PRESS RELEASE

Transgene and NEC Present New Data Confirming Clinical Proof of Principle for Neoantigen Cancer Vaccine, TG4050, in Head & Neck Cancer at SITC 2024

Compelling 24.1-month median follow-up data presented at SITC 2024 showed that all patients treated with TG4050 after completion of an adjuvant standard of care remain disease-free

TG4050 induced specific and sustained immune responses. A Phase II part is now enrolling patients internationally to build on this promising outcome

Strasbourg, France & Tokyo, Japan, November 7, 2024, 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, today announced 24.1-month median follow-up data from the ongoing randomized Phase I trial of TG4050 in the adjuvant treatment of head and neck cancers. The data will be presented in a poster at the *Society for ImmunoTherapy of Cancer* (SITC) 2024 Annual Meeting on November 9 in Houston, TX.

TG4050 is an individualized immunotherapy being developed for solid tumors that is based on Transgene's *myvac*® platform and powered by NEC's cutting-edge AI capabilities designed to optimize antigen selection.

After a median follow up of 24.1 months, all 16 patients who received TG4050 as adjuvant immunotherapy after completion of adjuvant standard of care remain disease-free and have not relapsed. Out of the 16 patients in the control observation arm, 3 patients have relapsed. There remains a high medical need for these head and neck cancer patients, as approximately 30% of them are expected to experience a relapse within 24 months after standard surgery and adjuvant chemoradiotherapy.

Immune responses targeting selected neoantigens were identified in 100% of patients who received TG4050, demonstrating the strong immunogenicity of the cancer vaccine, with both *de novo* and amplified responses. An analysis over 7 months also shows that immune responses are sustained, during the induction and boost periods.

All treatment-related adverse events continue to be mild to moderate.

Building on these promising data, the randomized Phase I trial has **been expanded to a randomized Phase I/II trial** in the adjuvant setting of head and neck cancer (NCT04183166), which is currently enrolling patients in the Phase II part.

Pr. Le Tourneau, MD, PhD, Head of the Department of Drug Development and Innovation (D3i) at Institut Curie, **and Principal Investigator**, said: *"There remains a significant unmet medical need in head and neck cancer patients in the adjuvant setting. It is therefore highly encouraging to see confirmation of TG4050's clinical and immune response data after a median follow-up of 24.1-months. TG4050 has demonstrated its potential to prime an adaptive immune response against tumor antigens and prevent relapse in patients with locally advanced resected head and neck squamous cell carcinoma (HNSCC)."*

Dr. Emmanuelle Dochy, MD, Chief Medical Officer of Transgene, added: *"We are very encouraged to observe that all the patients treated with our neoantigen cancer vaccine TG4050 remain disease-free after a median follow-up of 24.1 months. Looking at these results and at the long-lasting immune response, we are confident that TG4050 has the potential to benefit these patients, who still face a significant risk of relapse with current therapies. The Phase II part of our trial is currently enrolling patients internationally, with the aim of further confirming these promising findings."*

Motoo Nishihara, Corporate EVP and CTO, at NEC, added: *"These results illustrate the power of our collaboration with Transgene and our ability to develop a personalized approach to cancer patient treatment using our proprietary artificial intelligence and machine learning models. We have built a strong and compelling clinical data set to support the benefits of TG4050 as an individualized immunotherapy, and we remain committed to bringing novel AI-based treatments to patients across the globe."*

Poster details:

Title: **Randomized phase I trial of adjuvant individualized TG4050 vaccine in patients with locally advanced resected HPV-negative head and neck squamous cell carcinoma (HNSCC)**

- Abstract Number: 650
- Session: Clinical Trial In Progress
- Date: Saturday, Novembre 9, 2024
- Presenting Author: Prof. C. Le Tourneau, MD, PhD—Institut Curie

The SITC poster can be viewed in-person during the poster presentation at the SITC 2024 meeting and can be accessed on Transgene's website.

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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.

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

Disclaimer

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