

Transgene and NEC Present Durable Disease-Free Survival and Sustained T Cell Responses at 24 Months with Individualized Cancer Vaccine TG4050

All patients in the treatment arm remain disease-free after a minimum of 2-year follow-up in the randomized Phase I trial in resected HPV-negative locally advanced head and neck cancer – Demonstrating clinical proof of principle for TG4050

Single agent TG4050 induced long-lasting neoantigen-specific CD8+ T cell responses

Treatment was well-tolerated with no unexpected safety signals

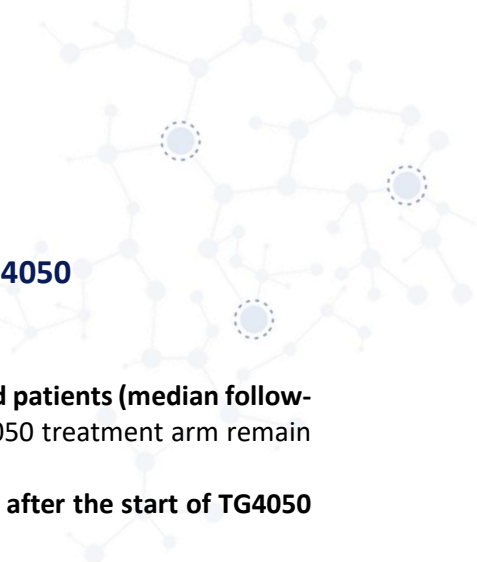
Data presented during rapid oral session at ASCO 2025

Conference call scheduled on Friday June 6, 2025 at 3:00 p.m. CET (in English). See details below

Strasbourg, France & Tokyo, Japan, June 1st, 2025, 7:15 p.m. CET – **Transgene (Euronext Paris: TNG)**, a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, and **NEC Corporation (NEC; TSE: 6701)**, a leader in IT, network and AI technologies, have presented new positive data on TG4050 in a rapid oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting.

These positive data confirm that individualized neoantigen therapeutic vaccine TG4050 is safe and feasible in the adjuvant setting of resectable HPV-negative locally advanced head and neck squamous cell carcinoma (HNSCC). **TG4050 induces, as monotherapy, long-lasting immune responses to vaccine neoantigens sustained for up to 2 years, and these results met all trial endpoints ([NCT04183166](https://clinicaltrials.gov/ct2/show/study/NCT04183166))** including safety, feasibility, immune activation and disease-free survival (defined as survival without recurrence or death for any cause).

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



Positive data from Phase I, confirming proof of principle of Transgene's viral vector based individualized cancer vaccine TG4050 in HPV-negative locally advanced head and neck cancer

- **100% disease free survival at a minimum of 2-year follow-up of treated patients (median follow-up: 30 months) in the Phase I part of the trial:** all patients in the TG4050 treatment arm remain disease free while 3 patients in the observational arm have relapsed.
- **Persistence of neoantigen-specific CD8+ T cell responses over 2 years after the start of TG4050 has been observed.**

Dr. Alessandro Riva, CEO of Transgene, commented: *"The sustained clinical and immunogenicity outcomes observed over two years of TG4050 monotherapy, along with the positive safety profile, mark an important milestone for Transgene. These results reinforce both the clinical promise of TG4050 and our commitment to accelerate the development of this individualized immunotherapy in adjuvant setting for patients with HPV-negative, locally advanced head and neck cancer."*

Motoo Nishihara, Corporate EVP, and CTO, at NEC, commented: *"This positive readout, combined with the durability of the efficacy data at two years, underscore the clinical potential of individualized cancer vaccine programs. It is a strong validation of our innovative AI platform and our dedication to advancing solutions that deliver meaningful, long-term value to patients and healthcare systems alike."*

Ongoing Phase II part of Phase I/II clinical trial of individualized neoantigen therapeutic cancer vaccine TG4050

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 the promising data obtained in the Phase I part of the trial, Transgene and NEC extended the joint development of TG4050 in this indication with a Phase II extension of the trial.

The Phase II part of the trial, aimed at confirming the encouraging results in a larger patient population and evaluating both immunological and clinical outcomes, is currently underway. All patients are expected to be randomized by Q4 2025. Altogether, the Phase I/II study will comprise approximately 80 patients.

Dr Christian Ottensmeier, MD, PhD, FRCP (University of Liverpool, La Jolla Institute for Immunology), will discuss the data presented at ASCO 2025, the unmet medical need and current treatment landscape for patients suffering from head and neck cancers in a live virtual event taking place on **June 6, 2025** (9:00 p.m. ET; 3:00 p.m. CET).

Webcast link to English language conference call:

<https://edge.media-server.com/mmc/p/x49uzc62>

Please log in to the following link to obtain your personal telephone IDs:

<https://register-conf.media-server.com/register/Bld8c981041ca84dad92bb2faa73fc5344>

A replay of the call will be available on the Transgene website (www.transgene.com) 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. 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](https://clinicaltrials.gov/ct2/show/study/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.

About NEC's Neoantigen Prediction System

NEC's neoantigen prediction system utilizes its proprietary AI, such as graph-based relational learning, trained on multiple sources of biological data to discover candidate neoantigen targets. These targets are carefully analyzed using proprietary machine learning algorithms that include in-house HLA binding and antigen presentation AI tools to evaluate the likelihood of eliciting a robust and clinically relevant T-cell response. With NEC OncoImmunity now on board, NEC continues to strengthen its top-class neoantigen prediction pipelines with the aim of maximizing the therapeutic benefits of personalized cancer immunotherapy for patients worldwide.

For more information, please visit NEC Bio at <https://www.nec-bio.com> or https://www.nec-bio.com/en_DD/research-and-innovation/our-approach/

About NEC Corporation

NEC Corporation has established itself as a leader in the integration of IT and network technologies while promoting the brand statement of "Orchestrating a brighter world." NEC enables businesses and communities to adapt to rapid changes taking place in both society and the market as it provides for the social values of safety, security, fairness and efficiency to promote a more sustainable world where everyone has the chance to reach their full potential.

For more information, visit NEC at <https://www.nec.com>

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.