Transgene to Collaborate with the EORTC on a Phase 2b Trial with TG4001 in Head and Neck Cancer

Strasbourg, November 13, 2012 - Transgene SA (Euronext Paris: FR0005175080) today announced that it will collaborate with the European Organization for Research and Treatment of Cancer (“EORTC”) for the conduct of a randomized phase 2b study of TG4001 in patients with HPV16 positive Oropharyngeal Squamous Cell Carcinomas (OSCCs).

The study will be a multinational, placebo controlled, randomized, phase 2b trial led by the EORTC in which TG4001 will be administered in combination with chemo-radiotherapy in patients with HPV16 positive OSCCs whose tumor is locally advanced (non-metastatic). The main objective of the study will be to show a reduction in the relapse rate in patients receiving TG4001 in addition to this standard of care. Approximately 200 patients should be enrolled.

“The EORTC welcomes this new partnership with Transgene aiming at improving outcomes for the HPV16-positive subset of patients” said EORTC Director Dr. Denis Lacombe. He added: “Currently the standard treatment is chemo-radiotherapy and we believe combining it with TG4001, an HPV-targeted immunotherapy, could potentially improve the survival rate of patients.”

The trial is scheduled to start in late 2013 and should deliver its first safety and efficacy results in 2016. Under certain conditions, to be further discussed between Transgene and EORTC, this clinical trial could be extended to a phase 3 that could serve as a registrational study for TG4001 in this indication.

Since 2011, Transgene has regained full rights to TG4001 from Roche. Clinical results (released in 2012) from a phase 2b trial conducted by Roche in 206 high grade cervical dysplasia (CIN2/3) patients demonstrated a significant level of activity of the therapeutic vaccine compared to placebo.

“We are very pleased to announce this collaboration with the EORTC, a leading independent European cancer research organisation which is at the forefront of the development new cancer treatment strategies” said Philippe Archinard, President and CEO of Transgene. He added: “This is an opportunity to improve the cure rate for patients and also a good opportunity for Transgene to explore and extract value from this asset, for which interesting proof of concept data were previously obtained in a monotherapy trial. The combination of therapeutic vaccine and chemotherapy is based on a strong clinical rationale as evidenced by Transgene in a previous trial combining TG4010, an MVA-MUC1 vaccine, to chemotherapy in non-small cell lung cancer”.

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About the Targeted Market:

The market for head and neck cancers was valued by Transgene at $1 billion in annual sales in 2010. It is currently growing fast and is expected to reach close to $2 billion in value by 2017. This growth is primarily attributed to the increasing prevalence and diagnosis rate of the disease but also to the introduction of new effective therapies as unmet medical needs are significant. Transgene estimates the eligible population (incidence) for the combination of TG4001 and radio-chemotherapy in the HPV16-related head and neck squamous cell carcinomas (“HNSCC”) to be between 10,000 and 15,000 patients. As the only HPV-targeted therapy in advanced clinical development in HNSCC, the combination could expect a penetration superior to 50% of the eligible population.

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 2 clinical developments: TG4010 and JXS94/TG6006 having already completed initial phase 2 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.

About the EORTC:

The EORTC is a unique organization – a vibrant example of the fact that academic science and research know no national boundaries. Established in 1962, the EORTC is a non-profit European research organization operating as an international association under Belgian law. The EORTC currently links a network of more than 2,500 pre-clinical scientists and oncologists in more than 300 hospitals in over 30 countries. It encompasses all aspects of cancer research, from translational research and new drug development to large phase III clinical trials and meta-analyses. The 170 members of the EORTC Headquarters staff handle some 6,000 new patients enrolled each year in cancer clinical trials, approximately 30 protocols that are permanently open to patient entry, over 50,000 patients who are in follow-up, and a database of more than 180,000 patients. The ultimate goal of the EORTC is to improve the future of cancer therapy by developing new agents and innovative approaches and to test more effective treatment strategies using commercially available drugs, or surgery and radiotherapy.

www.eortc.org
Disclaimer:

This press release contains certain forward-looking statements. Although the company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. In particular, the Company’s ability to commercialize its first product depends on the continuing success of clinical studies, ongoing financing for further product developments and marketing launch, a positive response from the medical community regarding the product’s costs and effectiveness. For a discussion of risks and uncertainties which could cause the company’s actual results, financial condition, performance or achievements to differ from those contained in the forward-looking statements, please refer to the Risk Factors (“Facteurs de Risque”) section of the Document de Reference prospectus, which is available on the AMF website (http://www.amf-france.org) or on Transgene’s website (www.transgene.fr). This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in Transgene in any country.

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