Transgene Receives Approval from the French Health Authority (ANSM) to Initiate Two Clinical Trials of its Lead *myvac*™ Individualized Immunotherapy TG4050

- ✓ *International Phase 1 clinical trials expected to start in 2019*
- ✓ *In France, the studies will be conducted at Institut Curie and Toulouse-Oncopole*
- ✓ *Clinical trials co-funded by Transgene and its collaboration partner NEC*

Strasbourg, France, September 16, 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 approval from the French National Agency for the Safety of Medicines and Health Products (ANSM) to proceed with two Phase 1 clinical trials of its lead *myvac*™ candidate TG4050. TG4050 is a novel individualized immunotherapeutic designed to elicit an immune response directed specifically against the patient's own tumor.

Two international clinical studies due to start in 2019

One trial is evaluating TG4050 as a potential treatment for patients with newly diagnosed, locoregionally advanced, **HPV negative, squamous cell carcinoma of the head and neck (SCCHN)**, that have received an adjuvant (first line) therapy. This multicenter, two-arm trial will include patients in the UK and in France. In France, it will be conducted at Institut Curie (Paris - Pr. Le Tourneau) and Toulouse-Oncopole (Pr. Delord); its principal investigator is Pr. Ottensmeier from Southampton University (United Kingdom). In July 2019, Transgene received approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA) to proceed with this Phase 1 clinical trial.

In the second trial, TG4050 will be assessed in patients with ovarian cancer after first-line surgery and chemotherapy. This multicenter, one-arm trial will recruit patients in the United States and in France. In France, the trial will be conducted at Institut Curie (Pr. Le Tourneau). Transgene was granted an Investigational New Drug (IND) clearance from the US FDA for this trial in May 2019.

Dr. Maud Brandely, MD, PhD, Chief Medical Officer of Transgene commented, "*This clearance from the ANSM, following the approval from the UK MHRA and the US FDA, will allow us to start both our Phase 1 studies with TG4050 later this year. These studies, which are co-funded by NEC and benefit from their artificial intelligence (AI) capabilities, will provide us with data that will be key to further develop novel individualized immunotherapeutics.*"

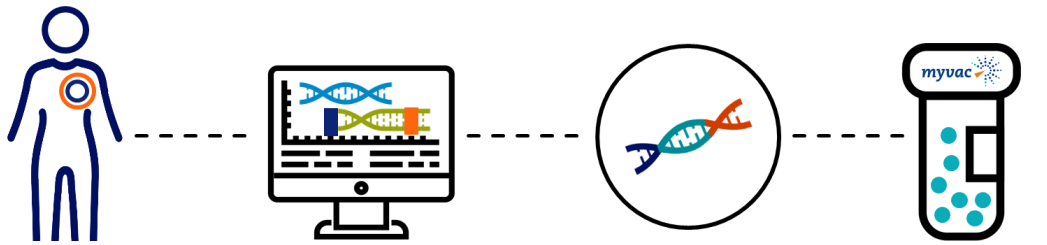
myvac™, an individualized immunotherapy that integrates leading AI capabilities

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.

Transgene's partner NEC will apply its advanced AI technology and capabilities, "NEC the WISE", in the frame of these studies. The AI engine will be used to analyze patient specific mutational patterns and to

select relevant target mutation for the design of the vaccine. NEC and Transgene are co-funding these studies.

The NEOVIVA collaborative project will also support the industrial development of the *myvac™* platform which combines bioengineering, bioIT and a recognized know-how in viral vectorization. Transgene in conjunction with NEOVIVA will use these Phase 1 studies to progress the development and validation of a manufacturing approach that would provide the solutions needed for the future development of TG4050 (see *press release dated March 13, 2019).*



Tumor cell | Identification and selection of neoantigens | Integration of neoantigens in the genome of the viral vector | Individualized immunotherapy

***

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 trained on public and proprietary datasets. 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, TG4001, a therapeutic vaccine against HPV-positive cancers, and TG6002, an oncolytic virus for the treatment of solid tumors.

With its proprietary platform 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 cancer.

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.