



## **Transgene Announces Promising Results in an Update from the Phase 2b Part of TIME Trial with TG4010 in Advanced Non-Small Cell Lung Cancer**

***Primary endpoint met with more mature data in normal TrPAL group***

***In addition, statistically and clinically significant PFS improvement in non-squamous lung cancer patients***

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**Strasbourg, France, May 27, 2014** – Transgene SA (NYSE-Euronext: TNG) today announced promising results in an update incorporating more mature data from the Phase 2b part of the Phase 2b/3 TIME trial<sup>1</sup> with TG4010 MUC-1 targeted immunotherapy in patients with advanced non-small cell lung cancer (NSCLC).

Following an analysis conducted with a more mature dataset, the primary endpoint of progression-free survival (PFS) to validate the TrPAL predictive biomarker was met<sup>2</sup> in the normal TrPAL<sup>3</sup> group. The high TrPAL group had not yet met the required number of events to conduct the primary analysis.

Importantly, in the subgroup of patients of non-squamous histology (191 out of 217 patients), the vast majority of patients in the trial, the difference in PFS was statistically significant and clinically meaningful with a p value of 0.02 and a stratified log rank hazard ratio (HR) of 0.71 [0.51; 0.98] (intent-to-treat analysis). As expected, in this non-squamous population, the PFS HR observed was even more notable in the normal TrPAL subgroup of patients.

Philippe Archinard, Chairman and Chief Executive Officer of Transgene, said: *“We are very pleased that data from the TIME trial are maturing positively, as expected. We are hopeful that mature overall survival data, a secondary endpoint of the TIME trial, will confirm the trend observed thus far in terms of clinical efficacy of this cancer immunotherapy.”* He added: *“Finding a partner for TG4010 remains our primary corporate objective for the upcoming months.”*

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<sup>1</sup> In January 2014, Transgene announced preliminary topline results from the TIME trial with a data cutoff date of September 30, 2013, as expected under the Novartis option agreement. The updated, more mature results announced today had a data cutoff date of March 31, 2014. At the time of the March 2014 data cut off, a total of 217 patients (170 normal TrPAL level, 47 high TrPAL level) were enrolled in the study, and the updated analyses were conducted after 137 progression events had occurred in the normal TrPAL group.

<sup>2</sup> The primary endpoint is based on a Bayesian probability analysis of progression-free survival from the Phase 2b part of the TIME trial and an earlier Phase 2 study in advanced NSCLC patients (the TG4010.09 study).

<sup>3</sup> Triple-positive activated lymphocytes.

TG4010 was well tolerated, and the nature and incidence of adverse events in the TG4010 arm were consistent with previous Phase 2 clinical trials. To date, over 350 patients have been treated with TG4010.

Data for overall survival, a secondary endpoint in the TIME trial, although not yet mature, are suggesting a clinically meaningful improvement in line with the one observed with the PFS data. Detailed results from the TIME trial, including overall survival, are expected to be presented at a major medical meeting later this year.

The Company will be interacting with regulatory authorities to discuss the data from the TIME trial in preparation of the phase 3 part of the trial.

### **About the TIME trial:**

The TIME trial is a randomized, placebo-controlled trial evaluating TG4010 in combination with chemotherapy compared to placebo plus chemotherapy in the first-line treatment of MUC-1 positive advanced non-small cell lung cancer (NSCLC) patients.

### **About TG4010:**

TG4010, a novel MUC1 targeting immunotherapy, is in development for the treatment of metastatic NSCLC in combination with first-line chemotherapy. 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. TG4010 is also being studied in pre-clinical tests in combination with immune checkpoint inhibitors.

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

Lung cancer is one of the most common malignancies worldwide with an estimated incidence of 1.6 million people and is the leading cause of cancer-related deaths, accounting for an estimated 1.4 million deaths in 2008, the latest figures available. NSCLC represents approximately 80 per cent of all lung cancers. Recent statistics estimate that over 287,000 people in the European Union (EU) were diagnosed with lung cancer in 2008, and approximately 252,000 people in the EU died from this disease. In the U.S., deaths due to lung cancer are expected to account for about 27% of all cancer deaths in 2013, more than from colon, breast and prostate cancers combined. It is estimated that there will be over 228,000 new cases of lung cancer in the U.S. in 2013 and over 159,000 deaths due to this disease. Lung cancer remains one of the cancer types with the worst prognosis (five-year survival rate for NSCLC of 18% in the U.S.), underlining the unmet need in this disease.

Current treatments for lung cancer include surgery, chemotherapy, radiation and targeted molecular therapy, but only one third of patients present resectable (able to be removed by surgery) disease at diagnosis. The poor prognosis in patients with advanced disease is improved by platinum-based chemotherapies that produce longer survival times. However, the medical need for developing new treatments for NSCLC remains extremely high and new approaches are necessary to significantly change the outcome of the disease.

### **About Transgene:**

Transgene (NYSE-Euronext: TNG), a member of the Institut Mérieux Group, is a publicly traded French biopharmaceutical company focused on discovering, developing and manufacturing targeted immunotherapies for the treatment of oncology and infectious diseases. Transgene's programs utilize well-tolerated viruses with the goal of indirectly or directly killing infected or cancerous cells. The Company's two lead clinical-stage programs are: TG4010 for non-small cell lung cancer and Pexa-Vec for liver cancer. The Company has several other programs in clinical and pre-clinical development that are based on its core viral vector technology; this includes clinical-stage TG4001 for oropharyngeal cancer and TG1050 for hepatitis B in advanced pre-clinical development. Transgene is based in Strasbourg, France, and has additional operations in Lyon, as well as satellite offices in China and the U.S. Additional information about Transgene is available at [www.transgene.fr](http://www.transgene.fr).

### **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. There can be no guarantee that (i) the results of the Phase 2b part of the TIME trial will be predictive of future results with TG4010, (ii) regulatory authorities will agree with the Company's plans for the Phase 3 part of the trial, or (iii) that the Company will find a development and commercialization partner for TG4010 in a timely manner, if at all. 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](http://www.transgene.fr)).*

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