Transgene and Léon Bérard Cancer Center Announce Dosing of the First Patient in a Phase 1 Immunotherapy Clinical Trial Evaluating the Intra-Tumoral Co-Administration of Pexa-Vec plus Ipilimumab (Yervoy®) in Solid Cancers

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Strasbourg, France, February 13, 2017, 6:00 p.m. CET - Transgene (Euronext Paris: TNG), a company focused on designing and developing viral-based immune-targeted therapies for the treatment of cancers and infectious diseases, today announces that the 1st patient in the ISI-JX trial has been treated at the Léon Bérard Cancer Center in Lyon, France. ISI-JX is a Phase 1 clinical trial evaluating the intra-tumoral co-administration of Pexa-Vec in combination with ipilimumab in solid tumors (NCT02977156). This investigator initiated trial promoted by the Leon Bérard Cancer Center will enroll patients with metastatic and/or locally advanced solid tumors.
Pexa-Vec is a GM-CSF expressing vaccinia derived oncolytic virus co-developed by Transgene and SillaJen. Ipilimumab is a monoclonal antibody targeted against the immune checkpoint CTLA-4 and is currently approved for the treatment of melanoma (Yervoy®, Bristol-Myers Squibb).

The open-label trial that will recruit up to 60 patients in several clinical centers in France. First readouts could be expected towards the end of 2017. The trial will evaluate the safety of the combination and evaluate the first signals for efficacy.

Dr Aurélien Marabelle MD, PhD, from Gustave Roussy, a world expert in immunotherapy clinical research and coordinating investigator of the study commented: *"We believe in the synergistic potential of the combination between oncolytic viruses and immune checkpoint-targeted antibodies. Also, we believe that the intra-tumoral co-delivery of these immunotherapies will trigger a better priming of the anti-tumor immune response while avoiding off-target toxicities. We hope this novel "in situ immunization" strategy will overcome the resistance to cancer immunotherapy that we observe in many patients."*

The combination of Pexa-Vec and ipilimumab aims at targeting two distinct steps in the immune response against cancer cells and is expected to be significantly more effective than either product alone. Pexa-Vec is an oncolytic virus designed to *(i)* selectively destroy cancer cells through the direct lysis (breakdown) of cancer cells via viral replication, *(ii)* reduce the blood supply to tumors through vascular disruption, and *(iii)* stimulate the body's immune response against cancer cells. Its mechanism of action and its safety profile make it an appropriate candidate for combinations with immune checkpoint inhibitors (ICIs) such as ipilimumab, which acts as a brake on the body's immune response to cancer cells thereby potentially improving Pexa-Vec's anti-cancer effects.

Maud Brandely, Chief Medical Officer of Transgene, said: *"This trial aims to first demonstrate that the regimen of our oncolytic virus Pexa-Vec plus ipilimumab is well tolerated. We expect that the intra-tumoral administration of ipilimumab will have less systemic toxicity thanks to its local administration. Another objective is to show the antitumor activity of the regimen in patients with advanced solid tumors which have exhausted all standard therapeutic options."*

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About Transgene

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biotechnology company focused on designing and developing targeted immunotherapies for the treatment of cancer and infectious diseases. Transgene's programs utilize viral vector technology with the goal of indirectly or directly killing infected or cancerous cells. The Company's two lead clinical-stage programs are: TG4010, a therapeutic vaccine against non-small cell lung cancer and Pexa-Vec, an oncolytic virus against liver cancer. The Company has several other programs in clinical and preclinical development. Transgene is based in Strasbourg, France, and has additional operations in Lyon, as well as a joint venture in China. Additional information about Transgene is available at www.transgene.fr.

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About Pexa-Vec

Pexa-Vec (JX594/TG6006 - pexastimogene devacirepvec) is an oncolytic immunotherapy armed with a GM-CSF gene that promotes an anti-tumor immune response. Pexa-Vec is designed to selectively target and destroy cancer cells through three different mechanisms of action: the lysis (breakdown) of cancer cells through viral replication, the reduction of the blood supply to tumors through vascular disruption, and the stimulation of the body's immune response against cancer cells. The lead indication for Pexa-Vec is hepatocellular carcinoma (HCC, liver cancer); trials in other cancer types are underway or planned.

Transgene has exclusive rights to develop and commercialize Pexa-Vec for the treatment of solid tumors in Europe. Its partner SillaJen, Inc. is focused on developing Pexa-Vec for the north American market and has also granted exclusive development and commercial rights to Pexa-Vec in Hong Kong and The People's Republic of China to Lee's Pharmaceutical.

Disclaimer

This press release contains forward-looking statements, which are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those anticipated. The occurrence of any of these risks could have a significant negative outcome for the Company's activities, perspectives, financial situation, results, regulatory authorities' agreement with development phases, and development. The Company's ability to commercialize its products depends on but is not limited to the following factors: positive pre-clinical data may not be predictive of human clinical results, the success of clinical studies, the ability to obtain financing and/or partnerships for product manufacturing, development and commercialization, and marketing approval by government regulatory authorities. 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 Référence, available on the AMF website (http://www.amf-france.org) or on Transgene's website (www.transgene.fr). Forward-looking statements speak only as of the date on which they are made and Transgene undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.

Yervoy® is a registered trademark of Bristol-Myers Squibb Company.