



Transgene Announces Positive New Results Presented at ASCO from Phase 2b TIME Trial with TG4010 Immunotherapy in Non-Small Cell Lung Cancer

- ***More mature data confirm strength of improvements in progression-free survival and overall survival, especially in non-squamous tumors***
- ***Improved response rate and longer duration of response***
- ***TG4010 shows activity in patients with low PD-L1 expressing tumors***

Strasbourg, France, June 1, 2015 – Transgene SA (Euronext: TNG) today announced the presentation¹ of new data from the Phase 2b part of the TIME trial with the TG4010 MUC1 targeted immunotherapy in non-small cell lung cancer (NSCLC) at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL USA.

The more mature data confirmed the strength of the previously reported improvements in progression-free survival (PFS) and overall survival (OS), particularly in patients with non-squamous tumors. In addition, patients treated with TG4010 plus chemotherapy demonstrated improved response rates and a longer median duration of response compared to the control group.

Also of note, in a retrospective analysis of PD-L1 expression in patient tumor cells from the trial, strong activity was seen with TG4010 in patients having low levels (<5%) of tumor cells expressing PD-L1, which accounted for approximately 70% of patients in the TIME trial. PD-L1 (programmed death-ligand 1) is a protein that is believed to play a major role in suppressing the immune system and is an important target for cancer treatment.

The data are further discussed below. The poster presented at ASCO can be found on the Company's website at www.transgene.fr.

Professor Elisabeth Quoix, M.D., Ph.D., Head of the Department of Pulmonology at the University Hospital of Strasbourg and Coordinating Investigator of the TIME study, said: *"It is gratifying to see the exciting breakthroughs being made with immunotherapies to treat a variety of cancers. The updated results with TG4010 presented at ASCO are encouraging and support further development of this novel immunotherapy product candidate in non-small cell lung cancer, both in combination with chemotherapy as well as with immune checkpoint blockers."*

¹ Abstract #3034. Quoix, E. et al. Results of the phase IIb part of TIME study evaluating TG4010 immunotherapy in stage IV non-small cell lung cancer (NSCLC) patients receiving first line chemotherapy.

The TIME trial is a randomized, double-blind, placebo-controlled study evaluating TG4010 in combination with chemotherapy in the first-line treatment of MUC1 positive advanced (Stage IV) NSCLC patients. A total of 222 patients were enrolled in the Phase 2b portion of the trial. The primary objective² of the Phase 2b part of the study was to prospectively validate the TrPAL predictive biomarker³; the safety and other efficacy parameters of TG4010 in combination with chemotherapy were also assessed.

In patients with non-squamous tumors - 88% of patients in the trial – a significant difference in PFS and clinically meaningful difference in OS were observed. Consistent with previous communications, these improvements were even more notable in the so-called “low”⁴ TrPAL group of patients. Key PFS and OS data are outlined below:

<i>Intent-to-treat (ITT)</i>	Progression-Free Survival		
Subgroup	Total # of patients (TG4010/placebo)	Hazard Ratio (95% CI*) p-value	At 9 months TG4010 vs placebo
Non-squamous	196 (98/98)	0.69 (0.51, 0.94) p=0.009	35% vs 19%
Non-squamous, low TrPAL	127 (61/66)	0.59 (0.40, 0.87) p=0.003	39% vs 19%

<i>Intent-to-treat (ITT)</i>	Overall Survival		
Subgroup	Total # of patients (TG4010/placebo)	Hazard Ratio (95% CI*) p-value	At 18 months TG4010 vs placebo
Non-squamous	196 (98/98)	0.75 (0.54, 1.06) p=0.049	40% vs 34%
Non-squamous, low TrPAL	127 (61/66)	0.64 (0.41, 0.98) p=0.019	44% vs 30%

*Confidence interval

Improvements in response rate and median duration of response were also observed. The observed response rate for the non-squamous group was 39.8% for TG4010 compared to 27.6% for placebo; the median duration of response was 40.9 weeks (TG4010) versus 18.1 weeks (placebo).

TG4010 was well tolerated, and the nature and incidence of adverse events in the TG4010 arm were consistent with previous Phase 2 clinical trials. The most frequent TG4010-related adverse events were mild to moderate injection site reactions. To date, over 350 patients have been treated with TG4010.

About TG4010:

² The primary endpoint is based on a Bayesian probability analysis of progression-free survival (PFS) from the Phase 2b part of the TIME trial and an earlier Phase 2 study (TG4010.09) in advanced NSCLC patients. (see press release of May 27, 2014)

³ The level of triple positive activated lymphocytes: CD16+CD56+CD69+ (TrPAL) cells at baseline.

⁴ The level of TrPAL cells at baseline as determined using a quartile approach; “low” TrPAL patients were in the three lowest quartiles.

TG4010, a novel MUC1 targeted immunotherapy, is being developed for the treatment of metastatic non-small cell lung cancer. 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.

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 and is the leading cause of cancer-related deaths, accounting for an estimated nearly 1.6 million deaths in 2012, the latest figures available. NSCLC represents approximately 85% or more of all lung cancers. Recent statistics 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. In the U.S., deaths due to lung cancer were expected to account for about 27% of all cancer deaths in 2014, more than any other cancer type. It is estimated that there were over 224,000 new cases of lung cancer in the U.S. in 2014 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 17% 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.

The work related to TG4010 is a contribution to ADNA (Advanced Diagnostics for New Therapeutic Approaches), a program dedicated to personalized medicine, coordinated by Institut Mérieux and supported and partially funded by the French public agency, BPI.

About PD-L1 expression:

PD-L1 expression was analyzed in 160 patients by immunohistochemistry staining on tumor slides using the E1L3N anti-PD-L1 monoclonal antibody. The cut-off used to determine the level of positive PD-L1 expression was set at 5% of tumor cells. A total of 138 patients had a non-squamous tumor, of which 97 patients (70%) had <5% PD-L1 tumor cell expression.

About Transgene:

Transgene (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biopharmaceutical company focused on discovering, developing and manufacturing 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 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. 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.

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 further development plans for TG4010, or (iii) the Company will find a development and commercialization partner for TG4010 in a timely manner and on satisfactory terms and conditions, 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).

Contacts:**Transgene**

Elisabetta Castelli, Director IR
+33 (0)3 88 27 91 21

Laurie Doyle, Director IR US
& Corporate Communications
+1 (339) 832 0752

investorrelations@transgene.fr

MC Services

Raimund Gabriel
+49 89 210 228 30
raimund.gabriel@mc-services.eu

Shaun Brown
+44 207 148 5998
shaun.brown@mc-services.eu