Transgene Announces Final Overall Survival Data from Phase 2b TIME Trial with TG4010 Immunotherapy in Non-Small Cell Lung Cancer Presented at World Conference on Lung Cancer

Data confirm strength of previously reported results

Strasbourg, France, September 8, 2015 – Transgene SA (Euronext: TNG) today announced the presentation[1] by Dr. Elisabeth Quoix of final data from the Phase 2b part of the TIME trial with TG4010 MUC1 targeted immunotherapy in non-small cell lung cancer (NSCLC) at the 16th World Conference on Lung Cancer in Denver, CO, USA.

The overall survival (OS) data confirm the strength of previously reported improvements and are significant in patients with a "low" level of triple positive activated lymphocytes (TrPAL[2]), as well as in those patients with low TrPAL and non-squamous disease.

Elisabeth Quoix, M.D., Head of the Department of Pulmonology at the University Hospital of Strasbourg and Coordinating Investigator of the TIME study, said: *"Lung cancer remains a devastating disease and there is an urgent need for new treatments. Immunotherapies are an area of great promise, and I look forward to the further development of TG4010 in combination with chemotherapy, as well as with immune checkpoint inhibitors, in this important indication."*

The TIME trial is a randomized, double-blind, placebo-controlled study evaluating TG4010 in combination with chemotherapy in the first-line treatment of advanced (Stage IV) NSCLC patients. A total of 222 patients were enrolled in the Phase 2b portion of the trial. The primary objective[3] of the Phase 2b part of the study was to analyze progression-free survival (PFS); OS, response rate, duration of response and the safety of TG4010 in combination with chemotherapy were also assessed.

[1] Quoix, E. et al. TG4010 Immunotherapy plus Chemotherapy as First Line Treatment of Advanced NSCLC: Phase 2b Results. 16th World Conference on Lung Cancer. September 2015.

[2] TrPAL=triple positive activated lymphocytes: CD16+CD56+CD69+ cells at baseline.

[3] 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 (TG4010.09) in advanced NSCLC patients. (see press release of May 27, 2014)

Data presented indicated that patients with low levels of TrPAL at baseline showed statistically significant differences in both PFS and OS when treated with TG4010 compared to placebo; a higher response rate and duration of response two times longer than the placebo group were also observed. These improvements were even more notable in the subgroup of patients with both non-squamous disease and low levels of TrPAL. In this important subgroup of patients, 40% were still alive at 24 months in the group treated with TG4010 plus chemotherapy compared to 19% in the control group. Key data presented are outlined below:

Intent-to-treat *(ITT)* Subgroup	**Total # of patients (TG4010/placebo)**	**PFS Hazard Ratio (95% CI*) p-value**	**OS Hazard Ratio (95% CI*) p-value**	**Response Rate TG4010 vs. Placebo**	**Duration of Response (weeks) TG4010 vs. Placebo**
Low TrPAL	147 (71/76)	0.66 (0.46-0.94) P=0.010	0.67 (0.46-0.98) p=0.018	39.4% vs. 31.6%	41.4 vs.18.7
Non-squamous	196 (98/98)	0.69 (0.51-0.94) p=0.009	0.73 (0.52-1.01) p=0.030	39.8% vs. 27.6%	40.9 vs. 18.1
Non-squamous, low TrPAL	127 (61/66)	0.59 (0.40-0.87) P=0.003	0.59 (0.39-0.91) p=0.007	39.3% vs. 30.3%	43.1 vs. 18.1

*Confidence Interval

In addition, as previously reported[4], clear activity was also seen with TG4010 in patients having low levels (<5%) of tumor cells expressing PD-L1. 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.

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.

Further development of TG4010 in NSCLC is planned in combination with chemotherapy and with immune checkpoint inhibitors, such as anti-PDL1 and anti-PD1 inhibitors.

About TG4010:

TG4010, a novel immunotherapy targeting the MUC1 protein, is being developed for the treatment of metastatic non-small cell lung cancer. TG4010 is a therapeutic vaccine expressing the MUC1 antigen and Interleukin-2 (IL2), a cytokine that stimulates the immune system. The MUC1 protein is normally found on the surface of certain cells in many tissue types. In tumor cells, several modifications of MUC1 can occur which distinguish it from MUC1 in normal cells. These changes transform the MUC1 protein into a highly immunogenic tumor associated antigen (TAA) and make it an attractive target for cancer immunotherapy. TG4010 is designed to help the body's immune system identify cancerous cells carrying the MUC1 TAA as a target to be destroyed. In addition to lung cancer, the MUC1 TAA is expressed in other solid tumor types, including breast, colorectal, kidney and prostate cancers.

[4] 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. ASCO Annual Meeting 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 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 percent 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.

About Transgene:
Transgene S.A. (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. 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.

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.

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).

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