PRESS RELEASE

Transgene Completes Patient Randomization in Phase 2 Part of Clinical Trial Evaluating TG4050 in the Adjuvant Treatment of Head and Neck Cancer

Two-year disease-free survival from evaluable Phase 2 patients expected by the end of Q1 2028.

Strasbourg, France, April 13, 2026, 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 patient randomization in the Phase 2 part of the Phase 1/2 clinical trial** evaluating TG4050, an individualized neoantigen therapeutic vaccine (INTV) developed from Transgene's *myvac*® platform.
38 patients have been randomized in the Phase 2 part of the Phase 1/2 trial for adjuvant treatment of head and neck cancer (HNSCC[1]). With the primary endpoint of the trial being 2-year disease-free survival (DFS), Transgene is advancing the study and expects to communicate top line results by the end of Q1 2028.

TG4050 is designed to stimulate a **strong and individualized immune response aimed at preventing relapse** in patients following surgery and adjuvant (chemo)radiotherapy.

Dr. Alessandro Riva, MD, Chairman and CEO of Transgene, commented: "*Completing randomization in the Phase 2 part of the study is an important milestone for TG4050 and for our* myvac® *platform and confirms the expected readout timing of the primary endpoint of the Phase 1/2 trial by the end of Q1 2028, while we plan to release first immunological data in H2 2026. We are grateful to the patients, investigators and site personnel who contribute to advancing this promising, individualized immunotherapy. We look forward to the upcoming analyses as we continue our efforts to provide an innovative individualized treatment option for patients diagnosed with operable squamous head and neck cancer.*"

The primary objective of the randomized multicenter Phase 1/2 trial (NCT04183166) is to compare the **efficacy of TG4050 as a single agent** versus watchful waiting in the adjuvant treatment of locoregionally advanced HPV-negative head and neck cancer (HNSCC).

[1] *Head and neck squamous cell carcinoma – HNSCC*

The primary endpoint of the trial is 2-year disease-free survival (DFS) and is expected to read out as soon as all patients from the Phase 2 part achieve 2-year follow-up from randomization unless an event (relapse, death) occurs earlier, with results anticipated by the end of Q1 2028.

Data from patients in the Phase 1 part of the trial have already shown that multiple subcutaneous injections of TG4050 were **well-tolerated with no unexpected safety signals**.
3-year DFS follow-up of Phase 1 patients is **expected in Q2/Q3 2026**.

TG4050, as a monotherapy, met all trial endpoints in the Phase 1 part of the trial and induced long-lasting immune responses to vaccine neoantigens that were sustained for up to two years after treatment initiation. All patients treated with TG4050 were disease-free at 2-years (median follow-up: 30 months), confirming robust **clinical proof of principle**.

The positive clinical and translational data[2] suggest that individualized treatment with TG4050 has the **potential to prevent cancer relapses when administered as monotherapy** in an adjuvant treatment regimen in patients with high risk, resected, locally advanced HPV-negative HNSCC.

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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. 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, demonstrated proof of principle in patients in the adjuvant treatment of head and neck cancers (HNSCC – Head and neck squamous cell carcinoma). The Company has other viral vector-based assets, including BT-001, an oncolytic virus based on the Invir.IO® viral backbone, which is in clinical development. The Company also conducts innovative discovery and preclinical work, aimed at developing novel immunotherapies.
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.
Additional information about Transgene is available at: www.transgene.com
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[2] *A comprehensive analysis of the clinical and translational data from the Phase 1 part of the randomized Phase 1/2 trial of INTV-TG4050 was published on the preprint platform medRxiv, in January 2026 (see press release). The article is under review by a peer-reviewed journal.*

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 an 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 Individualized Neoantigen Therapeutic Vaccine (INTV) 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 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.

About the Phase 1/2 Clinical Trial

TG4050 is being evaluated in a Phase 1/2 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 at the time of recurrence of the disease as an additional treatment to the standard of care (SoC). This randomized study is evaluating the treatment benefits of TG4050 in patients who are at risk of relapse. The first efficacy data (2-year disease-free survival – DFS) will become available at the latest by the end of Q1 2028.

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.com). 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.