

**First Patient dosed in Phase 2 Trial**  
**Evaluating Transgene's TG4010 in Combination with Opdivo® (nivolumab)**  
**for 2<sup>nd</sup> Line Treatment of Metastatic Non-Small Cell Lung Cancer (NSCLC)**

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**Strasbourg, France, March 13, 2017, 6:00 p.m. CET** - Transgene (Euronext Paris: TNG), a biotechnology company focused on designing and developing viral-based immune-targeted therapies for the treatment of cancers and infectious diseases, today announced the dosing of the first patient of the Phase 2 trial evaluating TG4010 in combination with Opdivo® (nivolumab) for the treatment of metastatic non-small cell lung cancer (NSCLC) after failure of one line of platinum-based chemotherapy.

Karen Kelly, MD, a world-renowned expert of lung cancer and Associate Director for Clinical Research at UC Davis Comprehensive Cancer Center (USA, California), is the Principal Investigator of this Phase 2 study.

The trial is being conducted via a collaborative arrangement with UC Davis. The investigator-initiated study led by UC Davis Medical Center is financially supported by Transgene. Bristol-Myers Squibb is supplying Opdivo®.

Maud Brandely, Chief Medical Officer of Transgene, said: *"We are convinced that the complementary mechanisms of action of TG4010 and Opdivo® can enhance response rates, increase the duration of response and extend overall survival in patients. Today, advanced lung cancer remains a severe disease with a poor prognosis. Major improvements are needed in the therapeutic options available to physicians."*

This study is a multi-center Phase 2 trial. Its primary objective is to evaluate the efficacy (overall response rate) of the TG4010 plus Opdivo® regimen in patients with stage IV non-squamous NSCLC who have progressed after one line of platinum-based chemotherapy. Secondary endpoints include progression-free survival (PFS), overall survival (OS), duration of response and safety. The trial will enroll up to 33 patients. First results could be expected from the end of 2017.

TG4010 is an active immunotherapy that has been designed by Transgene to express the coding sequences of the MUC1 tumor-associated antigen and the cytokine, Interleukin-2 (IL2). TG4010, which is based on a modified vaccinia virus (MVA), induces an immune response against MUC1 expressing tumors, such as non-squamous NSCLC. Its mechanism of action and excellent safety profile make TG4010 a very suitable candidate for combinations with other therapies, such as Opdivo®, a PD-1 immune checkpoint inhibitor that is designed to prevent the PD-1 pathway from suppressing the immune system's response against tumors. Opdivo® is approved in the USA for the 2<sup>nd</sup> line treatment of advanced non-small cell lung cancer.

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### **About non-small cell lung cancer**

Lung cancer is one of the most common malignancies worldwide with an estimated 1.8 million new cases annually. It is also a leading cause of cancer-related deaths, accounting for an estimated nearly 1.6 million deaths in 2012 (Source: GLOBOCAN 2012).

Advanced lung cancer remains one of the cancer types with the worst prognosis (five-year survival rate for advanced NSCLC of less than 5%), underlining the unmet need in this disease.

### **About TG4010**

TG4010 is a novel MUC1 targeting immunotherapy. This therapeutic vaccine is in development for the treatment of metastatic NSCLC. TG4010 is a recombinant vaccinia virus of the Ankara strain (MVA) expressing the coding sequences of the MUC1 antigen and of the cytokine, Interleukin-2 (IL2). In healthy cells, the MUC1 protein is normally found on the surface of epithelial cells in many types of tissue and works to protect these cells. In tumor cells, several modifications of MUC1 can occur: over expression, hypo-glycosylation and changes in cellular localization. These changes transform the MUC1 protein into a highly immunogenic tumor associated antigen (TAA) and make it an attractive target for cancer immunotherapy. Thus, the strategy is to induce MUC1 antigen expression in a non-tumor environment, i.e., where the immune system is fully functional, in order to induce both innate and MUC1 specific adaptive immunity. In addition to NSCLC, the MUC1 TAA is expressed in many other solid tumor types, such as lung, breast, colorectal, kidney and prostate cancers. The results from the Phase 2b TIME trial with TG4010 immunotherapy in non-small cell lung cancer (NSCLC) have been published in the peer-reviewed medical journal, [The Lancet Oncology](#) in December 2015.

### **About Transgene**

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biotechnology company focused on designing and developing immune-targeted viral-based therapies for the treatment of cancers 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 two lead clinical-stage programs are: TG4010, a therapeutic vaccine for non-small cell lung cancer, and Pexa-Vec, an oncolytic virus for liver cancer. The Company has several other programs, including TG4001, in clinical and preclinical development. Transgene is based in Strasbourg, France, and has additional operations in Lyon, as well as a joint venture in China.

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

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### **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.*

*Opdivo® is a registered trademark of Bristol-Myers Squibb Company.*