

First Head & Neck Cancer Patient Enrolled in the UK in a Phase I Trial with TG4050 (*myvac*[®] Platform), Transgene's Innovative Individualized Immunotherapy

Strasbourg, France, June 28, 2021, 07:00 am CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapeutics against cancer, today announces that the first UK patient has been enrolled in the Phase I clinical trial of TG4050, Transgene's innovative individualized cancer immunotherapy, currently being evaluated in HPV-negative head and neck cancer patients. TG4050 is a therapeutic vaccine based on Transgene's *myvac*[®] technology platform, which leverages Transgene's proprietary technologies and cutting-edge Artificial Intelligence (AI) capabilities to customize the treatment for each patient.

The innovative approach behind TG4050 combines Transgene's expertise in virus-based immunotherapies, NEC's longstanding AI technologies and the commitment of prestigious cancer care centers in the United Kingdom, the European Union, and the United States.

THE FIRST UK PATIENT OF THE TRIAL EVALUATING THIS INDIVIDUALIZED CANCER IMMUNOTHERAPY HAS BEEN INCLUDED IN LIVERPOOL, UK, in a trial enrolling patients with squamous cell carcinoma of the head and neck.

The trial is led by the coordinating investigator Professor Christian Ottensmeier, Consultant Medical Oncologist at The Clatterbridge Cancer Centre and Professor of Immuno-Oncology at the University of Liverpool. In the UK, the trial is being conducted in Liverpool and in Southampton (at the Clatterbridge Cancer Centre NHS Foundation Trust, at Liverpool University Hospitals and at the University Hospital Southampton NHS Foundation Trust / University of Southampton).

Professor Christian Ottensmeier, M.D., Ph.D., coordinating investigator of the study, added: *"We are pioneering the personalized cancer vaccine field. If successful, this technique could be a potentially game-changing development in the treatment of advanced head and neck cancers. We have spent the last 15 years working on the science behind this immunotherapy so it is very gratifying to be beginning clinical trials with the first patient being enrolled in the UK. Head and neck cancers are particularly complex to treat if they spread and cannot then be completely removed surgically. Personalized cancer vaccines are an extremely exciting development and, if successful, the same technique could also be applied to treat other forms of cancer."*

Dr. Maud Brandely, M.D., Ph.D., Chief Medical Officer of Transgene, added: *“We are delighted to start the clinical trial with our individualized myvac[®] immunotherapy in the UK. We have been collaborating for several years with Professor Ottensmeier on this novel therapy to better target tumor cells and we are excited to see that our world-leading innovations are now reaching patients in different countries in Europe and in the USA. We are convinced that, together with leading scientists and clinicians, we will be able to demonstrate the value of our individualized approach against head and neck cancer and leverage these future results to target other solid tumors.”*

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[®]*, 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[®]* technology platform has demonstrated that NEC’s AI-based tumor mutanome profiling tool accurately selects and prioritizes the most immunogenic neoantigens from each unique tumor¹.

Transgene is using its expertise in viral genome engineering to incorporate the selected neoantigens into the DNA of the *myvac[®]*-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 4Q 2021

In a first Phase I trial, TG4050 is being administered to patients with HPV-negative head and neck cancer ([NCT04183166](#)). 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, M.D., Ph.D., 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 the IUCT-Oncopole, Toulouse, by Prof. Jean-Pierre Delord, M.D., Ph.D. and at Institut Curie, Paris, by Prof. Christophe Le Tourneau, M.D., Ph.D., Head of the Department of Drug Development and Innovation (D3i). In the USA, the trial is being led by Dr. Yujie Zhao, M.D., Ph.D., at the Mayo Clinic.

¹ Mallone et al., “Performance of neoantigen prediction for the design of TG4050, a patient specific neoantigen cancer vaccine”, [AACR](#), June 2020

In parallel, a second Phase I clinical trial of TG4050 is enrolling patients with ovarian cancer ([NCT03839524](#)). This second trial is including patients after surgery and first-line chemotherapy. Dr. Matthew Block, M.D., Ph.D., 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. Christophe Le Tourneau at Institut Curie and by Dr. Alexandra Martinez, M.D., Associate Head of Surgical Department, at Toulouse-Oncopole.

The first data from the two trials evaluating TG4050 are expected in 4Q 2021.

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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.

This best-in-class candidate is being evaluated in two Phase I clinical trials for patients with ovarian cancers ([NCT03839524](#)) and HPV-negative head and neck cancers ([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. // Follow us on Twitter: [@TransgeneSA](https://twitter.com/TransgeneSA)

The Clatterbridge Cancer Centre NHS Foundation Trust provides highly-specialist cancer care for the 2.4m people of Cheshire & Merseyside. Its unique networked model includes cancer centres in Aintree, Liverpool and Wirral, clinics in hospitals across the region, and cancer treatment at home and in the workplace. www.clatterbridgecc.nhs.uk

The Liverpool Head and Neck Centre (LHNC) combines internationally recognised clinical and research strengths to deliver research-led improvements in the quality and safety of patient care. It is a formal collaboration between Liverpool University Hospitals NHS Foundation Trust (LUHFT), The Clatterbridge Cancer Centre NHS Foundation Trust, The Walton Centre NHS Foundation Trust and the University of Liverpool (UoL). <https://www.liverpool.ac.uk/liverpool-cancer-research-institute/research/liverpool-head-and-neck-centre/>

Liverpool Cancer Research Institute

The Liverpool Cancer Research Institute (LCRI) aims to consolidate the existing strengths in biomedical and translational cancer research in Liverpool, grow its capability and accelerate the translation of research into improved patient outcomes. At the heart of the endeavour is a partnership between the region's three biggest stakeholders in cancer research, namely the University of Liverpool (UoL), The Clatterbridge Cancer Centre NHS Foundation Trust (CCC) and North West Cancer Research (NWCR), working alongside Liverpool Health Partners. <https://www.liverpool.ac.uk/liverpool-cancer-research-institute/>

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.