



## Transgene Provides an Update after the Interim Futility Analysis of the PHOCUS Study of Pexa-Vec in Liver Cancer

*Transgene is continuing to advance the development of its proprietary oncolytic viruses, in line with its strategy*

*Conference call organized today at 6:30 pm CET*

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**Strasbourg, France, August 7, 2019, 5:35 pm CET – Transgene (Euronext Paris: TNG), a biotech company designing and developing virus-based immunotherapies for the treatment of solid tumors,** provides an update on the interim futility analysis of the PHOCUS study of Pexa-Vec in liver cancer. The independent Data Monitoring Committee (IDMC) of the PHOCUS trial has recommended to stop the study (see [press release distributed on August 2, 2019](#)). Transgene is currently analyzing the data of the trial it received from its partner SillaJen, notably in the context of the ongoing Phase 2 clinical trial evaluating the combination regimen of Pexa-Vec and the immunotherapy nivolumab in the same indication. The recommendation to stop the PHOCUS trial is not caused by safety issues of Pexa-Vec.

Transgene is convinced of the great potential of oncolytic viruses (OV) as this therapeutic class displays numerous advantages that are acknowledged by the scientific and medical community. These include the ability of the viruses to infect and selectively replicate within the tumor, inducing cancer cell destruction, and to elicit a strong immune response against the tumor.

Transgene novel proprietary OV platform Invir.IO® allows the arming of these viruses to trigger the expression of anticancer weapons directly in the tumor, thus increasing the efficacy of these molecules while reducing their possible side effects.

The oncolytic viruses derived from the Invir.IO® platform have been designed using an optimized strain of *Vaccinia Copenhagen*. These carry a double deletion TK-RR-, which makes their replication more selective than viruses carrying a simple TK deletion such as Pexa-Vec. In addition, the Invir.IO® platform is designed to incorporate several transgenes encoding for a range of specific anticancer weapons which involve well-established immunotherapy mechanisms such as anti-CTLA-4 antibodies.

The collaboration with AstraZeneca was formed on the merits of this platform. As described in the [press release distributed on May 2, 2019](#), Transgene is currently working to design five new oncolytic viruses for AstraZeneca.

**Philippe Archinard, PhD, Chairman and CEO of Transgene, commented:** *“We are obviously disappointed with the outcome of the PHOCUS study; however we remain convinced in the potential of our oncolytic virus pipeline. Our recent collaborative agreement with AstraZeneca highlights the industry interest in the multi-armed OVs that we can generate using our unique Invir.IO® platform. We also expect to announce the first clinical data with TG6002 in patients with colorectal cancer later this year. In addition, we expect to announce important clinical results from our most advanced therapeutic vaccines; TG4010 in lung cancer and TG4001 in HPV-Positive head and neck cancer. With funding through to 2022, a clear strategy and novel technology platforms such as Invir.IO® and myvac™,*

*Transgene is well placed to demonstrate the potential of its novel medicines designed to improve the treatment of solid tumors.”*

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**A conference call in English is scheduled on August 7, 2019, at 6:30 p.m. CET (12:30 pm EST).**

**Webcast link to English language conference call:**

[https://channel.royalcast.com/webcast/transgene/20190805\\_1/](https://channel.royalcast.com/webcast/transgene/20190805_1/)

**Participant telephone numbers:**

France: +33 (0) 1 7037 7166

Confirmation code: Transgene

United Kingdom: +44 20 3003 2666

United States: +1 202 204 1514

A replay of the call will be available on the Transgene website ([www.transgene.fr](http://www.transgene.fr)) following the live event.

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### **Contacts**

#### **Transgene:**

**Lucie Larguier**

Director Corporate Communications & IR

+33 (0)3 88 27 91 04

[investorrelations@transgene.fr](mailto:investorrelations@transgene.fr)

#### **Media: Citigate Dewe Rogerson**

EU: David Dible/Sylvie Berrebi

US: Marine Perrier-Barthez

+ 44 (0)20 3926 8507/+1 424 341 9140

[transgene@citigatedewerogerson.com](mailto:transgene@citigatedewerogerson.com)

### **About the PHOCUS trial**

The PHOCUS trial was 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 was 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.

### **About Pexa-Vec**

Pexa-Vec (formerly JX-594/TG6006 - pexastimogene devacirepvec) 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, TG4001, a therapeutic vaccine against HPV-positive cancers, and TG6002, an oncolytic virus for the treatment of solid tumors.

With its proprietary platform Invir.IO<sup>®</sup>, Transgene builds on its expertise in viral vectors engineering to design a new generation of multifunctional oncolytic viruses. *myvac*<sup>™</sup>, an individualized MVA-based immunotherapy platform designed to integrate neoantigens, completes this innovative research portfolio. TG4050, the first candidate selected from the *myvac*<sup>™</sup> 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](http://www.transgene.fr)

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### **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](http://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.*