transgene

2024 Half-Year Results and Business Update

PRESS RELEASE

Transgene to Report Major Clinical Data before the end of 2024 – Confirmed Financial Visibility until Q4 2025

Lead program TG4050 (individualized immunotherapy):

- First signs of clinical benefit in adjuvant head and neck cancer reported at AACR 2024, paved the way for the start of Phase II part of randomized Phase I/II clinical trial in Q2 2024
- Median 24-month follow-up data to be presented in Q4 2024

BT-001 (oncolytic virus):

Data presented at ESMO (Sept. 2024) showed promising antitumor activity in solid tumors that failed previous anti-PD(L)-1 treatment

TG4001 (HPV therapeutic cancer vaccine):

Randomized Phase II study expected to read out in Q4 2024

Financial visibility confirmed until Q4 2025

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

Strasbourg, France, September 24, 2024, 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, 2024, and provides an update on its product pipeline and upcoming plans.

"Transgene is at the forefront of innovation in cancer immunotherapy and 2024 marks a crucial turning point for the company, as we advance the development of our cutting-edge treatments. Recently, we initiated a global Phase II clinical trial in adjuvant head and neck cancer for our lead asset TG4050, our individualized therapeutic vaccine, leveraging the promising Phase I clinical data. We anticipate the upcoming median 24-month follow-up data from the Phase I patients to be presented before the end of 2024. Additionally, we are encouraged by the antitumor activity shown in the ongoing Phase I study of BT-001 which we presented at ESMO this month. We also eagerly anticipate the upcoming results for TG4001 by the end of the year, which could confirm its potential in the treatment of HPV-associated cancers and further solidify our strategy." commented **Dr. Alessandro Riva, MD, Chairman and CEO of Transgene**.

Key events and upcoming milestones

Neoantigen therapeutic cancer vaccine: TG4050

In H1 2024, promising randomized Phase I data on TG4050 were presented at AACR 2024 (see poster **here**). These data provide a robust clinical proof of principle for Transgene's lead candidate in the adjuvant head and neck cancer setting. **All patients who received TG4050 remained in clinical remission and disease-free after a median follow-up of 18.6 months, comparing favorably to the observational arm which had 3 out of 16 patients relapse** during the same period.

Specific cellular immune responses of CD8+ and CD4+ were detected in 16 out of 17 patients who received TG4050 (16 patients in the treatment arm and one patient from the observation arm treated after relapse) using stringent testing criteria. **Immunogenicity (the capacity of treatment to induce immune responses) is key to preventing relapses.**

TG4050 also induced **persistent immune responses** against multiple targets in several patients. In these patients, T cell responses were maintained beyond 211 days (7 months) after the initiation of the treatment. **The duration of the immune response is also a key factor to fight disease over time.**

Following these promising data, the randomized Phase I trial has **been expanded to a randomized Phase I/II trial** in the adjuvant setting of head and neck cancer. The Phase II part started enrolling patients in Q2 2024 within the framework of an extended collaboration between Transgene and NEC. **Patient enrollment is progressing at a good pace.**

Additional data on the 24-month median follow-up of Phase I patients will be reported in Q4 2024.

Although some advancements in the treatment of squamous cell carcinoma of the head and neck have been made, there remains a significant medical need for these patients, including in the adjuvant setting. With the current standard of care, 30% to 40% of patients are expected to relapse within 24 months following surgery and adjuvant therapy. Despite completed Phase III trials, immune checkpoint inhibitors have yet to demonstrate significant benefits for these patients.

TG4050 is the only individualized neoantigen cancer vaccine currently being developed in a randomized trial in the adjuvant treatment of head and neck cancer.

TG4050 has potential applicability across a range of solid tumors where there remains a significant unmet medical need, despite existing therapeutic options, including immunotherapies. As a result, Transgene is conducting preliminary work on a potential new Phase I trial in another undisclosed indication.

Shared antigen cancer vaccine: TG4001

In H1 2024, Transgene has completed the enrollment of 90 patients in the ongoing randomized Phase II trial evaluating TG4001 in HPV-positive anogenital cancers (NCT03260023) in combination with an immune checkpoint inhibitor. **Transgene confirms that topline readouts are expected in Q4 2024.**

The ongoing trial was launched based on promising results from the previous Phase I/II trial published in the September 2023 issue of the *European Journal of Cancer* (**here**). This study showed that TG4001 in combination with avelumab is safe and demonstrated antitumor activity in heavily pretreated HPV16-positive cancer patients.

Oncolytic Viruses

Transgene is developing **Invir.IO® oncolytic viruses, that have the potential to address a broad range of solid tumors, via intravenous, locoregional and intratumoral administration.**

BT-001 (intratumoral administration):

Preliminary data presented at ESMO 2024 demonstrate promising antitumor activity in solid tumors that failed previous anti-PD(L)-1 treatment in ongoing Phase I/IIa trial.

BT-001 is a multifunctional oncolytic virus encoding for an anti-CTLA4 antibody and the cytokine GM-CSF. In September 2024, Transgene and its partner BioInvent presented data showing the first signs of clinical efficacy of BT-001 in the ongoing Phase I trial evaluating this oncolytic virus in monotherapy and in combination with an immune checkpoint inhibitor (see poster **here**).

These results were obtained in tumors that failed previous anti PD(L)-1 treatment. In monotherapy, BT-001 induced tumor shrinkage in 2 of 6 injected lesions. In combination with KEYTRUDA® (pembrolizumab), partial responses were observed in 2 of 6 patients who failed previous treatment and who also showed tumor shrinkage (partial response) in non-injected lesions. BT-001 was well tolerated both alone and in combination with pembrolizumab.

