PRESS RELEASE

Transgene and NEC Present New Data on TG4050, an Individualized Cancer Vaccine, Showing it Induces Specific Immune Responses against Head and Neck Carcinoma at ASCO 2023

New immunological data assessed by tetramer staining confirms the induction of T cell responses in treated patients

All trial patients treated with TG4050 monotherapy continue to remain in remission to date

Transgene and NEC are preparing a Phase II trial to further demonstrate the potential of TG4050 as an adjuvant treatment of head and neck cancer

Strasbourg, France & Tokyo, Japan, June 6, 2023, 7:30 a.m. CET/3:30 p.m. JST – **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,** announced that **new data have been presented on TG4050, an individualized neoantigen cancer vaccine,** at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL. **TG4050 is based on Transgene's *myvac*® platform and powered by NEC's cutting-edge AI capabilities.**

The new positive data have been generated from patients with HPV-negative head and neck cancer who have been enrolled in an ongoing randomized Phase I trial assessing TG4050 (NCT04183166). **All patients treated with TG4050 in the trial have developed a specific immune response, as demonstrated by the results of additional immunological testing, and remained disease-free to date.**

Alessandro Riva, Chairman and CEO of Transgene, added: *"TG4050 is showing its potential to extend patient remission after surgery and firmly establishes Transgene among the leading pioneers in the emerging field of individualized cancer vaccines. The monotherapy data we are presenting at ASCO are a solid basis to accelerate the clinical development of this innovative therapy as an adjuvant treatment to HPV-negative head and neck carcinoma and potentially in other indications."*

Masamitsu Kitase, Corporate Senior VP, Head of Healthcare and Life Science Division, NEC Corporation, commented: *"We are excited by the additional data from immunological testing that is being presented in the poster at ASCO. It is certainly an encouraging outcome for NEC's AI prediction for neoantigens that are able to effectuate an immunological response. These are early results that underpin NEC's AI capability of making predictions that help in making TG4050 an efficacious product for patients across the globe. We look forward to working with Transgene to develop on this asset further."*

TG4050 has demonstrated the ability to induce strong immune responses against targeted antigens

The data presented at ASCO 2023 show that **all evaluable patients developed a specific immune response after treatment with TG4050 against multiple cancer neoantigens.** These immune responses were developed **in spite of patients having unfavorable systemic immunity and tumor micro-environment** at baseline (with the presence of non-functional immune cells or with low or negative levels of PD-L1 expression). These challenging characteristics are normally associated with limited responses to treatments, including immune checkpoint blockers.

Two patient case studies are also being reported. In these patients who are disease-free following treatment with TG4050, immunoreactive T cell response against targeted antigens was assessed by tetramer staining. The results confirm a large amplification of the frequency of immunoreactive T cells. These T cells were characterized as effector cytotoxic T cells, a cell population with potential anti-tumor activity. These data further demonstrate that TG4050 is able to induce an anti-tumor cellular immune response.

All patients in the trial who received TG4050 remain disease-free to date

As of May 2023, 32 patients were randomized in the head and neck cancer Phase I trial. **All 16 patients who received TG4050 remained disease-free, with a median follow-up time of 10.4 months.** This compares favorably to the control arm, in which two patients with similar characteristics experienced relapse. Two other patients also showed biochemical signs of relapse, as seen in the poster. These patients are still being followed in the ongoing trial.

To date, the vaccine has been well tolerated and no related Serious Adverse Events have been reported.

The abstract and poster can be accessed on the ASCO and Transgene websites.

Final results from randomized Phase I trial expected in mid-2024 – Phase II trial to start in H2 2023

The last patient has recently been randomized in the head and neck cancer trial. Transgene and NEC plan to achieve a median follow up of 18 months in mid-2024.

Transgene and NEC are preparing for a Phase II trial in head and neck cancer, in an adjuvant setting, which could be initiated in H2 2023.

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About the clinical trials

TG4050 is being evaluated in two Phase I clinical trials for patients with HPV-negative head and neck cancers (NCT04183166) and ovarian cancer (NCT03839524).

In a first Phase I trial, TG4050 is being administered to patients with HPV-negative head and neck cancer. An individualized treatment is created for each patient after they complete surgery and while they receive an adjuvant therapy. Half of the participants receive their vaccine immediately after they complete their adjuvant treatment. The other half is 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 have a high risk of relapse. Up to 30 patients will receive TG4050 in France, in 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 being 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 USA, the trial is being led by Yujie Zhao, MD, PhD, at the Mayo Clinic. Endpoints of the trial include safety, feasibility and biological activity of the therapeutic vaccine.

In parallel, a Phase I clinical trial of TG4050 is enrolling patients with ovarian cancer. This second trial is including patients at the time of asymptomatic relapse after surgery and first-line chemotherapy. Matthew Block, MD, PhD, Consultant Medical Oncology, Consultant Immunology and Associate Professor of Oncology at the Mayo Clinic (USA) is the principal investigator of the trial; in France, the trial is being conducted by Prof. Le Tourneau, MD, PhD, at Institut Curie and by Alexandra Martinez, MD, Associate Head of Surgical Department, at IUCT-Oncopole. Endpoints of the trial include safety, feasibility and biological activity of the therapeutic vaccine.

The first preliminary clinical data generated with TG4050 are very encouraging.

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, recognize and destroy tumors using the patient's 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) 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 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 TG6002, BT-001 and TG6050, three 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: 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 onboard, 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/

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