



## **TRANSGENE SIGNS AN AGREEMENT WITH VENTANA MEDICAL SYSTEMS, INC. TO DEVELOP A COMPANION DIAGNOSTIC TEST FOR TRANSGENE'S TG4010**

**Parc d'Innovation d'Illkirch, France, September 29, 2010** – Transgene (Euronext Paris: FR0005175080) and Ventana Medical Systems, Inc. today announced that they have entered into a collaboration agreement for the development of an immunohistochemistry (IHC) assay, as a companion diagnostic test for TG4010, Transgene's immunotherapy product.

TG4010 is about to enter into a Phase IIB/III clinical trial in advanced non-small cell lung cancer (NSCLC) patients with tumor cells expressing the MUC1 protein. A MUC1 IHC assay will initially be developed by Ventana to identify MUC1 positive tumor cells, as a diagnostic test for selecting patients to be enrolled in the upcoming Phase IIB/III trial.

In the event of successful completion of TG4010's clinical development, a New Drug Application (NDA) will be submitted by Transgene or its licensee, and Ventana will submit in parallel the companion MUC1 IHC test for Pre-market Approval (PMA) in the United States as a class III *in vitro* diagnostic device, a classification under the FDA regulation for companion diagnostic tests used for screening patients' eligibility for drugs. If regulatory approvals are granted, the MUC1 companion diagnostic IHC test will serve as a tool for physicians to identify patients who can be treated with TG4010.

Philippe Archinard, Chief Executive Officer and President of Transgene, said: "Ventana is the IHC market leader and is also committed to become a leader in the development of companion diagnostic tests. We are very pleased to partner with them so as to further develop a MUC1 IHC assay for TG4010. Development of such a test is critical for the product's entry into late stage clinical development, as well as for its future commercialization."

Doug Ward, Vice President of Translational Diagnostics for Ventana, said: "We are very excited to participate in the Phase IIB/III trial of Transgene's TG4010 immunotherapeutic product by developing a companion diagnostic to select patients. The development of a companion diagnostic assay at this critical stage further demonstrates our commitment to deliver personalized healthcare. At Ventana, we are committed to working with biopharmaceutical companies like Transgene to effectively tailor therapies for patients in order to better manage diseases such as non-small cell lung cancer."

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### **About TG4010:**

TG4010 (MVA-MUC1-IL2) uses the Modified Vaccinia Ankara (“MVA”) 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 for the stimulation of a specific T-cell response.

TG4010 is currently in development for the treatment of advanced NSCLC in combination with first line therapy. The pivotal global controlled Phase IIb/III trial of TG4010 is expected to start by the end of 2010. Transgene has granted Novartis an option for the exclusive development and commercialisation of TG4010. For additional information, visit [www.transgene.fr](http://www.transgene.fr).

### **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 450,000 deaths per year in Europe and the United States alone. Around 80% of lung cancer patients are diagnosed with NSCLC. Of these, some 70% 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.

### **About Ventana Medical Systems, Inc.:**

Ventana develops, manufactures, and markets instrument/reagent systems that automate tissue preparation and slide staining in clinical histology and drug discovery laboratories worldwide. The Company's clinical systems are important tools used in the diagnosis and treatment of cancer and infectious diseases. Ventana drug discovery systems are used to accelerate the discovery of new drug targets and evaluate the safety of new drug compounds. In addition, the Company offers premier workflow solutions designed to improve laboratory efficiency that enhance the quality of healthcare. Ventana is a wholly owned member of the Roche Group. For more information on Ventana Medical Systems, Inc. visit [www.ventanamed.com](http://www.ventanamed.com).

### **About Transgene:**

Transgene is a France-based biopharmaceutical company focused on the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases. The Company has four compounds in Phase II clinical trials: TG4001/RG3484, TG4010, TG 4040 and JX-594, and one compound in Phase I clinical trials: TG4023.

Transgene has entered into strategic collaborative agreements for the development of two of its immunotherapy products:

- An exclusive license agreement with Roche for the development of TG4001/R3484 to treat HPV-mediated diseases.

- An option agreement for an exclusive license with Novartis for the development of TG4010 to treat various cancers

The Company has also recently concluded an in-licensing agreement with US-based Jennerex Biotherapeutics, Inc., to develop and market JX-594, an oncolytic product.

Transgene has bio-manufacturing capacities for viral-based vectors. Additional information about Transgene can be found at [www.transgene.fr](http://www.transgene.fr).

Cautionary note regarding forward-looking statements

*This press release may contain forward-looking statements referring to the anticipated development, application for regulatory approval and commercialisation of one of Transgene's therapeutic product candidates. Clinical testing, regulatory approval 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 broad commercial use. For further information on the technical, regulatory and competitive risks and uncertainties involved in the development and commercialisation of product candidates, see Transgene's Document de référence on file with the French Autorité des marchés financiers at <http://www.amf-france.org> and Transgene's website at [www.transgene.fr](http://www.transgene.fr).*

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