Transgene Receives FDA IND Approval to Begin a Clinical Trial with TG4010 + Nivolumab + Chemotherapy in the First-Line Treatment of Lung Cancer (NSCLC)

Phase 2 Clinical Trial in Collaboration with Bristol-Myers Squibb

First patient expected to be enrolled at the end of 2017

Strasbourg, France, September 11, 2017, 5:45 p.m. CET - Transgene (Euronext Paris: TNG), a biotech company that designs and develops viral-based immunotherapies, today announces that the US Food and Drug Administration (FDA) has granted Transgene Investigational New Drug (IND) clearance to proceed with a Phase 2 clinical trial of TG4010 in combination with Opdivo® (nivolumab) and chemotherapy as a first-line treatment for advanced non-squamous non-small cell lung cancer (NSCLC) in the USA.

The Phase 2 clinical trial will explore the potential of combining Transgene's TG4010, an investigational therapeutic vaccine, in association with Bristol-Myers Squibb's immune checkpoint inhibitor, nivolumab, which acts by overcoming immune suppression. Both therapies will be combined with standard chemotherapy in first-line NSCLC patients, whose tumors express low and undetectable levels of PD-L1.

Transgene is the sponsor of this international trial. Transgene has signed a clinical collaboration agreement with Bristol-Myers Squibb, which will provide nivolumab for the study (see press release dated April 25, 2017).

The Phase 2 trial will evaluate objective tumor responses and disease control. The study will also assess the safety and tolerability of the regimen together with other efficacy parameters. This multi-center single-arm trial will enroll patients both in the USA and Europe.

The first patient is expected to be included into this Phase 2 study at the end of 2017.

"We are very pleased that the FDA approval for the trial combining TG4010, nivolumab and chemotherapy as a first-line treatment of non-squamous NSCLC has been granted to Transgene" said Maud Brandely, Chief Medical Officer of Transgene. *"Advanced lung cancer remains a high medical need, in particular for patients whose tumors express low or undetectable levels of PD-L1. We are looking forward to advancing this clinical trial and evaluate the potential of this triple combination regimen as a better treatment option for these patients."*

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About TG4010

TG4010 is an 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).

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. The results from the Phase 2b TIME trial with TG4010 in conjunction with chemotherapy in NSCLC have been published in the peer-reviewed medical journal, The Lancet Oncology in December 2015.

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 still unmet need in this disease.

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 and preclinical 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.

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