TRANSGENE: U.S. FOOD AND DRUG ADMINISTRATION GIVES GREEN LIGHT TO PROCEED TO PHASE III TRIAL WITH TG4010 TARGETED IMMUNOTHERAPY IN LUNG CANCER

ADDITIONAL TG4010 DATA PRESENTED AT ASCO CONFIRM PREVIOUS EFFICACY RESULTS AND BIOMARKER PROGRAM FINDINGS SUPPORT MECHANISM OF ACTION

Parc d'Innovation, Illkirch, France, June 9, 2009 – Transgene (Euronext Paris: FR0005175080) announces that it recently met with the U.S. Food and Drug Administration (FDA) for an end of Phase II meeting when results of its TG4010 controlled phase IIb clinical trial in non-small-cell lung cancer (NSCLC) were reviewed. As per the minutes of the meeting, the FDA agrees with the proposal to proceed as planned to a phase III study in combination with first line chemotherapy in patients with advanced NSCLC and with a normal level of activated Natural Killer (NK) cells before treatment.

Furthermore, Transgene presented additional TG4010 phase IIb data at the American Society of Clinical Oncology (ASCO) 2009 annual meeting in Orlando, Florida, on 31st May confirming the previously reported positive results for TG4010.

The additional data for TG4010 now reflects 24 months of median follow up. It confirms 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]. All other relevant parameters (response rate, progression-free survival at 6 months, time to progression) confirmed an improved clinical outcome for patients of this sub-population treated with TG4010. The latest data therefore confirm the identification of activated NK cells as an appropriate predictive biomarker associated with positive clinical outcome of the treatment with TG4010 in NSCLC.

Moreover, post-treatment sample analysis after six TG4010 injections showed a longer median survival for those patients treated with TG4010 and chemotherapy who had an increased level of activated T lymphocytes ($p = 0.026$), supporting the expected mechanism of action of the targeted immunotherapeutic product.

Philippe Archinard, Chief Executive Officer of Transgene said: *"Eighty percent of lung cancer patients are diagnosed with non-small-cell lung cancer and very frequently at an advanced stage where current treatments have limited impact. Our latest TG4010 clinical results confirm a significant increase in survival rates in a major sub-population of patients. We are very pleased with the FDA green-light for phase III planned developments and with the progress made in our discussions with potential pharmaceutical partners for the further development and commercialization of this product."*

You may find the ASCO poster on *www. transgene.fr* for further details.

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[1] The biomarker project is partly financed by an OSEO (French agency specialised in innovation & development funding) grant as part of the ADNA programme (Advanced Diagnostics for New Therapeutic Approaches).

About the phase IIb trial

The phase IIb trial is 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 enrolled 148 patients in 27 centres located in France, Poland, Germany, and Hungary. The patients had NSCLC of all histological sub-types expressing MUC1, either stage IIIB with effusion (8%) or stage IV (92%), and had not received prior systemic treatment for their advanced disease. Half of the patients were randomized to receive the combination regimen of TG4010 targeted immunotherapeutic product plus chemotherapy (experimental arm). The other half of the patients received chemotherapy alone (control arm). The statistical primary endpoint was to observe at least 40% of patients free of progression six months after randomization in the experimental arm. The primary end point was met with 45% of evaluable patients in the experimental arm showing progression-free survival at 6 months. Secondary endpoints were response rate, time to progression, overall survival, safety, immunological responses, proteomics and transcriptomics.

Further information on the phase IIb results for TG4010, including previous press releases, the ASCO and ESMO posters, and further information on the ADNA programme are available on Transgene's website (www.transgene.fr).

About TG4010 cancer targeted immunotherapy

TG4010 (MVA-MUC1-IL2) uses the Modified Vaccinia Ankara virus vector (MVA), 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. Approximately 80% of lung cancer patients are diagnosed with non-small-cell lung cancer. Of these, some 70% 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. Earlier 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 against cancerous cells.

About Transgene

Transgene is a France-based biopharmaceutical company dedicated to the development of immunotherapeutic products in oncology and infectious diseases. The company has three compounds in Phase II trials (TG4001/R3484, TG4010 and TG1042) and one compound in Phase I studies (TG4040). Transgene has concluded a strategic partnership agreement with Roche for the development of its TG4001/R3484 immunotherapeutic product to treat HPV-mediated diseases. Transgene has bio-manufacturing capacities for viral-based vectors. 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 immunotherapeutic 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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