PRESS RELEASE

Transgene and NEC Present First Clinical Benefits of Neoantigen Cancer Vaccine, TG4050, in Head & Neck Cancer at AACR 2024

Extensive Phase I immunology data confirm strong immunogenicity of TG4050 in the adjuvant treatment of head and neck cancers.

All treated patients remain disease-free after a median follow-up of 18.6 months.

Phase II part of the trial to start enrolling patients in coming weeks.

Strasbourg, France & Tokyo, Japan, April 9, 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,** announced that **new data will be presented on TG4050, an individualized neoantigen cancer vaccine,** at the American Association for Cancer Research **(AACR)** Annual Meeting in San Diego, CA. These data are highlighted in the AACR press conference being held today and in a poster presentation which will take place tomorrow, April 10, at 9:00 a.m. PDT.

TG4050 is based on Transgene's *myvac*® platform and powered by NEC's cutting-edge AI capabilities designed to optimize antigen selection.

Key findings of the poster include:

- **All 16 patients who received TG4050 are disease free after a median 18.6-month follow-up. Out of the 16 patients in the control observation arm, 3 patients have relapsed. For this head and neck cancer patient population** and with current standard of care, approximately 40% of patients are expected to relapse within 24 months following surgery and adjuvant therapy (chemoradiotherapy). Also, the tumor immune contexture, expression of immune factors, mutational burden, and tumor infiltrates are associated with challenging prognoses.
- **Specific cellular immune responses (CD8+ and CD4+) were detected in the 16/17 patients who received TG4050** (16 patients in the treatment arm and one patient from the observation arm treated after relapse) using stringent testing criteria**.** Immunogenicity or the capacity of treatment to induce immune responses are key to prevent relapses.
- **TG4050 induced persistent immune responses against multiple targets in several patients. T cell responses were maintained beyond 211 days (7 months) after the initiation of the treatment.** The duration of the immune response is also a key factor to fight disease over time.

Alessandro Riva, Chairman and CEO of Transgene, commented: *"We are honored by AACR's interest in the Phase I data generated from our individualized cancer vaccine TG4050. It is exciting to note that all patients who received TG4050 remain disease-free after a median follow-up of 18.6 months, which compares favorably to the observational arm which saw 3 out of 16 patients relapse during the same period."*
"More importantly, almost all treated patients developed a specific immune response against the antigen targets we selected, providing robust proof of principle for our lead candidate. TG4050 is now starting to show a potential benefit for head and neck cancer patients at high risk of relapse. We look forward to starting the Phase II part of the trial in the adjuvant setting for head and neck cancer."

Dr. Oliver Lantz, Head of the clinical immunology laboratory at Institut Curie, added: *"The immunological data generated by TG4050 demonstrate a robust and specific cellular immune response, even under stringent measurement criteria. The diversity, depth and duration of these responses were most certainly a key factor in preventing relapse in the patients treated with TG4050."*

Masamitsu Kitase, Corporate SVP and Head of the Healthcare and Life Sciences Division at NEC, concluded: *"Our state-of-the-art proprietary artificial intelligence and machine learning models have allowed us to identify immunogenic and clinically relevant mutations in all head and neck cancer patients for this TG4050 randomized Phase I trial. These tumors were characterized by a low tumor mutation burden, which presents an obstacle to designing a relevant vaccine. Our powerful platform enables us to identify mutations for individualized treatments which have now shown the first signs of clinical benefit for patients. Together with Transgene, we look forward to continuing to build on these promising data through our planned Phase II trial in the adjuvant treatment of head and neck cancer."*

TG4050 is being evaluated in a randomized multicenter Phase I/II trial as a **single agent in the adjuvant treatment of HPV-negative head and neck cancers** (NCT04183166). Based on promising data obtained in the Phase I part of the trial, Transgene and NEC are preparing a randomized Phase II extension of this trial slated to start in the second quarter of 2024.

The poster can be viewed in-person during the poster presentation at the AACR 2024 meeting and 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 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 in this trial under way in France, the UK, and 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 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. Initial immunological and clinical data presented at AACR 2023, ASCO 2023 and AACR 2024 are very encouraging. The Phase II part of the trial is expected to start in Q2 2024.

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/

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