

New Phase I Immunological Data Presented at SITC 2025 Support TG4050's Potential Role in Preventing Cancer Relapse

New data provide key mechanistic insights into how TG4050 induces and sustains potent, CD8+ T cell responses in operable HNSCC* patients

Comprehensive immunogenicity data demonstrate TG4050's ability to induce neoantigen-specific cytotoxic CD8+ T cell responses capable of targeting and eliminating tumor cells, supporting its potential to reduce risk of relapse

Conference call scheduled on November 14 at 4 p.m. CET (in English). See details below.

Strasbourg, France & Tokyo, Japan, November 4, 2025, 5:45 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, will jointly present **additional immunological data** profiling the immune response after treatment with the individualized neoantigen therapeutic vaccine (INTV) TG4050 **at the Society for Immunotherapy of Cancer (SITC) Annual Meeting**. The conference will be held in National Harbor, Maryland, USA, from November 5 to 9, 2025.

Comprehensive immunogenicity data confirm 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.**

Prof. Le Tourneau, MD, PhD, Medical Oncologist at Gustave Roussy, and Principal Investigator, commented: *"These new immunological data provide compelling evidence confirming TG4050's mechanism of action. They also offer a clear rationale for the sustained prevention of relapses, which is a critical outcome for long-term patient benefit."*

Data presented at SITC demonstrate that **TG4050 monotherapy induces a potent CD8+ T cell response consistent with durable anti-tumor immunity:**

- Vaccine-induced cytotoxic CD8+ T cells display an **effector phenotype** even one year after the end of treatment, suggesting potential long-term effector functions.

* Head and Neck Cell Carcinoma

- CD8+ T cells express high levels of **cytotoxic and tissue-resident biomarkers**, suggesting that these cells are effective at killing cancer cells and likely to be found not only in the blood but also in tissues, where they can scout for and eliminate tumor cells.

The **abstract** is available on both the [SITC](#) and [Transgene](#) websites. The **poster presentation** will take place on **November 8** and will be available that day on both the SITC and Transgene's websites.

Dr. Emmanuelle Dochy, MD, Chief Medical Officer of Transgene, said: *"We are extremely proud to present new immunological data that further characterize the CD8+ T cell responses against the selected neoantigens. These translational data confirm that the vaccine selected neoantigens induce an efficient immune response. TG4050 is currently being evaluated in the Phase II part of our ongoing Phase I/II study. The first immunogenicity data from this Phase II part are expected to be available in the second half of 2026."*

Motoo Nishihara, Corporate EVP and CTO, at NEC, added: *"These findings highlight the strong potential of NEC's AI-driven platform in enabling the development of individualized neoantigen therapeutic vaccines. The confirmation of the mechanism of action and evidence of durable relapse prevention mark important milestones that reinforce our dedication to revolutionizing cancer treatment through cutting-edge AI innovation."*

Transgene and NEC previously shared data (see [press release](#)) illustrating that CD8+ T cells specific to tumor neoantigens have been detected in patients treated with TG4050. These cells target multiple neoantigens encoded in the vaccine and their responses persist for up to two years after the start of the treatment.

Transgene will host a webcast (in English) to discuss the SITC data on November 14, 2025, from 10:00 a.m. to 11:00 a.m. ET (4 p.m. to 5 p.m. CET).

Webcast link to English language conference call:

<https://lifescievents.com/event/fsp25g74n/>

The webcast and the replay will be available [here](#) and on [Transgene's](#) website 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 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 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 through advanced Artificial Intelligence technologies.

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 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](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. 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.

About NEC's Neoantigen Prediction System

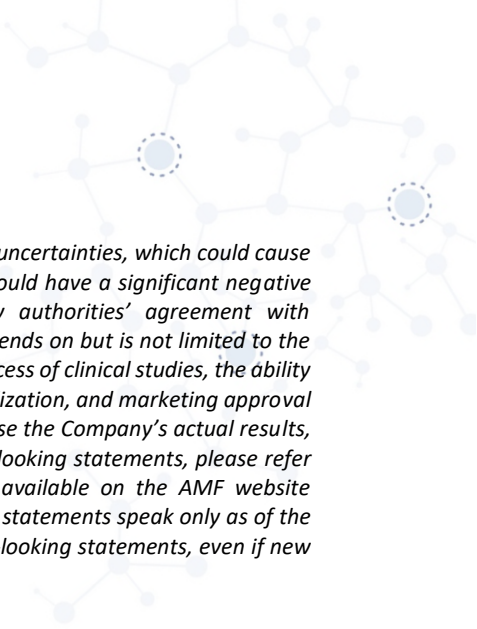
NEC's neoantigen prediction system utilizes its proprietary AI, such as graph-based relational learning, trained on multiple sources of biological data to discover candidate neoantigen targets. These targets are carefully analyzed using proprietary machine learning algorithms that include in-house HLA 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

The NEC Group leverages technology to create social value and promote a more sustainable world where everyone has the chance to reach their full potential. NEC Corporation was established in 1899. Today, the NEC Group's approximately 110,000 employees utilize world-leading AI, security, and communications technologies to solve the most pressing needs of customers and society.

For more information, please visit <https://www.nec.com>, and follow us on Instagram, Facebook, and LinkedIn.



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.