Transgene Receives MHRA Approval for Lead *myvac*™ Individualized Immunotherapy, TG4050, to Commence Clinical Development in HPV Negative Head and Neck Cancers in the UK

Phase 1 clinical trial, expected to start in H2 2019, will be co-funded by Transgene and its collaboration partner NEC

Strasbourg, France, July 10, 2019, 5:45 p.m. CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of solid tumors, today announces it has received the approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) to proceed with a Phase 1 clinical trial of its lead *myvac*™ candidate TG4050. TG4050 is being developed as a potential treatment for patients with newly diagnosed, locoregionally advanced, HPV negative, squamous cell carcinoma of the head and neck (SCCHN).

TG4050 is an individualized MVA-based immunotherapy derived from the *myvac*™ platform. It has been designed to stimulate and educate the patient's immune system to recognize and destroy tumor cells. Tumor cells accumulate mutations and each patient has a set of mutations that are unique to their tumor. TG4050 has been designed to target a panel of these patient specific mutations, which have been selected using NEC's Neoantigen Prediction System.

"This trial builds upon a long-term research collaboration in the field of immunology of cancer between Transgene and the University of Southampton. It will allow us to bring a very innovative individualized approach to patients. I expect the study to provide us with data demonstrating the safety and immunogenicity of TG4050. I believe such personalized vaccine approaches are the next paradigm in cancer care and could redefine the way patients with H&N cancer and other solid tumors will be treated" said **lead investigator Pr. Christian Ottensmeier, MD, PhD, FRCP, Professor of Experimental Medicine within Medicine at the University of Southampton.**

The Phase 1 clinical trial of TG4050 will be carried out in patients with SCCHN that have received an adjuvant (first line) therapy. Antitumor activity of TG4050 as monotherapy will also be measured. This multi-center, open label, two arms trial will include patients in the UK and in France.

The study, sponsored by Transgene, will be co-financed by Transgene and its partner NEC, which will also support the trial by contributing to the therapeutic vaccine design and the selection of target neoantigens (see press release dated March 5, 2019).

Dr. Maud Brandely, MD, PhD, Chief Medical Officer of Transgene commented, "*This approval from MHRA follows our recent IND from the FDA in ovarian cancer, allowing us to conduct Phase 1 clinical trials with TG4050 in both the US and Europe. With our partner NEC, we look forward to updating you on the progress on both of these clinical trials. These studies will also provide us with important insights into the optimal way to manufacture this novel individualized immunotherapy which is made specifically for each cancer patient.*"

TG4050 has also been granted an IND from the US FDA to evaluate TG4050 as a potential treatment for ovarian cancer patients (see press release dated May 13, 2019).

Contacts

Transgene:
Lucie Larguier
Director Corporate Communications & IR
+33 (0)3 88 27 91 04
investorrelations@transgene.fr

Media: Citigate Dewe Rogerson
EU: David Dible/Sylvie Berrebi
US: Marine Perrier-Barthez
+ 44 (0)20 7638 9571/+1 424 341 9140
transgene@citigatedewerogerson.com

About TG4050

TG4050 is an immunotherapy designed to stimulate the immune system of patients in order to induce a response that is able to recognize and destroy tumor cells in a specific manner.
This personalized immunotherapy is developed for each patient, on the basis of mutations identified through sequencing of tumor tissue, prioritized using NEC's Neoantigen Prediction System and delivered using the *myvac*™ technological platform which allows development and manufacture of a product that is specific to each patient and that is within time frames compatible with clinical management.

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 an "Investments for the Future" funding from Bpifrance for the development of its platform *myvac*™.

About NEC's Neoantigen Prediction System

NEC's neoantigen prediction utilizes its proprietary artificial intelligence (AI), such as graph-based relational learning, which is combined with other sources of data to discover candidate neoantigen targets. NEC comprehensively evaluates the candidate neoantigens with a primary focus placed on its in-house MHC-binding affinity prediction. These allow NEC to effectively prioritize the numerous candidate neoantigens identified in a single patient.

About Transgene

Transgene (Euronext: TNG) is a publicly traded French biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer and infectious diseases. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing infected or cancerous cells. The Company's lead clinical-stage programs are: TG4010, a therapeutic vaccine against non-small cell lung cancer, Pexa-Vec, an oncolytic virus against liver cancer, and TG4001, a therapeutic vaccine against HPV-positive head and neck cancers. The Company has several other programs in clinical development, including TG1050 (a therapeutic vaccine for the treatment of chronic hepatitis B) and TG6002 (an oncolytic virus for the treatment of solid tumors).
With its proprietary Invir.IO™, Transgene builds on its expertise in viral vectors engineering to design a new generation of multifunctional oncolytic viruses.
myvac™, an individualized MVA-based immunotherapy platform designed to integrate neoantigens, completes this innovative research portfolio. TG4050, the first candidate selected from the *myvac*™ platform, will enter the clinic for the treatment of ovarian cancer and head and neck cancers.
Additional information about Transgene is available at: www.transgene.fr.
Follow us on Twitter: @TransgeneSA

About NEC Corporation

NEC Corporation is a leader in the integration of IT and network technologies that benefit businesses and people around the world. The NEC Group globally provides "Solutions for Society" that promote the safety, security, efficiency and equality of society. Under the company's corporate message of "Orchestrating a brighter world," NEC aims to help solve a wide range of challenging issues and to create new social value for the changing world of tomorrow. For more information, visit NEC at www.nec.com.

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 Document de Référence, 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.