



Orchestrating a brighter world



## Transgene and NEC Start Two Clinical Trials with TG4050, an individualized AI-Powered Cancer Vaccine for Ovarian and Head & Neck Cancers

- ✓ *TG4050 moves therapeutic vaccination into the digital age: combines Transgene's expertise in viral vectors with NEC's cutting-edge Artificial Intelligence (AI) capabilities*
- ✓ *Novel immunotherapy is fully tailored to each individual by generating an immune response that targets highly specific patient tumor mutations*
- ✓ *First patients enrolled in two Phase 1 trials at the Mayo Clinic and Toulouse Oncopole*

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Strasbourg, France & Tokyo, Japan, January 7, 2020, 7:30 a.m. CET - Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of cancer, and NEC Corporation (NEC; TSE: 6701), a leader in IT and network technologies, today announced that the first patients have been enrolled in the first-in-human trials evaluating TG4050, an individualized therapeutic vaccine based on the *myvac*<sup>™</sup> technology and powered by NEC's cutting-edge AI capabilities. In these Phase 1 trials, TG4050 is being administered to patients with head and neck cancer who have a high risk of relapse after surgery and patients with ovarian cancer after surgery and adjuvant therapy.

**Transgene's highly innovative *myvac*<sup>™</sup> technology allows the generation of a virus-based immunotherapy within a very short time frame while encoding patient-specific mutations identified and selected by NEC's Neoantigen Prediction System.**

TG4050 has been designed to target up to 30 patient-specific neoantigens (cancer cell mutations). They are selected using NEC's Neoantigen Prediction System, an advanced AI technology that has already been applied in the field of oncology. The prediction system is based on more than two decades of expertise in AI and has been trained on proprietary immune data, allowing it to accurately prioritize and select the most immunogenic sequences.

Transgene uses its expertise in viral vectorization via *myvac*<sup>™</sup> to incorporate the selected neoantigen sequences in the genome of the Modified Vaccinia virus Ankara (MVA) viral vector. The Company has also set up a unique in-house good manufacturing practice (GMP) unit dedicated to the manufacturing of the individualized batches of TG4050 needed for the clinical development of this novel therapeutic vaccine.

*"As each patient's cancer is unique, we have developed a therapy that turns their solid tumor's genetic signature into a powerful highly specific anticancer weapon. TG4050 is based on an MVA viral vector that has proven biological activity and has the ability to elicit an immune response against tumor antigens. Our partnership with NEC ensures that TG4050 is benefitting from its world-leading expertise in artificial intelligence and its unique algorithm that is used to select up to 30 patient-specific antigens that allow this novel vaccine to induce a strong immune response. We are convinced that TG4050, which is at the crossroad of immunotherapy and big data sciences, will herald the start of a new era in the fight against cancer,"* explained Philippe Archinard, Chairman and Chief Executive Officer of Transgene.

*“We are excited to enroll our first patients in these trials and see TG4050 advance to the clinic. This is another step closer towards the realization of an AI-driven individualized immunotherapy for each patient. Our unique partnership with Transgene enables us to leverage its significant clinical development know-how and proven viral vector delivery platform. We are hopeful that TG4050 will make a significant difference for patients throughout the world”, commented Osamu Fujikawa, Senior Vice President, NEC Corporation.*

**A Phase 1 clinical trial of TG4050 is enrolling patients with ovarian cancer** after surgery and first-line chemotherapy. This multicenter, one-arm trial will recruit patients in the USA and in France. Endpoints of the trial include safety, feasibility and biological activity of the therapeutic vaccine. Dr. Matthew Block, immunologist and medical oncologist at the Mayo Clinic, is conducting the trial in the USA; in France, the trial will be conducted by Dr. Martinez at Toulouse-Oncopole and by Pr. Le Tourneau at Institut Curie.

**Another Phase 1 clinical trial of TG4050 is enrolling patients with newly diagnosed, locoregionally advanced, HPV negative, squamous cell carcinoma of the head and neck (SCCHN)** who have received an adjuvant therapy after surgery. This multicenter, open label, randomized two arms trial will include patients in the UK and in France. Patients will receive either TG4050 monotherapy after completion of the adjuvant therapy or in combination with the standard of care at the time of recurrence. Endpoints of the trial include safety, feasibility and biological activity of the therapeutic vaccine. In France, the trial is being conducted by Pr. Delord at Toulouse-Oncopole and by Pr. Le Tourneau at Institut Curie; in the UK, the trial is coordinated by Pr. Ottensmeier from Southampton University.

Both studies are sponsored by Transgene and are co-financed by Transgene and NEC.

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#### **Contacts**

##### **Transgene:**

**Lucie Larguier**

Director Corporate Communications & IR

+33 (0)3 88 27 91 04

[investorrelations@transgene.fr](mailto:investorrelations@transgene.fr)

##### **NEC Corporation**

**AI Drug Development Division**

Email: [contact@aidd.jp.nec.com](mailto:contact@aidd.jp.nec.com)

##### **Media:**

**Citigate Dewe Rogerson**

David Dible/Sylvie Berrebi

+ 44 (0)20 7638 9571

[transgene@citigatedewerogerson.com](mailto:transgene@citigatedewerogerson.com)

##### **NEC Corporation:**

**Joseph Jasper**

[j-jasper@ax.jp.nec.com](mailto:j-jasper@ax.jp.nec.com)

+81-3-3798-6511

#### **About TG4050**

TG4050 is an individualized immunotherapy based on Transgene’s *myvac*<sup>™</sup> technology and powered by NEC’s artificial intelligence. 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 for each patient and can be produced in a very short time frame.

#### **About myvac<sup>™</sup>**

*myvac*<sup>™</sup> is a viral vector (MVA) based, individualized immunotherapy platform that has been developed by Transgene to target solid tumors. *myvac*<sup>™</sup>-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 “Investment for the Future” funding from Bpifrance for the development of its platform *myvac*<sup>™</sup>. TG4050 is the first *myvac*<sup>™</sup>-derived product being evaluated in clinical trials.

### **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 major histocompatibility complex (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 clinical-stage programs are TG4001, a therapeutic vaccine against HPV-positive cancers, TG6002, an oncolytic virus for the treatment of solid tumors, and TG4050, the first individualized therapeutic vaccine based on the *myvac*<sup>™</sup> platform.

With its proprietary platform Invir.IO<sup>®</sup>, Transgene also builds on its expertise in viral vectors engineering to design a new generation of multifunctional oncolytic viruses.

Additional information about Transgene is available at: [www.transgene.fr](http://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 [www.nec.com](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](http://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.*