

Transgene to Present 24-month Disease-Free Survival Data from All Patients in Phase I Part of Trial of Individualized Cancer Vaccine, TG4050, at ASCO 2025

24-month follow-up data from randomized Phase I part of the Phase I/II trial of TG4050 in resected locally advanced head and neck cancer selected for rapid oral presentation at ASCO on June 1st, 2025

Strasbourg, France, May 22, 2025, 11:00 p.m. CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, today announces that it will present **two-year disease-free survival (DFS) data from all patients in the randomized Phase I part of the trial of its individualized neoantigen therapeutic cancer vaccine TG4050. The data will be shared during a rapid oral presentation** at the American Society of Clinical Oncology (ASCO) Annual Meeting, taking place in Chicago from May 30 to June 3, 2025.

TG4050 is a viral vector-based immunotherapy based on Transgene's myvac® platform and powered by NEC's cutting-edge AI capabilities designed to optimize antigen selection.

TG4050 is being evaluated in a randomized multicenter Phase I/II trial as a **single agent in the adjuvant treatment of HPV-negative head and neck cancers** ([NCT04183166](https://clinicaltrials.gov/ct2/show/study/NCT04183166)). Based on promising Phase I data, Transgene and partner NEC have advanced the joint development of TG4050 in this indication with a Phase II extension of the trial, which is currently enrolling patients.

Key data to be presented include:

**Safety in locally advanced HPV-negative resectable head and neck squamous cell carcinoma (HNSCC),
Disease free survival after 2-year follow-up,
Updated immunogenicity data.**

Prof. Le Tourneau, MD, PhD, Head of the Department of Drug Development and Innovation (D3i) at Institut Curie, and Principal Investigator commented: *"It is a privilege to present these study data which are based on the highly promising myvac® platform for individualized cancer vaccines. This oral presentation at ASCO offers an opportunity to highlight both the strength of the clinical data and the collaborative efforts of everyone involved in the trial."*

Dr. Emmanuelle Dochy, MD, Chief Medical Officer of Transgene, added: *"We are pleased to have our latest findings on TG4050 selected for presentation among so many high-quality submissions to ASCO. This*

recognition reflects the dedication of our teams and the significance of our work in advancing medical science and patient care for those suffering from cancer. The Phase II part of our trial is currently enrolling patients internationally, as we continue to evaluate TG4050's potential in this setting."

The rapid oral presentation will take place on June 1st at 1:30 p.m. CDT during [ASCO 2025](#) and will also be available to view on [Transgene's](#) website.

In addition, Transgene will present a poster at [ASCO](#) on TG4001, presenting randomized Phase II data in combination with avelumab in a cervical cancer subgroup. Following the previously reported topline results from this study in the overall patient population (see press release [here](#)), Transgene is currently evaluating potential partnership opportunities to determine the best path forward for the program.

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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 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

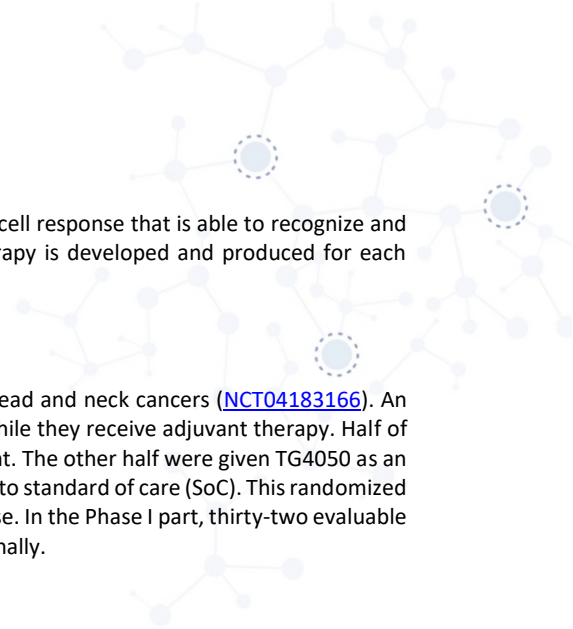
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About myvac[®]

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 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 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.

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 currently enrolling patients internationally.

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.