Transgene Receives FDA Fast Track Status for its Targeted Immunotherapy Product TG4010 for the Treatment of Non-Small Cell Lung Cancer

Parc d'Innovation, Illkirch, France, December 1, 2009 – Transgene (Euronext Paris: FR0005175080) today announced that the U.S. Food & Drug Administration (FDA) has granted Fast Track development designation to its immunotherapy product TG4010 (MVA-MUC1-IL2) for the first-line treatment of advanced non-small cell lung cancer (NSCLC) in combination with chemotherapy.

The FDA determined that TG4010 meets the criteria for the Fast Track designation, facilitating the development of TG4010 for the first-line treatment in combination with chemotherapy to improve survival in patients with advanced MUC1-positive NSCLC and normal levels of activated Natural Killer (NK) cells. The granting of Fast Track status follows the FDA's earlier clearance to proceed to phase III trial based on positive clinical data from a controlled phase IIb trial of TG4010 in patients with advanced NSCLC (see press release dated June 9, 2009 on www.transgene.fr).

The Fast Track program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track designated drugs ordinarily qualify for priority review, thereby expediting the FDA review process. In addition, the designation allows the TG4010 Biological License Application (BLA) to be considered for submission on a rolling basis, allowing the FDA to review sections of the BLA as they are completed.

"We are very pleased with the FDA's decision to grant Fast Track status to TG4010, which represents a key achievement in our regulatory strategy" said Philippe Archinard, Chief Executive Officer of Transgene. "We are actively preparing the next development steps for the product and look forward to working closely with the FDA. Discussions for the partnering of TG4010 have progressed and we hope to reach a collaborative agreement around year-end 2009."

About the Phase IIb trial in NSCLC:

The phase IIb trial was a randomized, open label and controlled study designed to assess the efficacy of TG4010 in combination with cisplatin and gemcitabine compared to the chemotherapy regimen alone. The trial completed the enrolment of 148 patients at the end of May 2007 in 27 centres located in France, Poland, Germany, and Hungary. The trial met its primary end point with a progression-free survival at 6 months of 45 % in the experimental arm.

Additionally, the phase IIb clinical data after 24 months of median follow-up confirmed a 6-month increase in median survival (17.1 months in the experimental arm versus 11.3 months in the control arm) in patients with normal levels of activated NK cells at baseline (some 75% of the patients in the trial) a sub-population identified by Transgene's biomarker programme[1]. Furthermore, all other relevant parameters confirmed an improved clinical outcome for patients of this sub-population treated with TG4010. Further information on the phase IIb results for TG4010, including previous press releases, and the ASCO and ESMO posters, is available on Transgene's website (www.transgene.fr).

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[1] The Biomarker program is partly financed by an OSEO grant as a part of the ADNA program (Advanced Diagnostics for New Therapeutic Approaches).

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 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% overexpress 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 NK Cells

Natural Killer cells (NK cells) are effector lymphocytes of the innate immune system that control several types of tumors and microbial infections by limiting their spread and subsequent tissue damage. Recent research highlights the fact that NK cells are also regulatory cells engaged in reciprocal interactions with dendritic cells, macrophages, T cells and endothelial cells. NK cells can thus limit or exacerbate immune responses.

About Transgene

Transgene is a France-based biopharmaceutical company dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases. The company has three compounds in phase II trials (TG4001/R3484, TG4010 and TG1042) and two compounds in phase I studies (TG4040 and TG4023). Transgene has concluded a strategic partnership agreement with Roche for the development of its TG4001/R3484 therapeutic vaccine to treat HPV-mediated diseases. Transgene has bio-manufacturing capacities for viral-based vectors and technologies available for out-licensing. 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. In addition, the entry into new partnerships involves a process of negotiation with partner candidates, including with respect to financial, technical, commercial and legal matters, and there is no certainty that appropriate partnerships will be established or will be successful. 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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