

New Data Showing that Transgene and NEC's Individualized Cancer Vaccine TG4050 Induces Strong and Specific Immune Responses against Tumors Presented at AACR 2023

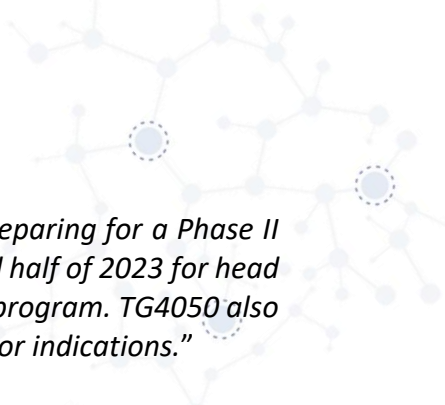
- New Phase I data confirm promising immunogenicity and efficacy profile of TG4050, an individualized neoantigen cancer vaccine developed by Transgene in collaboration with NEC Corporation
- In the head and neck cancer trial to date, all patients treated with TG4050 have remained disease-free, despite unfavorable systemic immunity and tumor micro-environment before treatment
- Transgene and NEC are considering the most appropriate path towards registration in head and neck, with a Phase II trial to be initiated in H2 2023

Strasbourg, France & Tokyo, Japan, April 18, 2023, 9:00 a.m. CET/4:00 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 will be presented today on TG4050, an individualized neoantigen cancer vaccine**, at the American Association for Cancer Research (AACR) Annual Meeting in **Orlando, Florida**. **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 and with ovarian cancer, who have been enrolled in two ongoing Phase I trials assessing TG4050.

TG4050 has demonstrated the ability to induce strong immune responses against targeted antigens in patients, which are expected to result in extended remission periods.

Hedi Ben Brahim, CEO of Transgene, added: *“Our individualized neoantigen vaccine TG4050 continues to deliver very encouraging clinical and immune response data, combined with an excellent safety profile. These results suggest that TG4050 has the potential to extend the remission period for cancer patients who have undergone surgery, giving new hope to a patient population who currently have no treatment options available except a watchful follow up. We are continuing to build a strong and compelling clinical data set to support the benefits of this*



novel personalized immunotherapy. In parallel, we, along with NEC, are preparing for a Phase II trial as part of the registration path, which could start as early as the second half of 2023 for head and neck cancer, which represents a \$1 billion+ market opportunity for the program. TG4050 also has the potential to be developed for preventing relapses in other solid tumor indications.”

Masamitsu Kitase, Corporate Senior VP, and Managing Director of Healthcare Life Sciences Business, NEC Corporation, commented: *“It is very encouraging to see such promising clinical and immune response data contributing to the momentum of TG4050’s development. We look forward to working closely with Transgene to maintain this advancement, and we are confident that our personalized therapy will benefit the health of individual patients across the globe.”*

New immune data confirm the ability of TG4050 to effectively prime the immune system in patients with poor immune status

The new set of comprehensive immunological data presented at AACR 2023 show that all evaluable patients developed a specific immune response after treatment with TG4050 against multiple cancer neoantigens and remained disease-free, in spite of having challenging immune contexts comprised of both unfavorable systemic immunity and tumor micro-environment at baseline. These are normally associated with limited responses to treatments, and in particular resistance to immune checkpoint blockades.

This suggests that TG4050 can boost the immune system of patients with a tumor micro-environment usually characterized as an immune desert or involving the presence of non-functional immune cells, or with low or negative levels of PD-L1 expression.

In addition, these data confirm that all evaluable patients developed robust T-cell responses against multiple targeted neoantigens (median of 9 positive responses per patient out of approximately 30 targets). T-cell responses were observed for class I and class II epitopes, consisting of both de novo responses and amplifications of preexisting responses.

Vaccination was well tolerated and associated with encouraging preliminary signs of anti-tumor efficacy

As of March 2023, 32 patients were randomized in the head and neck cancer trial. All 16 patients who received TG4050 remained disease-free, with a median follow-up time of 9.2 months. This compares favorably to the control arm, in which two patients with similar characteristics experienced relapse. These patients are still followed in the ongoing trial.

Transgene expects the last patient to be treated in the coming weeks. Final results from this trial are expected in mid-2024.

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

Phase II trial to start in H2 2023

Transgene and NEC are preparing for a Phase II trial in head and neck cancers which could be initiated in H2 2023.

An abstract and poster can be accessed on the [AACR](#) and [Transgene](#) websites.

Dr Christian Ottensmeier, MD, PhD, FRCP (University of Liverpool, La Jolla Institute for Immunology) will discuss the unmet medical need and current treatment landscape for patients suffering from head and neck cancers in a live virtual event taking place on April 19, 2023 (12:00 pm ET; 6:00 pm CET). Click [here](#) to register or listen to the replay.

Contacts

Transgene:

Lucie Larguier

Director Corporate Communications & IR

+33 (0)3 88 27 91 04

investorrelations@transgene.fr

Media: MEDiSTRAVA Consulting

David Dible/Sylvie Berrebi

+44 (0)203 928 6900

transgene@medistrava.com

NEC Corporation:

AI Drug Development Division

contact@aid.jp.nec.com

NEC Corporation:

Joseph Jasper

j-jasper@nec.com

+81-3-3798-6511

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 from the first patients treated with TG4050 were 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. Transgene has an ongoing Invir.IO® collaboration with AstraZeneca.

Additional information about Transgene is available at: www.transgene.fr

Follow us on social media: Twitter: [@TransgeneSA](https://twitter.com/TransgeneSA) – LinkedIn: [@Transgene](https://www.linkedin.com/company/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/>



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.fr). 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.