PRESS RELEASE

Transgene - First Patient Enrolled in Phase II Part of Randomized Phase I/II Trial Evaluating Lead Cancer Vaccine TG4050 in Head and Neck Cancer

Patient screening and enrollment initiated for the Phase II part of the international randomized Phase I/II trial with an overall sample size of approximately 80 patients.

Last patient enrollment for Phase II part expected in Q4 2025.

Strasbourg, France, June 3, 2024, 7:30 a.m. CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer today announces that the first patient has been enrolled in the Phase II part of the randomized Phase I/II clinical trial of the individualized therapeutic cancer vaccine, TG4050, in the adjuvant treatment of head and neck cancer. Patient screening and enrollment are active, with the aim of enrolling 80 patients internationally in the overall Phase I/II trial.

TG4050 is based on Transgene's *myvac*® viral vector platform and NEC's cutting-edge AI capabilities for the identification and prediction of the most immunogenic neoantigens for each patient. The therapeutic vaccine, TG4050, is being jointly developed by Transgene and NEC in head and neck cancer.

TG4050 advancing to Phase II part based on Phase I data showing immunogenicity and first signs of clinical benefit.

The promising TG4050 Phase I data presented at AACR 2024 (see press release distributed on April 9, 2024, here) showed strong immunogenicity, persistent cellular immune response as well as signs of clinical benefit for patients. At the time of the analysis, only patients in the control arm had relapsed, while all patients who received TG4050 were disease-free. Based on these promising data, Transgene and its partner NEC have decided to move forward with an extension of the randomized trial consisting of a Phase II part. This Phase II part will continue investigating single-agent TG4050 in patients with newly diagnosed, locoregionally advanced, HPV-negative, squamous cell carcinoma of the head and neck (SCCHN) in the adjuvant setting following completion of surgery and chemoradiotherapy.

Although some advancements in the treatment of SCCHN have been made, there remains a significant medical need for these patients, including in the adjuvant setting. With the current standard of care, 30% to 40% of patients are expected to relapse within 24 months following surgery and adjuvant therapy. Despite completed Phase III trials, immune checkpoint inhibitors have yet to demonstrate significant benefits for these patients.

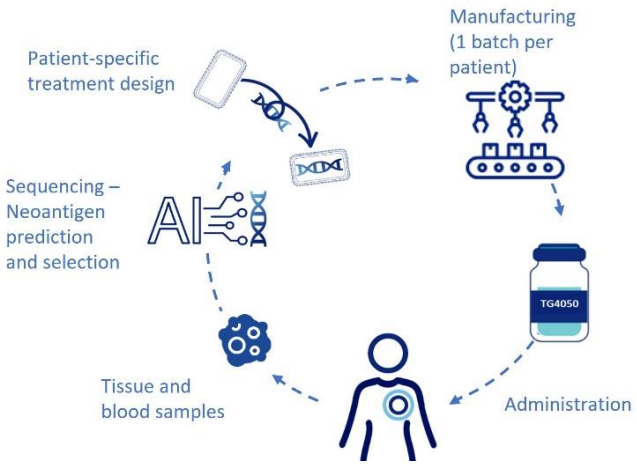
TG4050 is the only individualized neoantigen cancer vaccine currently being developed in a randomized trial in the adjuvant treatment of head and neck cancer.

Dr. Maud Brandely, MD, PhD, Chief Medical Officer of Transgene commented, *"The inclusion of the first patient in the Phase II part of our Phase I/II trial marks a further milestone for Transgene. In the ongoing trial, TG4050 is targeting patients with head and neck cancer at high-risk of relapse, with the aim of extending disease-free survival. The Phase I data we have generated indicate that TG4050 enables the induction of specific cellular immune responses that persist up to 7 months post treatment initiation, with all treated patients remaining disease-free after a median follow-up of 18.6 months. We are encouraged by these promising clinical outcomes and look forward to generating data from the Phase II part of the trial. Personalized cancer vaccines are an extremely exciting development and, if successful, could also be utilized to treat other forms of cancer to improve and extend the lives of patients."*

This international, multicenter, open label, two-arm trial is currently screening patients in France at IUCT-Oncopole (Toulouse) and Institut Curie (Paris). Additional sites in France, Europe and the US will be added in the coming months. Overall, the Phase I/II trial will randomize approximately 80 patients. The inclusion of the last patient in the Phase II part of the study is expected in Q4 2025.

TG4050 is designed based on each patient's tumor

TG4050 is an individualized immunotherapy derived from Transgene's *myvac*® platform, combining Transgene's biotechnology known-how and expertise with NEC's artificial intelligence (AI) capabilities. Cancer vaccines of this type are individually designed to stimulate and educate the patient's immune system to fight against their own cancer. This viral-based immunotherapy integrates about thirty tumor neoantigen, identified and selected from tumor sequencing to generate the most effective immune response.



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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 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 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 adjuvant therapy. Half of the participants receive their vaccine immediately after completing adjuvant treatment. The other half are 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 high-risk of relapse. In the Phase I/II study, approximately 80 evaluable patients will be included in France, the UK, and in the USA. The principal investigator of the trial is Prof. Christian Ottensmeier, MD, PhD, Consultant Medical Oncologist at the Clatterbridge Cancer Centre and Professor of Immuno-Oncology at the University of Liverpool. In France, the clinical trial is conducted at Institut Curie by Prof. Christophe Le Tourneau, MD, PhD, Head of the Department of Drug Development and Innovation (D3i), and at the IUCT-Oncopole, Toulouse by Prof. Jean-Pierre Delord, MD, PhD.

In the Phase I part of the trial, 32 evaluable patients have been included in France, the UK, and the USA. With a median 18.6-month follow-up, all the treated patients are disease free. Almost all treated patients (95%) developed specific cellular immune responses ($CD8^+$ and $CD4^+$) and the immune responses are persistent and induced against multiple targets. The Phase II part is currently enrolling patients. Endpoints of the trial include safety, feasibility, biological activity of the therapeutic vaccine, as well as disease-free survival (survival without recurrence or death for any cause).

About Transgene

Transgene (Euronext: TNG) is a biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing cancer cells.

The Company's clinical-stage programs consist of a portfolio of therapeutic vaccines and oncolytic viruses: TG4050, the first individualized therapeutic vaccine based on the *myvac*® platform, 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. 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.fr

Follow us on social media: X (formerly Twitter): @TransgeneSA – LinkedIn: @Transgene

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, visit NEC at www.nec.com.

For additional information, please also visit NEC OncoImmunity at https://www.oncoimmunity.com.

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 https://www.nec.com and NEC's AI Drug Development Business: https://www.nec.com/en/global/solutions/ai-drug/

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