

Transgene advances its innovative immunotherapy pipeline and extends financial visibility until the end of 2024

- *Promising data from ongoing clinical trials of neoantigen cancer vaccine TG4050 and HPV-positive cancer therapeutic vaccine TG4001 presented at key congresses in H1 2023*
- *Immunogenicity clinical data from ongoing trials confirm mechanism of action of Transgene's therapeutic vaccines TG4050 and TG4001*
- *Transgene plans to commence a randomized Phase II trial in head and neck cancer with TG4050 in 2024*
- *Dr. Alessandro Riva, MD, appointed Chairman and Chief Executive Officer, as of June 1, 2023*
- *Extended financial visibility secured until the end of 2024 through a non-dilutive financing provided by the major shareholder Institut Mérieux*

Conference call scheduled today at 6 p.m. CET (in English). See details below.

Strasbourg, France, September 20, 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 publishes its financial results for the six-month period ended June 30, 2023, and provides an update on its product pipeline and upcoming plans.

*“My first few months as CEO for Transgene have been busy and have confirmed just how much Transgene is a pioneering, innovative company, able to take advantage of the latest scientific and technological discoveries to offer potential treatments capable of changing the lives of cancer patients” commented **Dr. Alessandro Riva, MD, Chairman and CEO of Transgene.** “The results we have generated in the first half of 2023 with our therapeutic vaccines and oncolytic viruses show our strong momentum, with further important readouts expected by the end of 2024.*

“TG4050 has shown very promising immunological data and is a strong candidate for advancement. We are planning together with our partner NEC to start a randomized Phase II trial in 2024.

“For TG4001 in the treatment of HPV-positive cancers, our current Phase II trial in combination with avelumab is ongoing. Due to the availability of new treatment options, we have seen a slowdown in patient inclusion, and are assessing all options to ensure data read out in 2024. These results will be important in informing our decision on the best path forward.

“With the renewed support of our majority shareholder, Institut Mérieux, we have extended our financial visibility until the end of 2024 to successfully complete these programs and deliver further important readouts on our programs.”

Key events and upcoming milestones

Therapeutic cancer vaccines

TG4050: Based on strong immunological data from randomized Phase I trial, Transgene is preparing a randomized Phase II trial in head and neck cancer

New highly promising data were presented on TG4050 at AACR and ASCO 2023 (see poster [here](#)). These data show that this **individualized neoantigen cancer vaccine** can induce strong immune responses, which are expected to result in longer remission periods for patients.

The initial data from the randomized Phase I trial in the adjuvant treatment of head and neck cancer (NCT04183166) showed that all evaluable patients developed a robust and specific immune response against multiple cancer neoantigens (median of 9 positive responses per patient out of approximately 30 targets) after treatment with TG4050 and remained disease-free.

These T-cell responses were observed for class I and class II epitopes, consisting of both de novo responses and amplifications of preexisting responses.

These data suggest that TG4050 can boost the immune system of patients in the absence of pretreatment response and despite a challenging tumor microenvironment at the time of tumor resection.

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 unmet medical need in head and neck cancer and the potential of a virus-based immunotherapy such as TG4050.

The last patient has been randomized in the head and neck cancer Phase I study. **Transgene and its partner NEC plan to report updated data in H1 2024.**

Transgene and NEC intend to start a randomized Phase II trial in the adjuvant setting of head and neck cancer in 2024.

TG4001: Immunological data presented at the ASCO 2023 conference

Promising results from the previous Phase I/II trial evaluating TG4001 in combination with an immune checkpoint inhibitor were published in the September 2023 issue of the European Journal of Cancer (<https://doi.org/10.1016/j.ejca.2023.112981>). This study showed that TG4001 in combination with avelumab is safe and demonstrated antitumor activity in heavily pretreated HPV16+ cancer patients. It also served as the basis for the ongoing randomized Phase II trial.

Transgene's ongoing randomized Phase II trial evaluating TG4001 in HPV-positive anogenital cancers is currently enrolling patients. This study compares TG4001 in combination with avelumab vs. avelumab alone (NCT03260023).

New immunological data from TG4001 were presented in a poster at ASCO (see poster [here](#)).

Key updates on the Phase II trial include:

- The immunological data confirm that **TG4001 can induce *de novo* immune responses against HPV16 antigens E6 and E7** in patients with advanced HPV16-positive anogenital cancers. Patients with complete objective response showed strong vaccine-induced immunoreactivity.
- Over recent months, Transgene has seen a slowdown of patient inclusions in this study following the availability of new treatment options, in particular in cervical cancer. Transgene is assessing all options to ensure data read out in 2024 from the trial as previously communicated.
- Despite the recent availability of new treatment options, there remains a strong medical need in HPV-positive cancers, including cervical cancer. Based on the compelling data generated by TG4001 and the evolving treatment landscape, Transgene is currently in discussion with key stakeholders to define the optimal path forward to continue its development in the most appropriate target patient population.

