

Transgene Announces Publication in “The Lancet Oncology” of Phase 2b TIME Trial Results with TG4010 Immunotherapy in Non-Small Cell Lung Cancer

Strasbourg, France, December 23, 2015– Transgene SA (Euronext: TNG) today announced that 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*. The article, entitled “TG4010 immunotherapy and first-line chemotherapy for advanced non-small-cell lung cancer (TIME): results from the phase 2b part of a randomised, double-blind, placebo-controlled, phase 2b/3 trial,” by E. Quoix et al is now available online at [http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(15\)00483-0/abstract](http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)00483-0/abstract).

The article discusses the results of this 222-patient randomized, double-blind, placebo-controlled study evaluating TG4010 in combination with first-line chemotherapy in Stage IV NSCLC patients. As previously reported, improvements were seen in progression-free survival, overall survival, response rate and duration of response in the TG4010 group compared to control, and these improvements were even more notable in patients with a “low” level of the triple positive activated lymphocytes (TrPAL¹) biomarker, as well as in those patients with both low TrPAL and non-squamous disease. 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.

“The TIME trial results published today support the further development of TG4010 for the treatment of advanced non-small cell lung cancer,” said Elisabeth Quoix, M.D., Head of the Department of Pulmonology at the University Hospital of Strasbourg, Coordinating Investigator of the TIME study and lead author. *“There is an urgent need for new lung cancer treatments, and immunotherapies are an area of great promise. It is important to continue to advance new treatments, particularly in combination with other therapies, and I look forward to the further development of TG4010 with chemotherapy, as well as with immune checkpoint inhibitors, in this important indication.”*

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.

¹ TrPAL=triple positive activated lymphocytes: CD16+CD56+CD69+ cells at baseline. Patients with “low” TrPAL were defined as being in the three lowest quartiles (<Q3).

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 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 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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