PRESS RELEASE

Transgene Publishes Phase I Data Supporting TG4050's Potential in Preventing Head and Neck Cancer Relapse

TG4050 elicits strong polyepitopic, polyclonal, durable cytotoxic and effector neoantigen-specific CD8 T cell responses

Results reinforce TG4050 potential as an individualized cancer immunotherapy

Strasbourg, France, January 9, 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 preprint publication on medRxiv of **a comprehensive analysis of both the clinical and translational data from the Phase I part of its randomized Phase I/II trial of TG4050, an individualized neoantigen therapeutic vaccine (INTV).**
The manuscript is now available on medRxiv - a preprint platform that enables early scientific visibility by sharing research ahead of journal peer review.
In parallel, the article has been submitted to a peer-reviewed journal and is currently under evaluation.

TG4050: an individualized therapeutic cancer vaccine shows 100% two-year disease-free survival as monotherapy in the adjuvant treatment of operable head and neck cancers

Despite the availability of current treatments, including immune checkpoint inhibitors, about one-third of patients with head and neck squamous cell carcinoma (HNSCC) experience recurrence within two years after surgery. Transgene's trial with TG4050 was designed to assess whether inducing neoantigen-specific T-cell responses following treatment with an INTV encoding up to 30 predicted tumor neoantigens delivered via a Modified Ankara Virus (MVA) vector could help reduce the risk of relapse.

Half of the participants received TG4050 immediately after completing primary adjuvant treatment, while the other half were administered the vaccine at the time of disease recurrence, as an additional therapy alongside the standard of care.

With 100% disease-free survival at two years, the data suggest that individualized treatment with TG4050 does have 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. In addition, TG4050 was well-tolerated and showed no unexpected safety signals.

Detailed translational findings from patients treated with TG4050 confirm durable, neoantigen-specific T-cell responses

The translational data show that TG4050 induced neoantigen-specific T cell responses in the majority of treated patients (73% of 15 evaluable patients). These responses were **durable, with cytotoxic and effector phenotype markers expressed up to one year after the end of treatment**.

An overview of these data were first presented at **the 2025 Society for Immunotherapy of Cancer (SITC) Annual Meeting** (see press release) and support TG4050's ability **to induce neoantigen-specific cytotoxic CD8+ T cell responses capable of targeting and eliminating tumor cells, thereby contributing to the prevention of cancer relapse, when used as monotherapy in patients with HNSCC**.

TG4050 is currently under further evaluation in a randomized Phase I/II clinical trial (NCT04183166), in patients with HNSCC.

"The publication of TG4050's Phase I results on medRxiv is an important step for Transgene. Making these data available to the global scientific community underscores our commitment to transparency and scientific rigor. The findings show encouraging evidence of TG4050's ability to induce durable, neoantigen-specific immune responses and its potential in preventing relapse in patients with HPV-negative operable head and neck cancer. We look forward to advancing TG4050 through Phase II with the same determination and patient-centered approach" said **Katell Bidet-Huang, Head of translational medicine at Transgene.**

The preprint on medRxiv provides early access to these important clinical findings ahead of peer-reviewed journal publication.

Title: "Viral-based individualized neoantigen vaccine as adjuvant treatment in resected head and neck squamous cell carcinoma: immunogenicity and efficacy from a randomized Phase I trial"

The preprint is available on medRxiv and on Transgene websites.

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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 is the Company's lead asset, with demonstrated proof of principle in patients in the adjuvant treatment of head and neck cancers. 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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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 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.

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. First immunogenicity data from the Phase II part of the trial are expected to be available in H2 2026. The first efficacy data will become available as soon as all patients display two-year follow-up from randomization unless an event (relapse, death or lost to follow-up) occurs earlier.

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.