Transgene Reports on the Combination Trial of TG4010, Chemotherapy and Nivolumab in Non-Small Cell Lung Cancer

Study fails to meet primary endpoint of overall response rate in patients whose tumors express low-to-no PD-L1

Conference call scheduled today at 6:30 p.m. CET

Strasbourg, France, December 12, 2019, 5:45 p.m. CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapeutics against cancer, today announces that the primary endpoint (overall response rate) of the Phase 2 trial evaluating TG4010 in combination with chemotherapy and Opdivo® (nivolumab) was not reached. This combination regimen was assessed as a first-line treatment for patients with advanced non-squamous non-small cell lung cancer (NSCLC) with low-to-no expression of PD-L1 by the tumor cells (PD-L1<50%). Transgene has taken the decision to stop further development of TG4010.
This multi-center single-arm Phase 2 trial enrolled 40 evaluable patients in the USA and Europe. It was conducted under a clinical collaboration agreement with Bristol-Myers Squibb, which is supplying nivolumab.

Philippe Archinard, PhD, Chairman and CEO of Transgene, added:
"We are obviously very disappointed with the outcome of this Phase 2 trial which showed that the triple combination regimen of TG4010, chemotherapy and nivolumab did not sufficiently increase the response rate in this patient population with advanced NSCLC whose tumor express low or undetectable levels of PD-L1. Additional data analyses are still ongoing and the complete study results will be presented at an upcoming scientific conference.
With funding until 2022 and a diversified portfolio of novel immunotherapies targeting solid tumors, our strategy remains clear and unchanged. The Phase 2 combination trial of TG4001 in HPV-positive cancers is recruiting well and we expect to report the next clinical readout as planned in H1 2020. We are also advancing our two novel technology platforms myvac™ *and Invir.IO®. Clinical sites have been initiated and the first two trials evaluating TG4050, the first* myvac™ *candidate, will soon be enrolling patients. These trials will be jointly funded with NEC. A trial with TG6002 administered via the intrahepatic artery is also about to enroll its first patient. In addition, we expect to submit a clinical trial application in the first half of 2020 for BT-001, the first Invir.IO® oncolytic virus encoding for an anti-CTLA4 antibody. Finally, our collaboration with AstraZeneca focused on generating novel multi-armed Invir.IO® oncolytic viruses is making excellent progress.*
These multiple advances give me great confidence that Transgene is well placed to demonstrate and deliver the potential of its novel therapeutic vaccines and oncolytic viruses designed to improve the treatment of solid tumors."

A conference call in English is scheduled on December 12, 2019, at 6:30 p.m. CET.

Webcast link to conference call: https://channel.royalcast.com/webcast/transgene/20191212_1/

Participant telephone numbers:
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Confirmation code: Transgene

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

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About TG4010

TG4010 is an immunotherapy that has been designed to express the coding sequences of the MUC1 tumor-associated antigen and the cytokine, Interleukin-2 (IL2). It is based on a modified *Vaccinia* virus (MVA) and has been shown to induce an immune response against MUC1 expressing tumors, such as non-small cell lung cancer (NSCLC). Its mechanism of action and safety profile make TG4010 a very suitable candidate for combinations with other therapies. The combination of TG4010 immunotherapy and chemotherapy has demonstrated significant efficacy in terms of progression-free survival and overall survival in patients with advanced stage NSCLC in a Phase 2b trial (Quoix et al. Lancet Oncol. 2015).

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 clinical-stage programs include 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®, 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, is entering 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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