

## First Head & Neck Cancer Patient Treated in France in a Phase I trial with TG4050 (*myvac*<sup>®</sup> Platform), Transgene's Innovative Individualized Immunotherapy

Strasbourg, France, January 21, 2021, 07:30 am CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapeutics against cancer, today announces that a first patient with head and neck cancer has been dosed with the Company's innovative individualized immunotherapy, TG4050. This novel therapeutic vaccine is based on Transgene's *myvac*<sup>®</sup> technology platform, which leverages cutting-edge Artificial Intelligence (AI) capabilities to customize the treatment for each patient.

This innovative approach combines Transgene's expertise in virus-based immunotherapies, NEC's longstanding AI technologies and the commitment of prestigious cancer care centers.

**THE FIRST PATIENT HAS BEEN DOSED AT THE IUCT ONCOPOLE IN TOULOUSE**, France, where the trial enrolling head and neck cancer patients, is being conducted by Prof. Jean-Pierre Delord, Director of the Claudius Regaud Institute and General Manager of the IUCT Oncopole.

**Prof. Jean-Pierre Delord** added: *"Each tumor has its own very specific potential immune targets. The goal of TG4050 is to provide the immune system with the information it needs to identify cancer cells and trigger a targeted immune response to treat the disease. Head & neck cancer patients currently have no effective treatments to prevent recurrence of the disease and half of these high-risk patients will relapse within the first year after initial treatment. TG4050 can address the medical need of these patients either as single agent or in combination with standard of care. The IUCT Oncopole is an institution with a state-of-the-art cancer research unit and can rely on highly specialized teams to conduct this clinical trial and evaluate how TG4050 has the potential to benefit cancer patients."*

### **TG4050 IS A CANCER VACCINE FULLY CUSTOMIZED FOR EACH PATIENT COMBINING BEST-IN-CLASS THERAPEUTIC VACCINE RESEARCH AND CUTTING-EDGE AI TECHNOLOGY**

Transgene's highly innovative technology platform, *myvac*<sup>®</sup>, enables the generation of a virus-based immunotherapy, which encodes patient-specific cancer cell mutations (neoantigens) identified and selected by NEC's Neoantigen Prediction System (NPS), an advanced AI technology approach. TG4050 has been designed to target up to 30 patient-specific neoantigens.

With more than 20 years of AI expertise, NEC's NPS has been trained using both proprietary and public immune databases. Preclinical work with the *myvac*<sup>®</sup> technology platform has demonstrated that NEC's AI-based tumor mutanome profiling tool accurately selects and prioritizes the most immunogenic neoantigens from each unique tumor<sup>1</sup>.

<sup>1</sup> Mallone et al., "Performance of neoantigen prediction for the design of TG4050, a patient specific neoantigen cancer vaccine", [AACR](#), June 2020

Transgene is using its expertise in viral genome engineering to incorporate the selected neoantigens into the DNA of the *myvac*<sup>®</sup>-MVA viral vector.

The company has also set up a unique in-house Good Manufacturing Practices (GMP) unit dedicated to the manufacturing of the individualized batches of TG4050 that are needed for the ongoing Phase I clinical studies with this novel therapeutic vaccine.

## **FIRST DATA FROM TWO ONGOING CLINICAL TRIALS EXPECTED IN 2H 2021**

In a first Phase I trial, TG4050 is being administered to patients with HPV-negative head and neck cancer. A personalized 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 will be given TG4050 as an additional treatment at the time of recurrence of the disease. 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, 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, Paris, by Prof. Christophe Le Tourneau, M.D., Ph.D., Head of the Department of Drug Development and Innovation (D3i) and at the IUCT-Oncopole, Toulouse, by Prof. Jean-Pierre Delord.

In parallel, a Phase I clinical trial of TG4050 is enrolling patients with ovarian cancer. The first patient has been dosed in the USA. This second trial is including patients after surgery and first-line chemotherapy. Dr. Matthew Block, 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 at Institut Curie and by Dr. Alexandra Martinez, Associate Head of Surgical Department, at Toulouse-Oncopole.

**The first data from the two trials evaluating TG4050 are expected in 2H 2021.**

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### **About TG4050**

TG4050 is an individualized immunotherapy being developed for solid tumors that is based on Transgene's *myvac*<sup>®</sup> 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.

This best-in-class candidate is being evaluated in two Phase I clinical trials for patients with ovarian cancers ([NCT03839524](https://clinicaltrials.gov/ct2/show/study/NCT03839524)) and HPV-negative head and neck cancers ([NCT04183166](https://clinicaltrials.gov/ct2/show/study/NCT04183166)).

### **About myvac®**

*myvac*® is a viral vector (MVA) 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 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 two therapeutic vaccines (TG4001 for the treatment of HPV-positive cancers, and TG4050, the first individualized therapeutic vaccine based on the *myvac*® platform) as well as two oncolytic viruses (TG6002 for the treatment of solid tumors, and BT-001, the first oncolytic virus based on the Invir.IO™ platform).

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//](http://www.transgene.fr) Follow us on Twitter: [@TransgeneSA](https://twitter.com/TransgeneSA)

### **About IUCT-Oncopole**

Located in the heart of Future Health Campus, the IUCT-Oncopole gathers the Institut Claudius Regaud, a cancer center, and several teams from Toulouse University Hospital Center. Both group together 1 600 professionals specialized in onco-hematology. The IUCT-Oncopole carries out 3 missions to fight against cancer: care, research and training. Stand against its building, the Toulouse Cancer Research Center (CRCT) includes 21 basic and transfer research team, i. e. 430 researchers, clinicians and staff.

[www.iuct-oncopole.fr](http://www.iuct-oncopole.fr)

### **Disclaimer**

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