



Transgene Presents Additional Positive Clinical Data from Phase 2b Part of TIME Trial with TG4010 at ESMO

- ***Statistically significant difference in progression-free survival continues to be seen in non-squamous patient population***
- ***Promising overall survival data, notably in subgroups of interest for the upcoming Phase 3 trial***
- ***Company to hold conference call today, Monday, September 29 at 1:30 PM EDT/7:30 PM CET to discuss data***

Strasbourg, France, September 29, 2014 – Transgene SA (NYSE-Euronext: TNG) today announced the presentation¹ of more mature data from the Phase 2b part of the TIME trial with TG4010 MUC1 targeted immunotherapy at the European Society of Medical Oncology (ESMO) 2014 Congress in Madrid, Spain. The data presented show promising and consistent results in progression-free survival (PFS) and overall survival (OS), particularly in the large subgroup of patients with non-squamous disease. The poster presented at ESMO can be found on the Company's website at www.transgene.fr.

Elisabeth Quoix, M.D., Head of the Department of Pulmonology at the University Hospital of Strasbourg and Coordinating Investigator of the TIME study, said: *"The field of cancer immunotherapy holds great promise, and we have recently seen some exciting breakthroughs for treating various cancers with this type of treatment. The results presented at ESMO with Transgene's TG4010 in lung cancer are promising and I look forward to seeing this novel immunotherapy product candidate advance further through development."*

Philippe Archinard, Chairman and Chief Executive Officer of Transgene, said: *"We are excited about the results presented this week with TG4010 in advanced non-small cell lung cancer. While the overall survival data are not yet fully mature, they show a clear trend in favor of the TG4010 arm, and we are hopeful that they will improve further over time. With such positive results, as well as recent encouraging interactions with regulatory authorities, we continue to advance our plans for the Phase 3 trial, as well as our strategic partnering discussions."*

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)

¹ Abstract # 5152 - Quoix, E. et al. *TIME, a phase 2b/3 study evaluating TG4010 in combination with first line therapy in advanced non small cell lung cancer (NSCLC). Phase 2b results.*

NSCLC patients. A total of 222 patients were enrolled in the Phase 2b portion of the trial, and enrollment is now completed. The primary endpoint² of the Phase 2b part of the study is to prospectively validate the TrPAL predictive biomarker³; the safety and efficacy of TG4010 in combination with chemotherapy in this patient population were also assessed, including in pre-specified subgroups.

On May 27, 2014, the Company announced that the primary endpoint of PFS in the normal TrPAL group was met. The high TrPAL group has not yet met the required number of events to conduct the primary analysis.

A recent analysis was conducted with a more mature data set. In the subgroup of patients with non-squamous histology - 88% of patients in the trial - statistically significant differences in PFS, as well as compelling and clinically meaningful differences in OS, continue to be observed. The OS data continue to mature.

Consistent with previous communications, these improvements were even more notable in the so-called “low”⁴ TrPAL groups of patients.

Key data are outlined below:

<i>Intent-to-treat (ITT)</i>		Progression-Free Survival	Overall Survival
Subgroup	Total # of patients (TG4010/placebo)	Hazard Ratio (95% confidence interval)⁺	Hazard Ratio (95% confidence interval)⁺
Non-squamous	195 (97/98)	0.71 (0.51, 0.97)	0.73 (0.50, 1.07) ⁺⁺
Non-squamous, low TrPAL	131 (64/67)	0.60 (0.41, 0.88)	0.70 (0.45, 1.10) ⁺⁺⁺

⁺ Stratified Cox proportional hazards model

⁺⁺ Overall survival analysis based on 56% of possible events

⁺⁺⁺ Overall survival analysis based on 60% of possible events

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

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 using a pre-defined threshold level, the so-called “upper limit of normal” or ULN; patients were classified as “normal” or “high” TrPAL using this method.

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

events were mild to moderate injection site reactions. To date, over 350 patients have been treated with TG4010 and the product has been consistently well tolerated across trials.

Recent interactions with regulatory authorities have encouraged Transgene to move forward with the preparations for the Phase 3 part of the TIME trial. This trial is planned to enroll only patients with non-squamous disease. Transgene is seeking a global development and commercialization partner for TG4010 and talks are ongoing with potential partners.

Conference call scheduled

A conference call in English has been scheduled for Monday, September 29, 2014 at 1:30 PM EDT/7:30 PM CET. A replay of the call will be available on the Transgene website (www.transgene.fr) following the live event.

Webcast link to English language conference call:

EN: <http://www.media-server.com/m/p/6y2aowh4>

Webcast access on mobile devices - QR code:



Participant telephone numbers:

France:	+33 1 76 77 22 31
United Kingdom:	+44 20 3427 1918
USA:	+1-646-254-3361

Confirmation Code: 3930606

Participants will need to provide the above code when dialing into the call.

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.

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 non-small cell lung cancer:

Lung cancer is one of the most common malignancies worldwide with an estimated 1.8 million cases and 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 approximately 313,000 cases of lung cancer in the European Union (EU) in 2012, and 268,000 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 2014, more than any other cancer type. It is estimated that there will be 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 (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 cancer 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. 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 plans for the Phase 3 part of the trial, 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 Investor Relations
+33 (0)3 88 27 91 21

Laurie Doyle, Director Investor Relations 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