Transgene to Present Positive Results from Phase 1b Trial of TG1050 in Patients with Chronic Hepatitis B at Upcoming AASLD Liver Meeting 2018

- *Prof Fabien Zoulim will report that the Phase 1b trial reached its safety primary endpoint and that the therapeutic vaccine TG1050 breaks immune tolerance in patients with chronic hepatis B virus (HBV) infection*
- *Transgene will also present new and promising preclinical data set on combination studies of TG1050 with antivirals and immunomodulators*

Strasbourg, France – October 10, 2018, 6:00 pm CET – Transgene (Euronext Paris: TNG), a biotech company that designs and develops virus-based immunotherapies, announces that **the detailed results of the Phase 1b clinical trial using TG1050 confirm that the safety primary endpoint was reached and that TG1050 breaks immune tolerance through improvement of immune response directed against HBV antigens in patients with chronic HBV receiving standard antiviral therapies**. The complete Phase 1b data will be presented by Prof Fabien Zoulim, MD, PhD, on November 9, 2018, at the annual meeting of the AASLD (*American Association for the Study of Liver Diseases*) in San Francisco (USA).

Transgene will also present new and promising preclinical data that showed an improved antiviral activity of TG1050 (including on the decrease of circulating HBV surface antigen - HBsAg) when administered in combination with direct acting antivirals or immunomodulators in HBV-persistent mice.

Safety and Immunogenicity of Single and Multiple Injections of the Therapeutic Vaccine TG1050 in NUC-Suppressed Chronic Hepatitis B (CHB) Patients: Unblinded Analysis of a Double-Blind, Placebo-Controlled Phase 1b Study

- Presenter: Prof Fabien Zoulim, principal investigator of the trial and head of the gastro-enterology service of the Croix-Rousse Hospital (Lyon, France)
- Abstract number: 426
- Session date, time and location: Session I, November 9, 2018, 12 pm-1.30 pm (PT), Hall C

Investigational treatment combining TG1050, an HBV-specific immunotherapeutic, with direct acting antivirals or immunomodulators, improves sustained antiviral effects and immune responses in HBV-persistent mice

- Presenter: Roland Kratzer, Transgene
- Abstract number: 438
- Session date, time and location: Session I, November 9, 2018, 12 pm-1.30 pm (PT), Hall C

Both abstracts published in *Hepatology* can be downloaded from the AASLD website.

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About TG1050

TG1050 is a targeted immunotherapy candidate for the treatment of chronic hepatitis B, based on a viral vector expressing three HBV antigens (POL, CORE, ENV). The first-in-man Phase 1/1b trial met its primary safety endpoint and also showed that TG1050 is able to break immune tolerance in patients chronically infected with HBV.
Preclinical results have demonstrated TG1050's capacity to induce robust, broad, and long-lasting HBV-specific T cells with characteristics similar to those found in patients whose infection has been resolved. Antiviral effects of TG1050 have also been shown[1] [2].
The technology of TG1050 is also being developed in Greater China by Tasly Biopharmaceuticals Co., Ltd.

About the Phase 1b trial evaluating TG1050

This international first-in-man Phase 1/1b trial of TG1050 has recruited patients who are being treated for chronic HBV infection with standard-of-care antiviral therapies. This trial is randomized, multi-center, double-blind, and placebo-controlled. The primary objectives of the Phase 1/1b study are safety and tolerability of TG1050 administered in single and multiple doses and to determine the dose and schedule of TG1050 administration for further development. Secondary objectives correspond to the exploration of antiviral activity and immune responses to TG1050.
48 patients were enrolled (Europe and North America), randomized 1:1:1 across 3 dose levels of 10^9, 10^{10}, 10^{11} viral particles (vp) and then 3:1 within each dose level to placebo. 12 patients were enrolled in the single dose cohort and received a single subcutaneous (sc) injection while 36 patients enrolled in the multiple dose cohort received 3 weekly sc injections. At inclusion, patients had to be HBV DNA negative after at least 2 years of NUC therapy.

About Chronic Hepatitis B

Hepatitis B is a potentially life-threatening liver disease caused by HBV infection. It puts patients at high risk of death from cirrhosis and liver cancer. Recent figures indicate the number of patients being treated for chronic hepatitis B was 200,000 in total in the United States, Germany, France, Italy, Spain and the United Kingdom and 100,000 patients in Japan. The eligible Chinese market represents 500,000 patients. Those numbers are expected to increase (Sources: ECDC- Incidence of Hepatitis B, Decision Resources: expert opinions). Currently available antiviral treatments can control the disease but not cure it. Patients in the developed world must take these treatments for an average of 15 years and often throughout their lifetime. Therefore, there is an urgent need to develop new therapeutic approaches to improve the cure rate.
The latest publications on TG1050 are available on: www.transgene.fr.

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 integrating neoantigens, completes this innovative research portfolio.
Additional information about Transgene is available at www.transgene.fr.Follow us on Twitter: @TransgeneSA

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[1] *Gut. 2015 ; TG1050, an immunotherapeutic to treat chronic hepatitis B, induces robust T cells and exerts an antiviral effect in HBV-persistent mice.Martin P et al., 2015 Dec, 64(12):1961-71. doi: 10.1136/gutjnl-2014-308041*
[2] *Hum Vaccin Immunother. 2018;* A meta-analysis of the antiviral activity of the HBV-specific immunotherapeutic TG1050 confirms its value over a wide range of HBsAg levels in a persistent HBV pre-clinical model, Kratzer R. et al., 2018 Jun 3;14(6):1417-1422.

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.