

Transgene and NEC Extend their Collaboration to Continue Joint Clinical Development of Neoantigen Cancer Vaccine TG4050

Transgene and NEC plan to start an extension of the randomized Phase I trial into a randomized Phase I/II study in 2024 to further demonstrate the potential of TG4050 as an adjuvant treatment of head and neck cancers

Strasbourg, France & Tokyo, Japan, January 8, 2024, 5:45 p.m. CET/January 9, 2024, 09:00 a.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, have announced the signing of a further development collaboration agreement to continue the clinical evaluation of the individualized neoantigen cancer vaccine TG4050.

TG4050 is currently being evaluated in a randomized multicenter Phase I trial as a **single agent in the adjuvant treatment of HPV-negative head and neck cancers**. Based on promising data obtained in the Phase I* trial ([NCT04183166](#)), Transgene and NEC are preparing a randomized Phase I/II extension of this trial slated to start in 2024. This new trial builds on compelling first signs of efficacy and induction of specific T-cell responses with the aim of generating a comprehensive set of immunological and clinical data to further demonstrate the potential of TG4050.

Transgene and NEC expect to present additional immunological and clinical data from the Phase I trial at a scientific conference in the first half of 2024.

TG4050 is based on Transgene's viral vector based *myvac*[®] platform and powered by NEC's cutting-edge AI capabilities for the identification and prediction of the most immunogenic neoantigens.

Alessandro Riva, Chairman and CEO of Transgene, commented: *"We are pleased to announce the extension of our agreement with NEC, which marks a significant milestone in our collaboration. We are looking forward to continuing to treat patients in our clinical studies with our individualized cancer vaccine TG4050. The compelling initial Phase I data presented with NEC at ASCO 2023 showed that all evaluable patients treated with TG4050 monotherapy developed a specific immune response and remained disease-free.*

Our joint clinical development plan builds on these promising data in a setting where there is no approved treatment to prevent patient relapse after adjuvant chemoradiotherapy. We believe that TG4050, by

* Ottensmeier et al., "Safety and Immunogenicity of TG4050: a personalized cancer vaccine in head and neck carcinoma" [ASCO 2023](#), June 6, 2023, Poster presentation

combining a powerful and immunogenic viral vector with an extremely sophisticated neoantigen selection tool, has the potential to address major medical needs in the adjuvant treatment of solid tumors.”

Masamitsu Kitase, Corporate SVP, Head of Healthcare and Life Sciences Division, NEC Corporation, commented: “Transgene has been our trusted partner in developing our joint neoantigen asset TG4050. I am excited that the positive results from the Phase I study have encouraged us to further collaborate on this very promising asset for treating head and neck cancers. We are happy that our state-of-the-art artificial intelligence (AI)/machine learning (ML) models help in predicting clinically meaningful neoantigens, which impact patient outcomes. NEC’s Healthcare and Life Sciences Division is committed to bringing novel AI-based treatments to patients across the globe and achieving meaningful advances in the pharmaceutical industry.”

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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 clinical trial for patients with HPV-negative head and neck cancers ([NCT04183166](https://clinicaltrials.gov/ct2/show/study/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. Thirty-two 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 and ASCO 2023 are very encouraging.

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](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 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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