Transgene receives FDA IND Clearance for Lead *myvac*™ Individualized Immunotherapy, TG4050, to Commence Clinical Development in Ovarian Cancer

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

Strasbourg, France, May 13, 2019, 7:30 a.m. CET - Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of solid tumors, today announces that it has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA) to proceed with a Phase 1 clinical trial of its lead *myvac*™ candidate TG4050 as a potential treatment for ovarian cancer patients after first-line surgery and chemotherapy.

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

"We are very pleased to have been granted an IND for TG4050 by the FDA allowing us to commence the first trial with our lead myvac™ *candidate in ovarian cancer patients who have already received first-line treatment"* said **Maud Brandely, Chief Medical Officer of Transgene**. "*We believe individualized vaccination is a promising solution with significant potential to transform treatment outcomes for a wide range of solid tumors. With TG4050, we are confident that we can show that this therapeutic modality will improve patient outcome. We look forward to updating you on the progress of this clinical trial, which is expected to start later this year."*

The Phase 1 clinical trial will evaluate the safety and the tolerability of TG4050 in patients with ovarian, fallopian or peritoneal serous cell carcinoma. Antitumor activity will also be measured. This multi-center, one-arm trial will recruit patients in the United States and Europe.

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).

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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 the patient 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. The *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 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 cancer.
Additional information about Transgene is available at www.transgene.fr.
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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 http://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.