In addition, BT-001 treatment was able to **turn "cold" tumors into "hot" tumors** inducing **T cell infiltration** and a **shift to PD(L)-1 positivity in the tumor microenvironment in certain patients**. Preliminary translational data indicate that **BT-001 replicates in the tumor** where the **payloads are expressed with undetectable systemic exposure**.

In this part of the clinical trial, KEYTRUDA® (pembrolizumab) is provided to the trial by MSD (Merck & Co). KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

TG6050 (intravenous administration):

Initial Phase I data expected in Q4 2024 from this novel Invir.IO® oncolytic virus candidate administered intravenously.

TG6050 is a novel oncolytic virus 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. Initial data from the trial is expected in Q4 2024**.

Preclinical data were recently published in the *Journal for ImmunoTherapy of Cancer* (*JITC*) demonstrating that TG6050 induces tumor regression in numerous "hot" and "cold" murine tumor models investigated in these studies. This antitumoral activity was further amplified when TG6050 was combined with an anti-PD1 (article available **here**).

Major milestones communicated to date and expected before the end of 2024

TG4050	Randomized **Phase I part** (head and neck)	*- Poster presentation (AACR)* ✓ *- Additional data: expected Q4 2024*
	Randomized **Phase II part** (head and neck)	*Enrollment initiated* ✓
	Preliminary work to launch an additional **Phase I** trial (new indication)	*Early-stage assessment: ongoing*
TG4001	Randomized **Phase II** trial	*Topline results: expected Q4 2024*
BT-001	Combination part of **Phase I**	*Poster presentation (ESMO)* ✓
TG6050	**Phase I** trial	*Initial data: expected Q4 2024*

Key financial elements

The Board of Directors of Transgene met on September 24, 2024, and closed the financial statements for the six-month period ended June 30, 2024. 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

(in thousands of euros)	June 30, 2024	June 30, 2023
Operating revenue	**3,357**	**4,763**
Research and development expenses	(15,423)	(15,569)
General and administrative expenses	(4,558)	(3,251)
Other expenses	129	(1,276)
Operating (expenses)	**(19,852)**	**(20,096)**
Operating income/(loss)	**(16,495)**	**(15,333)**
Financial expense	10	(569)
Net income/(loss)	**(16,485)**	**(15,902)**

Operating revenue amounted to €3.4 million for the first six months of 2024 compared to €4.8 million for the same period in 2023.

- The research tax credit for the first half of 2024, amounted to €3.2 million versus €3.5 million for the same period in 2023.
- Revenue from research and development collaborations amounted to €23 thousand in the first half of 2024, compared to €1.2 million in the first half of 2023. In the first half of 2023, AstraZeneca had informed Transgene of its decision to end the collaboration. Over this period in 2023, €1.1 million in revenue was recognized under this collaboration agreement.

As of June 30, 2024, Transgene had €15.3 million in cash and other current financial assets, compared to €15.7 million as of December 31, 2023.

Transgene's cash burn amounted to €20.4 million in the first half of 2024 compared with €19.5 million for the same period in 2023.

New medical and scientific leadership appointed to accelerate the development of Transgene's innovative immunotherapy portfolio

As Transgene enters a pivotal phase of its future development, marked by key upcoming data points, the Company benefits from the formation of a strong senior management team. This leadership will be crucial in guiding Transgene through its next stage of growth. Following the recent appointments of Emmanuelle Dochy as Chief Medical Officer and Maurizio Ceppi as Chief Scientific Officer, the executive committee now comprised of the following members:

- Alessandro Riva, Chairman & Chief Executive Officer (CEO);
- Christophe Ancel, Chief Pharmaceutical Operations Officer & Qualified Pharmacist;
- Maurizio Ceppi, Chief Scientific Officer (CSO);
- Emmanuelle Dochy, Chief Medical Officer (CMO);
- John Felitti, General Counsel, Corporate Secretary;
- Lucie Larguier, Chief Financial Officer (CFO);
- Christelle Schwoerer, Chief Human Resources Officer;
- James Wentworth, Chief Business Officer (CBO).

In addition, on May 15, 2024, the Combined General Meeting of Transgene's shareholders appointed one new non-independent director, Michel Baguenault de Puchesse.

Financial visibility confirmed until Q4 2025; post-closing financing event

Transgene confirms financial visibility until Q4 2025 enabling the Company to deliver significant news flow on its portfolio over the next 12 months.

At the end of July 2024, Transgene announced the conversion into shares of €33 million of debt drawn from the current account advance granted by the Company's major shareholder TSGH, in accordance with the terms of an agreement signed for the first time in 2023. As a result, the share capital of Transgene held by TSGH increased from 59.7% to 69.1% of the outstanding shares. In carrying out this transaction, Transgene has strengthened its balance sheet, reduced its debt levels and its debt burden as a result of lower interest payments. As of July 30, 2024, Transgene had the capacity to draw down an additional €30.4 million from the current account advance provided by TSGH.

A conference call **in English** is scheduled today, **September 24, 2024, at 6:00 p.m. CET (12:00 p.m. ET)**.

Webcast link to English language conference call:
https://edge.media-server.com/mmc/p/yb6znnez

Please log in to the following link to obtain your personal telephone IDs.
https://register.vevent.com/register/BIb09850b62b064fd0b5693d8ec1723d93

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

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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 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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