



Transgene Provides Update on PHOCUS Study of Pexa-Vec in Liver Cancer Following Planned Interim Futility Analysis

Strasbourg, France, August 2, 2019 – Transgene (Euronext Paris: TNG), a biotech company designing and developing virus-based immunotherapies for the treatment of solid tumors, today announces that the independent Data Monitoring Committee (“IDMC”) of the PHOCUS study of Pexa-Vec in Liver Cancer has completed a planned interim futility analysis. SillaJen has informed Transgene of the IDMC’s recommendation to stop enrolment in the study, as the study is unlikely to meet its primary objective by the time of the final analysis. SillaJen has not reported safety concerns. Transgene will provide an update in an upcoming conference call.

The PHOCUS trial is a Phase 3 clinical trial evaluating the oncolytic immunotherapy Pexa-Vec for advanced liver cancer patients who have not received prior systemic treatment for their cancer. The study is being conducted by Transgene’s partner, SillaJen.

In the PHOCUS study, patients were randomized to one of two treatment groups: one receiving Pexa-Vec followed by sorafenib and one receiving sorafenib alone. The primary objective of the study was to determine the overall survival of patients treated with Pexa-Vec, followed by sorafenib versus sorafenib alone. Secondary objectives included safety as well as assessments for tumor responses between the two groups as measured by the following endpoints: time to progression, progression-free survival, overall response rate and disease control rate.

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About Pexa-Vec

Pexa-Vec (JX-594) is an oncolytic immunotherapeutic 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.

In a Phase 2 study, results of patients with advanced liver cancer showed that patients receiving the high dose had a statistically significant clinical improvement in terms of overall survival compared to the group receiving the low dose. Median overall survival was respectively 14.1 months in the high-dose group and 6.7 months in the low-dose group, which compares favorably with current approved treatments. (Heo J. et al., Nature Medicine, March 2013, [doi: 10.1038/nm.3089](https://doi.org/10.1038/nm.3089))

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.

About Transgene

Transgene (Euronext: TNG) 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 lead clinical-stage programs are: TG4010, a therapeutic vaccine against non-small cell lung cancer, Pexa-Vec, an oncolytic virus against liver cancer, and TG4001, a therapeutic vaccine against HPV-positive head and neck cancers. The Company has several other programs in clinical development, including TG1050 (a therapeutic vaccine for the treatment of chronic hepatitis B) and TG6002 (an oncolytic virus for the treatment of solid tumors). With its proprietary Invir.IO™, Transgene builds on its expertise in viral vectors engineering to design a new generation of multifunctional oncolytic viruses. *myvac*™, an individualized MVA-based immunotherapy platform designed to integrate neoantigens, completes this innovative research portfolio. TG4050, the first candidate selected from the *myvac*™ platform, will enter the clinic for the treatment of ovarian cancer and head and neck cancer.

Additional information about Transgene is available at www.transgene.fr

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