

Transgene and NEC Report 100% Three-Year Disease-Free Survival with TG4050 and Publish Phase 1 Results in *Nature Communications*

TG4050 as a single agent has the potential to prevent recurrence in head and neck cancer

Peer-reviewed publication in *Nature Communications* highlights the Phase 1 clinical and translational findings, including durable neoantigen-specific T cell responses

Together, the long-term clinical and translational data further strengthen confidence in Transgene's individualized neoantigen therapeutic vaccine approach and *myvac*® platform

Strasbourg, France & Tokyo, Japan, September 2, 2026, 6:00 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, today report sustained 100% three-year disease-free survival (DFS) in patients treated with TG4050 in the Phase 1 part of a randomized Phase 1/2 trial evaluating TG4050, the first individualized neoantigen therapeutic vaccine (INTV) based on the *myvac*® platform, in patients with resected, locally advanced HPV-negative head and neck squamous cell carcinoma (HNSCC).

The companies also announced the publication of the Phase 1 comprehensive clinical and translational data from the study, for the first time in the peer-reviewed journal *Nature Communications*.

Three-year follow-up data from the Phase 1 trial continue to demonstrate durable clinical outcomes in the adjuvant setting, with all 16 TG4050-treated patients remaining disease-free while three of 16 patients in the control arm experienced relapse after a median follow-up of 41 months. TG4050, encoding up to 30 patient-specific neoantigens, also continues to demonstrate a favorable safety profile with no unexpected safety findings.

The peer-reviewed publication builds on the Phase 1 results first shared with the scientific community through a prepublication on [medRxiv](#) and presents comprehensive clinical and

translational findings based on the study's primary data cut-off, including detailed analyses of vaccine-induced immune responses. Together, the clinical and translational findings provide further evidence supporting TG4050 as a potential individualized immunotherapy for patients with head and neck cancer at high risk of relapse following surgery and (chemo)-radiotherapy.

*"The publication of these data in Nature Communications, together with the sustained three-year disease-free survival observed with TG4050 monotherapy, represents an important milestone for Transgene," commented **Alessandro Riva, MD, Chairman and Chief Executive Officer of Transgene.** "Beyond the encouraging clinical outcomes, the sustained neoantigen-specific immune responses observed over time provide important evidence that our individualized therapeutic vaccine approach can generate durable anti-tumor immunity, strengthening our confidence in TG4050 as a potential new treatment option for head and neck cancer patients at high risk of relapse."*

*"The latest three-year follow-up data further reinforce the ability of individualized neoantigen-based immunotherapy and the capacity of TG4050 to deliver continued clinical benefit for patients with head and neck cancer," said **Masaki Kondo, Corporate Executive and Managing Director, Life Science Division of NEC Corporation.** "These results additionally demonstrate that NEC's AI-powered neoantigen prediction can identify highly relevant tumor targets capable of generating clinically meaningful immune responses. We are proud of our collaboration with Transgene and remain committed to advancing innovative technologies that help bring individualized cancer treatments to patients."*

The Phase 1 clinical and translational data published in *Nature Communications* demonstrate robust and persistent neoantigen-specific CD8+ T-cell responses consistent with the proposed vaccine's mechanism of action. Vaccine-induced responses were detected in 73.3% of patients treated with TG4050, with a median of three responding neoantigens per responder. These responses were maintained throughout treatment and persisted for more than one year after the last vaccination, providing evidence of durable anti-tumor immunity.

*"Robust and persistent CD8+ T-cell responses against patient-specific tumor neoantigens were observed following TG4050 vaccination, supporting the vaccine's ability to generate a targeted anti-tumor immune response. These results further reinforce the potential of TG4050 as an individualized immunotherapy for patients with head and neck cancer at risk of recurrence for whom there is a major unmet need," added **Prof. Christian Ottensmeier, MD, PhD, FRCP, University of Liverpool, La Jolla Institute for Immunology and Principal Investigator.***

TG4050 continues to be evaluated in the ongoing randomized Phase 1/2 clinical trial ([NCT04183166](#)) in patients with resected HNSCC. Key upcoming milestones include first immunological data and two-year efficacy data (DFS) from the Phase 2 study respectively in H2 2026 and Q1 2028.

References

C. Ottensmeier *et al.* A viral-based individualized neoantigen vaccine as adjuvant treatment in resected head and neck squamous cell carcinoma: a randomized Phase I trial. *Nature Communications*, 2026.

Online publication: <https://doi.org/10.1038/s41467-026-76667-1>

The article is available on [Nature Communications](#), and via the NEC Bio and 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. TG4070, a second individualized vaccine candidate derived from the *myvac*® platform, is in Phase 1 clinical development in combination with nivolumab in adjuvant non-small lung cancer (NSCLC). 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 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. To support this approach, Transgene has established a highly integrated set of end-to-end capabilities combining artificial intelligence, bioengineering, digital transformation, established vectorization know-how and unique manufacturing capabilities. TG4050, its first candidate, is currently evaluated in a randomized Phase 2 in resected HNSCC. TG4070, its second candidate, is being evaluated in a randomized Phase 1 trial in NSCLC. Transgene has been awarded "Investment for the Future" funding from Bpifrance for the development of its platform *myvac*®. 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 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.

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.

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

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

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