



**UC Davis to Conduct Phase 2 Trial
of the Combination of TG4010 with Opdivo® (nivolumab)
for 2nd Line Treatment of Metastatic Non-Small Cell Lung Cancer (NSCLC)**

The trial will be supported by Transgene and Bristol-Myers Squibb

Strasbourg, France, December 7, 2016, 5:45 pm CET — Transgene (Euronext Paris: TNG), a company focused on designing and developing targeted immunotherapies for the treatment of cancer and infectious diseases, today announced the signature of a collaborative arrangement with UC Davis (USA, California) to support an investigator-initiated study led UC Davis Medical Center that will evaluate TG4010 in combination with Opdivo® (nivolumab) for the treatment of 2nd line metastatic non-small cell lung cancer (NSCLC). This trial is supported by Transgene through financial support and supply of TG4010 and by Bristol-Myers Squibb through supply of nivolumab for use in the clinical study.

Karen Kelly, MD, a world-renowned expert of lung cancer and Associate Director for Clinical Research at UC Davis Comprehensive Cancer Center, is the Principal Investigator of this Phase 2 study. The enrollment of the first patients is expected in the coming weeks.

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). 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 2nd line treatment of advanced non-small cell lung cancer.

This study is a Phase 2, multi-center, single arm, open-label trial. Its primary objective is to evaluate the efficacy (Overall Response Rate) of the combination of TG4010 plus Opdivo® 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.

Immunotherapy, particularly the use of immune checkpoint blockers such as the anti-PD-1 Opdivo®, is rapidly transforming cancer care, due to its demonstrated antitumor activity. There is increasing interest among the medical community in exploring whether combining different immunotherapy agents could provide additional benefit to patients. This study will evaluate the efficacy of this combination of immunotherapies that target distinct stages of the immune cycle.

Philippe Archinard, Chairman and CEO of Transgene, added: *"We are delighted to start a collaboration with a highly respected clinical investigator, Dr. Karen Kelly of UC Davis. We are also glad that Bristol-Myers Squibb, a leader in cancer immunotherapy research, is supporting this trial. The interest from such a leading company in investigating the potential of TG4010 in combination with Opdivo® supports confidence in researching whether our active immunotherapies are complementary to an immune checkpoint inhibitor."*

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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). NSCLC represents approximately 85% or more of all lung cancers of which about 75% are non-squamous. According to the American Cancer Society, deaths due to lung cancer were expected to account for about 27% of all U.S. cancer deaths in 2015, more than any other cancer type. It is estimated that there will be over 221,000 new cases of lung cancer in the U.S. in 2015 and over 158,000 deaths due to this disease. Recent statistics from GLOBOCAN 2012 estimate that there were over 448,000 cases of lung cancer in Europe in 2012, and over 388,000 people in Europe died from this disease. 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 part of the Phase 2b/3 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 biopharmaceutical 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 cancerous or infected 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 in clinical and pre-clinical development, including TG4001. Transgene is based in Strasbourg, France, and has additional operations in Lyon, in China and in the U.S. Additional information about Transgene is available at www.transgene.com.

Disclaimer

This press release contains forward-looking statements about the future development of TG4010. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements 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 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 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, which is available on the AMF website (<http://www.amf-france.org>) or on Transgene's website (www.transgene.fr).

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