

First Patient Dosed in a Phase 1/2 Trial of Pexa-Vec + Opdivo® for the First-Line Treatment of Advanced Liver Cancer

Strasbourg, France, July 31, 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 has been treated in a Phase 1/2 clinical trial evaluating the combination of Pexa-Vec with Opdivo® (nivolumab) as a first-line treatment of advanced hepatocellular carcinoma (HCC), which accounts for approximately 75% of liver cancers. This open-label trial will assess the safety and tolerability as well as the anti-tumor activity and efficacy of this immunotherapy combination regimen in up to 36 patients ([NCT03071094](#)).

The principal investigator of this multi-center trial is Prof Olivier Rosmorduc, MD, Head of Hepato-gastroenterology department at La Pitié-Salpêtrière Hospital in Paris (France).

More information on the trial is available on clinicaltrials.gov.

Pexa-Vec: an oncolytic immunotherapy that has shown efficacy

Pexa-Vec is an oncolytic immunotherapy product based on an oncolytic vaccinia virus expressing GM-CSF. In a Phase 2 trial of Pexa-Vec in first-line HCC, overall survival was improved in a dose dependent manner. The median overall survival was 14.1 months for the high-dose group compared to 6.7 months for the low-dose group.

Pexa-Vec is designed to:

- selectively destroy cancer cells through the direct lysis (breakdown) of cancer cells via viral replication,
- reduce the blood supply to tumors through tumor vascular disruption, and
- stimulate the body's immune response against cancer cells.

Pexa-Vec + Opdivo® (nivolumab): a promising immunotherapy combination regimen

Pexa-Vec's mechanism of action and its safety profile make it an appropriate candidate for use in combination with immune checkpoint inhibitors (ICIs) such as nivolumab.

Nivolumab (Opdivo®, Bristol-Myers Squibb) is a monoclonal antibody targeted against the PD-1 receptor. It is approved in several cancer indications and is currently being investigated in HCC within a global Phase 3 trial.

By targeting two distinct steps in the immune response against cancer cells, the combination of Pexa-Vec and nivolumab has the potential to be significantly more effective than either product alone. There is a strong scientific rationale that suggests that Pexa-Vec's anti-cancer effects could be enhanced by combining it with nivolumab, which suppresses the cancer cells' ability to escape the body's immune response.

Commenting on this innovative clinical trial, Prof Olivier Rosmorduc, MD, head of Hepato-gastroenterology department at La Pitié-Salpêtrière Hospital in Paris and principal investigator of the trial, added: *"Improving the treatment of HCC needs a therapeutic approach capable of significantly boosting the immune system. I am confident that combining immunotherapies with local and systemic effects such as anti-PD1 nivolumab and the oncolytic virus Pexa-Vec is a powerful strategy to better treat patients with advanced hepatocellular carcinoma."*

Maud Brandely, Chief Medical Officer of Transgene, said: *“HCC has a dismal prognosis which has been marginally improved by current therapeutic options. Preclinical and clinical data generated respectively with Pexa-Vec and nivolumab suggest that, in combination, these novel immunotherapies, with their complimentary modes of action, have the potential to be more active than each single agent alone. This may translate into better response rate and increased overall survival in HCC patients.”*

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About Transgene

Transgene (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, including TG4001 (HPV-positive head and neck cancers), TG1050 (chronic hepatitis B) and TG6002 (solid tumors). 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 product based on an oncolytic vaccinia virus 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: selectively destroy cancer cells through the direct lysis (breakdown) of cancer cells through viral replication, reduce the blood supply to tumors through vascular disruption, and stimulate 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.

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