Oncolytic Viruses

Clinical data presented at AACR 2023 confirmed the mechanism of action and the safety of our Invir.IO® based oncolytic viruses, which offer a key competitive advantage with the ability to be administered intravenously. **These findings support the potential of Invir.IO®-based oncolytic viruses, which have possible applications in a broad range of solid tumors, via intravenous, locoregional and intratumoral administration.**

BT-001: Positive single agent data — Part B of the Phase I trial (combination with pembrolizumab) to start in H2 2023

Transgene and partner BioInvent have communicated positive data from Part A (monotherapy) of the ongoing Phase I trial in May 2023 (NCT04725331). Out of 18 patients who received escalating doses of BT-001, two showed a decrease of injected lesion size of 50% or more, and eleven had a stabilization of the injected lesion. No safety concerns were reported.

Part B of the Phase I trial in combination with pembrolizumab (KEYTRUDA®) will include patients in H2 2023. KEYTRUDA® is provided by MSD (Merck & Co).

TG6050: First patient treated with novel Invir.IO® candidate designed to express IL-12 and anti-CTLA4 antibody and administered intravenously

In May 2023, a first patient was dosed with TG6050, a novel oncolytic virus from the 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 Phase I Delivir trial (NCT05788926) is evaluating TG6050 in patients with advanced non-small cell lung cancer who have failed standard therapeutic options. **Completion of the trial is expected in H2 2024.**

As announced on May 5, 2023, AstraZeneca terminated its oncolytic virus research and development collaboration with Transgene following a strategic review of its pipeline.

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.** Alessandro Riva, who started as new CEO on June 1, 2023, 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, with responsibility for the approval of personalized oncology treatments in the US and in Europe, in particular CAR-T cell therapies.

In addition, on May 5, 2023, the Combined General Meeting adopted all resolutions recommended by the Board of Directors, including the **appointment of Carol Stuckley, MBA, as an independent Director of the Company.** 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. Hedi Ben Brahim resigned from the Board of Directors on September 19, 2023.

In March 2023, Transgene appointed **Dr. John C. Bell and Dr. Pedro Romero, key opinion leaders in cancer immunotherapy, as key scientific advisors.** John C. Bell is an internationally renowned expert in using oncolytic viruses. Pedro Romero is an honorary professor at the University of Lausanne, focusing on tumor immunology and cancer immunotherapy, particularly on the biology and dynamics of cytolytic CD8 T lymphocyte (CTL) responses. He has also been Editor-in-Chief of the Journal for ImmunoTherapy of Cancer.

Key financial elements

The Board of Directors of Transgene met on September 20, 2023, and approved the financial statements for the six-month period ended June 30, 2023. The Statutory Auditors have conducted a limited review of the interim consolidated financial statements.

The half-year financial report is available on Transgene's website, www.transgene.fr.

Key elements of the income statement

<i>(in thousands of euros)</i>	June 30, 2023	June 30, 2022
Operating income	4,763	6,087
Research and development expenses	(15,569)	(16,974)
General and administrative expenses	(3,251)	(3,944)
Other expenses	(1,276)	(4)
Operating expenses	(20,096)	(20,922)
Operating income/(loss)	(15,333)	(14,835)
Financial income/(loss)	(569)	(444)
Net income/(loss)	(15,902)	(15,279)

Operating income amounted to €4.8 million for the first six months of 2023 compared to €6.1 million for the same period in 2022.

- Revenue from research and development collaboration amounted to €1.2 million in the first half of 2023, compared to €2.3 million in the first half of 2022. It came mainly from the collaboration with AstraZeneca. In the first half of 2023, AstraZeneca informed Transgene of its decision to end the collaboration.
- The research tax credit amounted to €3.5 million for the first half of 2023, compared to €3.7 million for the first half of 2022.

Research and Development (R&D) expenses amounted to €15.6 million in the first half of 2023 compared to €17.0 million for the same period in 2022.

General and administrative expenses amounted to €3.3 million for the first half of 2023 compared to €3.9 million for the same period in 2022.

Financial income is a loss of €0.6 million in the first half of 2023 compared to a loss of €0.4 million for the same period in 2022.

Net loss amounted to €15.9 million for the first half of 2023 compared to a loss of €15.3 million for the same period in 2022.

Transgene's **cash burn** amounted to €19.5 million in the first half of 2023 compared with €6.8 million for the same period in 2022.

As of June 30, 2023, the Company's **cash, cash equivalents and other financial assets** amounted to €7.3 million (€26.8 million as of December 31, 2022).

During the reporting period, the Company reached an agreement for the sale of its remaining shares held in Tasly BioPharmaceuticals for a total amount of US\$15.3 million (€14 million). The transaction was closed in July 2023 upon receipt of the funds.

Financial visibility extended until the end of 2024

On September 20, 2023, the Company signed a current account advance agreement with Institut Mérieux (TSGH) for a maximum of €36 million. This non-dilutive credit facility extends Transgene's financial visibility until the end of 2024, enabling the Company to deliver significant news flow on its portfolio in the next 12 months.

The credit facility will have a 24-month term and Transgene will be able to draw on and repay the facility at its discretion.

A conference call in English is scheduled today, on September 20, 2023, at 6 p.m. CET / 12 p.m. EST.

Webcast link to English language conference call:

https://channel.royalcast.com/landingpage/transgene/20230920_1/

Participant telephone numbers:

France: +33 (0) 1 70 37 71 66

Confirmation code: Transgene

United Kingdom: +44 (0) 33 0551 0200

United States: +1 786 697 3501

A replay will be available on the Transgene website (www.transgene.fr) following the live event.

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 BT-001 and TG6050, two 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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