PRESS RELEASE

Transgene Completes Initial Patient Screening in Phase II Part of TG4050 Trial in Operable Head and Neck Cancer

Phase I part showed 100% Disease-Free Survival (DFS) after a minimum of 2-year follow-up – providing clinical proof of principle for TG4050

Randomization of all patients expected to be completed by end 2025

First immunogenicity data of Phase II part expected in H2 2026

Preliminary efficacy data expected in H2 2027

Strasbourg, France, June 19, 2025, 8:00 a.m. CET – **Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer,** today announced the **completion of initial patient screening in the randomized multicenter Phase II part of its Phase I/II clinical trial with TG4050, an individualized neoantigen therapeutic vaccine**, as a single agent in the adjuvant treatment of HPV-negative squamous head and neck cancers (NCT04183166). TG4050, Transgene's lead asset, is based on its proprietary *myvac*® platform and powered by NEC's cutting-edge AI capabilities designed to optimize antigen selection for individual patients.

All patients treated with TG4050 in the Phase I part of the trial remained disease-free after a minimum of two years of follow-up, confirming clinical proof of principle. Translational data showed sustained T cell responses at 24 months in these patients. The results, which met **all trial endpoints** including safety, feasibility, immune activation and disease-free survival (DFS, defined as survival without recurrence or death for any cause), were presented in an oral presentation at the recent American Society of Clinical Oncology (**ASCO 2025**) annual meeting.

Transgene expects to complete randomization of all patients in the Phase II part by the end of 2025, following a second screening of patients conducted after surgery and adjuvant (chemo)radiotherapy. These screenings represent key steps during which patients are evaluated to determine whether they meet the eligibility criteria to participate in the clinical trial. In total, approximately 80 patients with a complete response to adjuvant therapy are anticipated to be enrolled and subsequently randomized in the Phase I/II trial. **First immunogenicity data from the Phase II part of the trial are expected to be available in H2 2026, and preliminary efficacy data are expected in H2 2027.**

Dr. Emmanuelle Dochy, MD, Chief Medical Officer of Transgene added: "*Timely completion of first patient screening of the Phase II part of our Phase I/II trial is an important milestone for Transgene and brings us one step closer to providing a new treatment option for patients living with operable squamous head and neck cancer. With meaningful data readouts expected over the next two years, we are preparing to deliver important data for TG4050 and at the same time explore its wider potential. We are grateful to the patients, their families, investigators, and clinical staff whose commitment made this achievement possible*."

Dr. Alessandro Riva, CEO of Transgene commented: "*The positive results from the Phase I part of our TG4050 trial support the strong potential of our* myvac® *platform. The successful completion of the first screening of the randomized Phase II part in less than a year and ahead of schedule underscores the investigators' commitment to rapidly advance the development of TG4050. In the ongoing Phase II part of the trial, we have been able to scale efficiently, strengthen our manufacturing capabilities and operate with the agility needed to lead in a highly competitive and fast-moving environment*.
The myvac® *individualized cancer vaccine platform can be applied across a range of solid tumors where in many cases a significant unmet medical need remains. Consequently, Transgene is starting initial preparations for a* ***new Phase I trial*** *in a second, undisclosed indication in an early treatment setting,* ***with the aim to initiate the trial in Q4 2025****."*

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Contacts

Media:
Caroline Tosch
Corporate and Scientific Communications Manager
+33 (0)3 68 33 27 38
communication@transgene.fr

MEDiSTRAVA
Frazer Hall/Sylvie Berrebi
+ 44 (0)203 928 6900
transgene@medistrava.com

Investors & Analysts:
Lucie Larguier
Chief Financial Officer (CFO)
Nadege Bartoli
Investor Relations Analyst
and Financial Communications Officer
+33 (0)3 88 27 91 00/03
investorrelations@transgene.fr

About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. The Company's clinical-stage programs consist of a portfolio of viral vector-based immunotherapeutics. TG4050, the first individualized therapeutic vaccine based on the *myvac®* platform is the Company's lead asset, with demonstrated proof of principle in patients in the adjuvant treatment of head and neck cancers. The portfolio also includes other viral-vector-based immunotherapies: 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. The Company also conducts innovative discovery and preclinical work, aimed at developing novel viral vector-based modalities.
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.com
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About myvac®

myvac® is a viral vector (MVA – Modified Vaccinia Ankara) based, individualized immunotherapy platform that has been developed by Transgene to target solid tumors. *myvac®*-derived products are designed to stimulate the patient's immune system to recognize and destroy tumors using their own cancer specific genetic mutations. Transgene has set up an innovative network that combines bioengineering, digital transformation, established vectorization know-how and unique manufacturing capabilities. Transgene has been awarded "Investment for the Future" funding from Bpifrance for the development of its platform *myvac®*. TG4050 is the first *myvac®*-derived product being evaluated in clinical trials. Click here to watch a short video on *myvac®*.

About TG4050

TG4050 is a clinical stage individualized immunotherapy being developed for solid tumors that is based on Transgene's myvac® technology and powered by NEC's longstanding artificial intelligence (AI) and machine learning (ML) expertise. This virus-based therapeutic vaccine encodes neoantigens (patient-specific mutations) identified and selected by NEC's Neoantigen Prediction System. The prediction system is based on more than two decades of expertise in AI and has been trained on proprietary data allowing it to accurately prioritize and select the most immunogenic sequences.

TG4050 is designed to stimulate the immune system of patients in order to induce a T-cell response that is able to recognize and destroy tumor cells based on their own neoantigens. This individualized immunotherapy is developed and produced for each patient. Positive data have been generated in the adjuvant setting of head and neck cancer (NCT04183166). A Phase II part is ongoing, Transgene is preparing an additional trial in a second indication, with aim to initiate the trial in Q4 2025.

About the Phase I/II clinical trial

TG4050 is being evaluated in a Phase I/II clinical trial for patients with HPV-negative head and neck cancers (NCT04183166). An individualized treatment is created for each patient after they complete surgery and while they receive adjuvant therapy. Half of the participants received their vaccine immediately after completing adjuvant treatment. The other half were given TG4050 as an additional treatment at the time of recurrence of the disease as an additional treatment to standard of care (SoC). This randomized study is evaluating the treatment benefits of TG4050 in patients who are at risk of relapse. In the Phase I part, thirty-two evaluable patients have been included. The Phase II part is ongoing internationally. Overall approximately 80 patients will be randomized in the trial.

Disclaimer

This press release contains forward-looking statements, which are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results, regulatory authorities' agreement with development phases, and development. The Company's ability to commercialize its products depends on but is not limited to the following factors: positive pre-clinical data may not be predictive of human clinical results, the success of clinical studies, the ability to obtain financing and/or partnerships for product manufacturing, development and commercialization, and marketing approval by government regulatory authorities. For a discussion of risks and uncertainties which could cause the Company's actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors ("Facteurs de Risque") section of the Universal Registration Document, available on the AMF website (http://www.amf-france.org) or on Transgene's website (www.transgene.fr). Forward-looking statements speak only as of the date on which they are made, and Transgene undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.