

## Transgene and Institut Bergonié Start the Phase 2 Part of the METROmaJX Trial

*Study Is Evaluating the Co-Administration of Metronomic Cyclophosphamide+ Pexa-Vec  
in Soft Tissue Sarcoma (STS) and in Breast Cancer*

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**Strasbourg, France, April 12, 2017, 5:45 p.m. CET** - Transgene (Euronext Paris: TNG), a company that designs and develops viral-based immunotherapies, today announces that the first patient with soft tissue sarcoma (STS) has been treated in the Phase 2 part of the METROmaJX clinical trial at Institut Bergonié (Bordeaux, France). METROmaJX is a Phase 1/2 clinical trial evaluating the tolerability and efficacy of the co-administration of Pexa-Vec with metronomic cyclophosphamide (low doses given with high frequency) in patients with advanced solid tumors such as breast cancer and STS ([NCT02630368](#)).

In the Phase 1 part of the trial, the combination of Pexa-Vec and low-dose cyclophosphamide demonstrated a satisfactory tolerability profile, allowing the trial to progress to the Phase 2 part. The results of the Phase 1 part of the study will be presented at upcoming scientific congresses.

The Phase 2 stage of this open-label trial will enroll patients with soft tissue sarcoma (STS) and HER2 negative-breast cancer. It will primarily assess the anti-tumor efficacy of this novel combination regimen. This investigator-initiated trial is supported by INCa (French National Cancer Institute) within the frame of the CLIP<sup>2</sup> projects.

Pexa-Vec is a GM-CSF expressing vaccinia derived oncolytic virus co-developed by Transgene and SillaJen. Cyclophosphamide is a chemotherapy. Metronomic administration involves giving low doses of the drug at a higher frequency and is known to have an immunomodulating activity.

Pr Antoine Italiano, MD, PhD, from Institut Bergonié, an expert in early phase research and principal investigator of the study, commented: *“The METROmaJX trial has confirmed the good tolerability of intravenous administration of the oncolytic virus Pexa-Vec, when associated with low-dose cyclophosphamide. We hope this novel regimen will demonstrate its efficacy in the Phase 2 part of the trial.”*

The combination of Pexa-Vec and cyclophosphamide aims at targeting two distinct steps in the immune response against cancer cells and has the potential 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. Pexa-Vec’s mechanism of action and its safety profile make it an appropriate candidate for combinations with other immunomodulating therapies to potentially improve its anti-cancer effects.

Maud Brandely, Chief Medical Officer of Transgene, said: *“We are grateful to Institut Bergonié and INCa for supporting the METROmaJX trial. We hope that the Phase 2 part of the study will demonstrate that this novel oncolytic virus plus chemotherapy regimen can be synergistic resulting in a high response rate which could translate into improved overall survival. Advanced breast cancer and soft tissue sarcoma are two diseases which clearly require better treatment options for the patients.”*

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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](http://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**

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