Transgene Receives Positive Scientific Advice from the European Medicines Agency for the Phase IIb/III trial of its Targeted Immunotherapy Product TG4010 for the Treatment of Non-Small Cell Lung Cancer

Parc d'Innovation, Illkirch, France, September 1st, 2010 – Transgene (Euronext Paris: FR0005175080) today announced that it has received positive Scientific Advice from the European Medicines Agency (EMA) regarding the Phase IIb/III trial of its immunotherapy product TG4010 for the treatment of advanced non-small cell lung cancer (NSCLC).

Following its review, the EMA has agreed with the design of the proposed pivotal phase IIb/III study intended to be supportive of the Marketing Authorisation Application of TG4010 used in combination with first line therapy, in patients with advanced MUC1 expressing NSCLC and with normal levels of activated Natural Killer (aNK) cells before treatment. The EMA also agreed with the proposed development strategy of the companion tests used to identify this subpopulation of patients.

The study will involve approximately 1,200 patients. Transgene expects to obtain regulatory clearance, to initiate this study, before year end. The final results are expected to become available by the end of 2013.

Philippe Archinard, Chairman and CEO of Transgene stated: "The EMA's positive Scientific Advice for TG4010 in NSCLC represents a major milestone in the clinical development plan of this compound. We are also actively preparing the next steps and look forward to working closely with the FDA in order to further validate the design of this proposed pivotal Phase IIB/III study as part of the Special Protocol Assessment FDA process (SPA)."

About Scientific Advice

Scientific Advice is a procedure offered by the EMA to stakeholders for clarification of questions arising during development of medicinal products. The scope of Scientific Advice is limited to scientific issues, i.e. to quality, non-clinical and clinical aspects of the concerned medicinal product not yet unequivocally covered by published scientific guidelines. Scientific Advice focuses on development strategies rather than pre-evaluation of data to support a Marketing Authorization Application. Scientific Advice is legally non-binding and is based on the current scientific knowledge which may be subject to future changes

…/…

About the Phase IIb/III trial in NSCLC

The proposed study consists of a single large global pivotal Phase IIb/III study to support the MAA of TG4010. This will be a randomized, double-blind and placebo controlled clinical trial with two parallel arms: first line therapy plus TG4010 versus first line therapy plus placebo. The Phase IIb/III study will be open to patients with advanced MUC1 expressing Stage IV NSCLC (adenocarcinoma, squamous cell carcinoma, or other including large cell carcinoma) and with normal levels of activated Natural Killer (aNK) cells before treatment

The Phase IIb part of the study is aimed at assessing the safety of the combination of TG4010 with other anti-neoplastic regimens not yet tested in previous Phase II studies. The Phase III part of the study is powered to demonstrate a significant improvement of Overall Survival (OS) when TG4010 is added to first line chemotherapy in this population of patients with advanced NSCLC. The study design foresees a seamless transition from the phase IIb part into a phase III part.

About TG4010

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 Non-Small-Cell Lung Cancer (NSCLC)

Lung cancer is a major public health issue with over 1 million new cases a year across the world, and accounts for some 350,000 deaths per year in Europe and the United States alone. Around 80% of lung cancer patients are diagnosed with non-small-cell lung cancer. Of these, some 60% over-express MUC1, which is the target for TG4010. The efficacy of current treatments for NSCLC is limited, and TG4010 is targeting first line treatment of metastatic NSCLC in combination with chemotherapy. Other NSCLC stages of disease and all other epithelial cancers expressing MUC1 (prostate, breast, kidney, pancreatic and colorectal cancers) are also potential future targets for TG4010.

About Transgene

Transgene is a French biopharmaceutical company dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases. The company has four compounds in clinical development: TG4010 having completed Phase II trials, TG4001/RG3484 in Phase IIb trial, TG4040 in Phase II trial and TG4023 in Phase I trial. Transgene has concluded strategic agreements for the development of two of its immunotherapy products:

- a license agreement with Roche for the development of TG4001/RG3484 to treat HPV-mediated diseases, and
- an option agreement with Novartis for the development of TG4010 to treat various cancers.

Transgene has bio-manufacturing capacities for viral-based products. Additional information about Transgene is available on the Internet at www.transgene.fr.

Cautionary note regarding forward-looking statements

This press release contains forward-looking statements referring to the planned clinical testing and development of one of Transgene's therapeutic vaccine candidates. However, 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 .

For further information please contact:

Transgene

Philippe Archinard, CEO
+33 (0)3 88279122

Elisabetta Castelli, Director IR
+33 (0)1 44085505

MC Services

Raimund Gabriel
+49 89 210 228 30