

Transgene provides business update and Q1 2023 financial position

Dr. Alessandro Riva, MD, appointed as the Company's Chairman and CEO to accelerate the development of Transgene's innovative immunotherapy portfolio

New clinical data to be communicated in Q2 2023 on TG4001, TG4050 and BT-001

€17.0 million in cash and cash equivalents as of March 31, 2023 — Financial visibility until early 2024

Strasbourg, France, May 10, 2023, 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 provides a business update, including its financial position as of March 31, 2023.**

Key events and upcoming milestones

Since the beginning of the year, all of Transgene's clinical and preclinical assets have progressed in line with expectations. Promising data were presented on all clinical-stage immunotherapies at the AACR 2023 conference (April 2023). New data will be communicated in Q2 2023 on TG4001, TG4050 and BT-001.

Therapeutic cancer vaccines

TG4001: New data to be presented at the ASCO 2023 conference — Preparing for a planned potentially registrational trial in an HPV-positive indication

Transgene anticipates that the last patient will be randomized in the current Phase II clinical study in the first half of 2024. This study is comparing TG4001 in combination with avelumab vs avelumab alone in patients with HPV16-positive anogenital tumors. **Final results will be communicated in 2024.**

A trial-in-progress poster was presented at the AACR conference in April 2023. New translational data from TG4001 will be presented in another poster at the upcoming ASCO conference (June 2–6, 2023). Transgene is working on the design of a potentially registrational trial to further confirm the benefit of this novel therapeutic cancer vaccine.

TG4050: Strong clinical potential confirmed by initial data from the two ongoing Phase I trials — Transgene is preparing a Phase II trial in head and neck cancers

New data were presented on TG4050 at AACR 2023. These data show that this **individualized neoantigen cancer vaccine** is able to induce strong immune responses, which are expected to result in longer remission periods for patients.

All evaluable patients developed a specific immune response against multiple cancer neoantigens after treatment with TG4050 and remained disease-free in the head and neck cancer trial. These data suggest that TG4050 can boost the immune system of patients in the absence of pre-existing response and despite a challenging tumor micro-environment at baseline.

Transgene hosted a key opinion leader (KOL) event with the participation of Professor Christian Ottensmeier, MD, PhD, FRCP (University of Liverpool, La Jolla Institute for Immunology) who highlighted the medical need in head and neck cancer and the potential of a virus-based immunotherapy such as TG4050.

Transgene expects the last patient to be treated in the Phase I study in head and neck cancer in the coming weeks. **Final results from this trial are expected mid-2024.**

Transgene and NEC are preparing for a Phase II trial in head and neck cancers which could be initiated in H2 2023.

Transgene will present new data from TG4050 at the upcoming ASCO conference in June.

Oncolytic Viruses

TG6002: New data presented at AACR support the potential of intravenous administration (IV) of Invir.IO®-based oncolytic viruses, which offers a competitive advantage

Clinical data presented at AACR 2023 confirmed the mechanism of action and the safety of our Invir.IO® based oncolytic viruses, which offers a key competitive advantage.

These findings support the potential of Invir.IO®-based oncolytic viruses to be given by IV administration. This extends their potential use to a much broader range of solid tumors. At present, the use of oncolytic viruses is limited by their intratumoral administration.

BT-001: Ongoing Phase I trial — Monotherapy data expected in H1 2023

Transgene and BioInvent intend to communicate data from the Part A (monotherapy) of the ongoing Phase I trial in H1 2023. The Part B of the Phase I trial (in combination with pembrolizumab) is expected to start in the second half of 2023. KEYTRUDA® (pembrolizumab) will be provided to the trial by MSD (Merck & Co).

TG6050: First patient treated with novel Invir.IO® candidate designed to express IL-12 and be administered intravenously

In early 2023, Transgene announced the regulatory approval to initiate a clinical trial of TG6050, a novel oncolytic virus from its Invir.IO® platform. This innovative candidate has been designed to express human IL-12, a cytokine known to trigger a potent antitumor immune response, and an anti-CTLA4 antibody.

The Delivir trial is evaluating TG6050 in patients with advanced non-small cell lung cancer who have failed standard therapeutic options. **The first patient has been dosed. Completion of the trial is expected in H2 2024.**

AstraZeneca collaboration update

As previously announced on 5 May 2023, the Company was informed by AstraZeneca of its decision to terminate its oncolytic virus research and development collaboration with Transgene that was signed in 2019. The decision was made by AstraZeneca following a strategic review of its pipeline. Following termination, Transgene will regain the global rights to the oncolytic virus drug candidate that was licensed by AstraZeneca in December 2021. This intravenous drug candidate has been granted a US IND.

Operating revenue

In millions of euros	Q1	
	2023	2022
Revenue from collaborative and licensing agreements	0.1	0.4
Government financing for research expenditures	1.5	1.7
Other income	-	0.1
Operating revenue	1.6	2.2

During the first quarter of 2023, revenue from collaborative and licensing agreements was mainly composed of revenue from the collaboration with AstraZeneca.

As of March 31, 2023, government financing for research expenditures mainly consisted of accrual of 25% of the research tax credit expected for 2023 (€1.5 million in the first quarter of 2023 compared to €1.7 million for the same period in 2022).

Cash, cash equivalents and other financial assets

Cash, cash equivalents and other financial assets stood at €17.0 million as of March 31, 2023, compared to €26.8 million as of December 31, 2022. In the first quarter of 2023, Transgene's net cash burn was €9.8 million, compared to €2.8 million for the same period in 2022. In Q1 2022, cash burn was reduced due to an \$8 million payment from AstraZeneca following the exercise of a license option for an oncolytic virus developed by Transgene.

The Company holds shares of Tasly BioPharmaceuticals valued at €14.3 million at the end of December 2022. The Company is expecting to sell its shareholding in Tasly BioPharmaceuticals in mid-2023.

As a result, the Company confirms its financial visibility until early 2024.

New leadership structure appointed to accelerate the development of Transgene's innovative immunotherapy portfolio

On May 5, 2023, Transgene announced its **Board of Directors' decision to appoint Dr. Alessandro Riva, MD, as the Company's new Chairman and CEO** to accelerate the development of Transgene's innovative immunotherapy portfolio. Alessandro Riva has been the Chairman of the Company's Board of Directors since May 2022. Dr. Riva has an outstanding track record in the pharmaceutical and biotechnology industry, leading to the approval of innovative oncology treatments in the US and in Europe. Dr. Riva's appointment will be effective on June 1st, 2023. Hedi Ben Brahim will retire from the CEO position and will stay on as a strategic advisor until the transition is complete.

In addition, on May 5, 2023, the Combined General Meeting adopted all resolutions recommended by the Board of Directors, including the **appointment of Ms. Carol Stuckley, MBA, as an independent Director of the Company**. Ms. Carol Stuckley brings more than 35 years of experience as a strategic and international financial executive, with proven success leading finance teams and creating shareholder value for healthcare companies.

In March 2023, Transgene appointed **Dr. John C. Bell and Dr. Pedro Romero as key scientific advisors**. These key opinion leaders in cancer immunotherapy bring considerable expertise to Transgene.

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 a portfolio of therapeutic vaccines and oncolytic viruses: TG4050, the first individualized therapeutic vaccine based on the *myvac*[®] platform, TG4001 for the treatment of HPV-positive cancers, as well as TG6002, BT-001 and TG6050, three oncolytic viruses based on the Invir.IO[®] viral backbone.

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.

Additional information about Transgene is available at: www.transgene.fr

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