

## First Patient Dosed in a Phase 2 Trial with Transgene's TG4010 + Nivolumab + Chemotherapy for the First-Line Treatment of Lung Cancer (NSCLC)

*Clinical Trial in Collaboration with Bristol-Myers Squibb*

*Trial Will Enroll Patients whose Tumors Express Low or Undetectable Levels of PD-L1*

*First results expected in H2 2018*

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Strasbourg, France, January 16, 2018, 5:45 p.m. CET - **Transgene (Euronext Paris: TNG), a biotechnology company that designs and develops virus-based immunotherapies, announces the dosing of the first patient in the Phase 2 trial evaluating TG4010 in combination with Opdivo® (nivolumab) and chemotherapy as a first-line treatment for advanced non-squamous non-small cell lung cancer (NSCLC) with low or no expression of PD-L1 by the tumor cells.**

The Phase 2 clinical trial is exploring the tolerability and efficacy of the combination regimen of Transgene's TG4010, an investigational active immunotherapy against MUC1 tumor-associated antigen, with Bristol-Myers Squibb's immune checkpoint inhibitor, Opdivo® (nivolumab), which acts by overcoming immune suppression, and standard platinum doublet chemotherapy.

This multi-center single-arm trial will enroll up to 39 patients (without EGFR activating mutations or ALK-rearrangements), both in the USA and Europe. The trial has objective tumor responses rate (ORR) as primary endpoint. The study will also assess the safety and tolerability of the regimen together with other efficacy and immunological parameters. The first results are expected in H2 2018.

More information on the trial can be found on [clinicaltrials.gov](http://clinicaltrials.gov) ([NCT03353675](https://clinicaltrials.gov/ct2/show/study/NCT03353675)).

This trial is conducted by Transgene under a clinical collaboration agreement with Bristol-Myers Squibb, which is supplying nivolumab (see [press release dated April 25, 2017](#)).

*"Advanced lung cancer remains a devastating disease, in particular for patients whose tumors express low or undetectable levels of PD-L1. We are excited to start a trial that combines our active immunotherapy TG4010, with nivolumab and chemotherapy as a first-line treatment" said Maud Brandely, Chief Medical Officer of Transgene. "We believe that this trial could confirm the promising efficacy data that we previously obtained with TG4010 in combination with chemotherapy, and show that the triple regimen could be an attractive treatment option in this patient population."*

**Elisabeth Quoix, M.D., Head of the Department of Pulmonology at the University Hospital of Strasbourg, and coordinating investigator of the trial, added:** *"The three complementary mechanisms of action of TG4010, nivolumab and chemotherapy are believed to enhance the immune cellular response and lead to an increase in antitumor activity. This combination regimen aims at achieving a higher response rate, and ultimately an improvement in the survival rate in advanced-stage NSCLC patients."*

The combination of TG4010 immunotherapy and chemotherapy has demonstrated significant efficacy in terms of increased response rate, progression-free survival and overall survival in a randomized, double-blind, placebo-controlled Phase 2b trial in first-line treatment of patients with advanced non-squamous NSCLC (Quoix et al. [Lancet Oncol.](#) 2015).

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### About TG4010

TG4010 is an active immunotherapy that has been designed to express the coding sequences of the MUC1 tumor-associated antigen and the cytokine, Interleukin-2 (IL2). It is based on a modified *Vaccinia* virus (MVA), and has been shown to induce an immune response against MUC1 expressing tumors, such as non-small cell lung cancer (NSCLC). Its mechanism of action and excellent safety profile make TG4010 a very suitable candidate for combinations with other therapies, including immune checkpoint inhibitors and chemotherapy. The combination of TG4010 immunotherapy and chemotherapy has demonstrated significant efficacy in terms of progression-free survival and overall survival in patients with advanced stage NSCLC (Quoix et al. [Lancet Oncol.](#) 2015).

TG4010 is being investigated in combination with nivolumab (ICI) for the 2<sup>nd</sup>-line treatment of advanced NSCLC ([NCT02823990](#)) and for 1<sup>st</sup>-line treatment of NSCLC in combination with nivolumab and chemotherapy in patients whose tumors express low or undetectable levels of PD-L1 ([NCT03353675](#)).

### 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 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 still unmet need in this disease despite recent progress.

### About Transgene

Transgene (Euronext: TNG), part of Institut Mérieux, 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 (chronic hepatitis B) and TG6002 (solid tumors). 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

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