Last Patient Enrolled in the Phase 2 Trial with Transgene's TG4010 + Nivolumab + Chemotherapy for the First-Line Treatment of Advanced Lung Cancer (NSCLC)

Clinical Trial in Collaboration with Bristol-Myers Squibb

Trial has Enrolled Patients whose Tumor Expresses Low or Undetectable Levels of PD-L1

Results for the Primary Endpoint (ORR) Expected in Q4 2019

Strasbourg, France, May 27, 2019, 5:45 p.m. CET - Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies for the treatment of solid tumors, today announces that the last patient has been included in the Phase 2 trial evaluating TG4010 in combination with Opdivo® (nivolumab) and chemotherapy as a first-line treatment for advanced non-squamous non-small cell lung cancer (NSCLC) with low or no expression of PD-L1 by the tumor cells. **Transgene confirms that the study's primary endpoint (objective response rate - ORR) on a minimum of 35 evaluable patients will be reported in Q4 2019.**

The Phase 2 clinical trial is exploring the tolerability and efficacy of the combination regimen of Transgene's TG4010, an investigational active immunotherapy against MUC1 tumor-associated antigen, with Bristol-Myers Squibb's immune checkpoint inhibitor, Opdivo® (nivolumab), which acts by overcoming immune suppression, and standard platinum doublet chemotherapy.

This multi-center single-arm trial has enrolled patients both in the USA and Europe.

The trial has overall ORR as primary endpoint. The study will also assess the safety and tolerability of the regimen together with other efficacy and immunological parameters. More information on the trial can be found on clinicaltrials.gov (NCT03353675).

This trial is being conducted by Transgene under a clinical collaboration agreement with Bristol-Myers Squibb, which is supplying nivolumab.

"We are looking forward to reporting the first efficacy data of our active immunotherapy TG4010, with nivolumab and chemotherapy as a first-line treatment of advanced lung cancer for patients whose tumors express low or undetectable levels of PD-L1", **said Maud Brandely, Chief Medical Officer of Transgene.** *"Today anti-PD-1 therapy is relatively less effective in this large subset of NSCLC patients. With this triple combination regimen, we aim to significantly improve treatment outcomes in this major oncology indication."*

The combination of TG4010 immunotherapy and chemotherapy has demonstrated significant efficacy in terms of increased response rate, progression-free survival and overall survival in a randomized, double-blind, placebo-controlled Phase 2b trial in first-line treatment of patients with advanced non-squamous NSCLC (Quoix et al. Lancet Oncol. 2015).

Contacts

Transgene:
Lucie Larguier
Director Corporate Communications & IR
+33 (0)3 88 27 91 04
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

About TG4010

TG4010 is an active 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 excellent safety profile make TG4010 a very suitable candidate for combinations with other therapies, including immune checkpoint inhibitors and chemotherapy. 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 (Quoix et al. Lancet Oncol. 2015).
TG4010 is being investigated for the first-line treatment of NSCLC in combination with nivolumab and chemotherapy in patients whose tumors express low or undetectable levels of PD-L1 (NCT03353675).

About Non-Small Cell Lung Cancer (NSCLC)

Lung cancer is one of the most common malignancies worldwide with an estimated 2.1 million new cases annually. It is also a leading cause of cancer-related deaths, accounting for an estimated 1.7 million deaths (Source: GLOBOCAN 2018). Advanced lung cancer remains one of the cancer types with the worst prognosis (five-year survival rate for advanced NSCLC of less than 5%), underlining the still unmet need in this disease despite recent progress.

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
Follow us on Twitter: @TransgeneSA

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). 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.

Opdivo® is a registered trademark of Bristol-Myers Squibb Company.