BioInvent
- ✓ Trial ongoing in France and Belgium
- ✓ First patient enrolled in February 2021 – Inclusions and patient dosing progressing in line with forecast
- ➔ **US IND expected in 2021**
- ➔ **First Phase I data expected in 1H 2022**

## TG6002

Phase I/IIa

NCT03724071

### Payload: FCU1 for the local production of a 5-FU chemotherapy

Gastro-intestinal cancer (colorectal cancer for Phase II) – Intravenous (IV) administration

- ✓ Multicenter trial ongoing in Belgium, France and Spain
- ✓ **Poster presentation at AACR 2021 on initial data of the trial, demonstrating the clinical proof of concept of the intravenous route of administration**
- ➔ **Phase I part ongoing**

## TG6002

Phase I/IIa

NCT04194034

Colorectal cancer with liver metastasis – Intrahepatic artery (IHA) administration

- ✓ Multicenter trial ongoing in the United Kingdom
- ➔ **First observations expected in 2H 2021**

## OPERATING REVENUE

In millions of euros	Q1	
	2021	2020
Revenue from collaborative and licensing agreements	0.9	1.3
Government financing for research expenditures	1.5	1.5
Other income	-	0.2
<b>Operating revenue</b>	<b>2.4</b>	<b>3.0</b>

During the first quarter of 2021, revenue from collaborative and licensing agreements was mainly composed of the revenue from the collaboration with AstraZeneca.

As of March 31, 2021, government financing for research expenditures mainly consisted of 25% of the research tax credit expected for 2021 (€1.5 million in the first quarter of 2021, in line with the same period in 2020).

## CASH, CASH EQUIVALENTS AND OTHER FINANCIAL ASSETS

**Cash, cash equivalents and other financial assets stood at €19.1 million as of March 31, 2021,** compared to €26.3 million as of December 31, 2020. In the first quarter of 2021, Transgene's cash burn was €7.2 million, compared to €8.0 million for the same period in 2020.

In addition, Transgene has access to a €15 million credit line available from Natixis, the maturity date of which has been extended to April 15, 2023. The Company holds shares of Tasly BioPharmaceuticals valued at €32.3 million at the end of December 2020.

As a result, the Company has a financial visibility until the second half of 2022.

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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*<sup>®</sup> 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*<sup>®</sup> platform, therapeutic vaccination enters the field of precision medicine with a novel immunotherapy that is fully tailored to each individual. The *myvac*<sup>®</sup> 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](http://www.transgene.fr)

Follow us on Twitter: [@TransgeneSA](https://twitter.com/TransgeneSA)

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