Transgene Updates on the Therapeutic Vaccine TG4010 Developed in Lung Cancer

- **First regulatory authorisations granted in EU for the launch of a Phase IIb/III clinical trial**
- **Publication of earlier Phase II data in *The Lancet Oncology***

Strasbourg, France, October 28, 2011 – Transgene S.A. (NYSE-Euronext Paris: TNG) announces that its Phase IIb/III trial testing TG4010 in patients with advanced Non-Small Cell Lung Cancer ("NSCLC") expressing MUC1[1] has recently started receiving approvals from regulatory agencies and ethical committees in Europe (UK and France notably) and is expecting more in the coming weeks.

The Phase IIb part of the trial will recruit around 200 patients in 70 clinical centers, in 11 countries. TG4010 will be administered as an adjunct to chemotherapy, as a first line of treatment, to patients who have not previously received a chemotherapy treatment. Its primary objective will be to measure progression-free survival ("PFS").

Recruitment of patients should start in December 2011 and will enroll both patients with normal and high levels of activated NK cells at baseline[2].

Overall survival will also be observed as a secondary endpoint in the Phase IIb and will be the primary endpoint of the Phase III part of the study, which is set to start in 2013 and to recruit around 800 patients in more than 200 clinical sites.

Depending on the Phase IIb data, the Phase III part of the trial should recruit only patients with normal levels of activated NK cells, the population for which a meaningful clinical benefit in terms of overall survival was observed in the study detailed in an article published online on October 22, 2011, in *The Lancet Oncology* journal (the article was also referenced in *The Lancet* the same day). The publication presents the key clinical findings of Transgene's previous Phase II data with TG4010 in NSCLC. These data had previously been reported at the annual meeting of the American Association of Cancer Research as well as at the annual meeting of the American Society of Clinical Oncology in 2009.

Novartis has an exclusive option to in-license TG4010 based on Phase IIb data.

"We are very pleased to have the previous Phase II data published in such a prestigious journal as The Lancet Oncology, as it further demonstrates the medical relevance of our very innovative approach" said Philippe Archinard, Chairman and CEO of Transgene. He added: *"We are now all set to start the most ambitious clinical trial Transgene has ever begun, with the parallel development of a therapeutic vaccine and two companion diagnostics in a landmark, seamless Phase IIb/III trial".*

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[1] Selection of MUC1-positive patients with a companion diagnostic test in development
[2] Measure of activated NK cells by another companion diagnostic test in development

About TG4010 cancer vaccine:

TG4010 (MVA-MUC1-IL2) uses the Modified Vaccinia Ankara virus vector, a poxvirus that combines distinguishing advantages for an optimized systemic vaccination:

- MVA is a highly attenuated strain which has been tested extensively in humans as a smallpox vaccine and is known to strongly stimulate innate and adaptive immune responses to antigens.
- MUC1 is a major tumor-associated antigen that provides a viable target for immunotherapy.
- TG4010 expresses the entire MUC1 gene sequence and has the potential to generate an immune response to all antigenic epitopes of MUC1.
- The sequence coding for the cytokine Interleukin 2 (IL2) is included to help stimulate specific T-cell response.

About the study published in *The Lancet Oncology*:

The efficacy and safety of TG4010 have been assessed in a randomized, controlled Phase II study evaluating the therapeutic vaccine TG4010 as an adjunct to standard chemotherapy in 148 patients with advanced NSCLC. The primary objective of the study was met (Progression free survival at 6 months of at least 40% in the experimental arm).

During the phase II trial, Transgene retrospectively identified a subpopulation of patients who benefited from the treatment with TG4010 and chemotherapy, versus chemotherapy alone. This sub-population consisted of patients with normal levels of activated NK cells (natural killer cells) at baseline and represented some 73 per cent of the evaluable patient population (101 out of 138 patients). The phase II clinical results have demonstrated an improved clinical outcome for patients in this subpopulation with a statistically significant 6 month increase in median survival (17.1 months in the experimental arm versus 11.3 months in the control arm).

About Transgene:

Transgene, a member of the Institut Mérieux Group, is a publicly traded French biopharmaceutical company dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases and has four compounds in Phase II clinical development: TG4010 and JX594/TG6006 having already completed initial Phase II trials, TG4001 and TG4040. Transgene has concluded strategic agreements for the development of two of its immunotherapy products: an option agreement with Novartis for the development of TG4010 to treat various cancers and an in-licensing agreement with US-based Jennerex, Inc. to develop and market JX594/TG6006, an oncolytic virus. Transgene has bio-manufacturing capacities for viral-based products. Additional information about Transgene is available at www.transgene.fr.

Disclaimer:

This press release contains forward-looking statements referring to the clinical testing and development of Transgene's product candidates. Clinical testing and successful product development depend on a variety of factors, including the timing and success of future patient enrolment and the risk of unanticipated adverse patient reactions. Results from future studies with more data may show less favorable outcomes than prior studies, and there is no certainty that product candidates will ever demonstrate adequate therapeutic efficacy or achieve regulatory approval or commercial use. For further information on the risks and uncertainties involved in the testing and development of Transgene's product candidates, see Trangene's Document de Référence on file with the French Autorité des marchés financiers on its website at http://www.amf-france.org and Transgene's website at www.transgene.fr .

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