First Patient Randomized in Multiple Dose Cohort of Phase 1/1b Trial with Transgene's TG1050 in Chronic Hepatitis B Patients

- *Continuation of the trial following the positive recommendation of the Safety Review Committee (July 2016)*
- *First data readout expected in H2 2017*

Strasbourg, France, October 17, 2016, 6:00 p.m. CET—Transgene (Euronext Paris: TNG), a company focused on designing and developing targeted immunotherapies for the treatment of cancer and infectious diseases, today announced that the first patient has been included in the multiple dose cohort of the Phase 1/1b trial with TG1050, Transgene's immunotherapy product candidate for the treatment of chronic hepatitis B virus (HBV) infection (NCT: 02428400).

The continuation of the trial in the multiple dose cohorts follows the positive recommendation of the Safety Review Committee (July 2016) as no severe adverse events have been observed in patients receiving a single dose of TG1050.

This first-in-man trial is an international, randomized, multi-center, double-blind, placebo-controlled study evaluating TG1050 in patients who are currently being treated for chronic HBV infection with standard-of-care antiviral therapy. The primary objectives of the Phase 1/1b study are to evaluate the 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 include evaluating the antiviral activity of and immune responses to TG1050. First data readout is expected in H2 2017.

TG1050 is a targeted immunotherapy candidate for the treatment of chronic hepatitis B, based on a viral vector expressing three HBV antigens. It is a therapeutic vaccine that has been designed and developed by Transgene's antiviral research team. 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[1]. Antiviral effects of TG1050, including seroconversion to the surface antigen (HBsAg), have also been shown[1 2].

Chronic hepatitis B is a major unmet medical need, as current treatments only cure about 3% of the patients. With TG1050, Transgene is looking to provide a much more-effective treatment that is urgently needed for this viral liver disease, which can lead to cirrhosis and liver cancer.

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[1] *Gut. 2015 Dec;64(12):1961-71. doi: 10.1136/gutjnl-2014-308041*
[2] *J Hepatol, 2015, Vol 62 (Suppl N° 2), S205*

About Chronic Hepatitis B

Hepatitis B is a potentially life-threatening liver infection caused by HBV infection. It can result in chronic infection and liver disease and, if left untreated, puts people at high risk of death from cirrhosis of the liver 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 as more patients are to be diagnosed and treated for their disease in the coming years (Sources: ECDC- Incidence of Hepatitis B, Decision Resources: expert opinions). Currently available antiviral treatments cure only an estimated 3% of cases, and patients in the developed world must take these treatments for an average of 15 years and often for their lifetime. Therefore, there is an urgent need to develop new therapeutic approaches to improve the cure rate.

About TG1050

TG1050 is a targeted immunotherapy candidate for the treatment of chronic hepatitis B, based on a viral vector expressing 3 HBV antigens. Transgene has initiated a randomized, multi-center, double-blind, placebo-controlled safety and dose-finding first-in-man study (NCT02428400) evaluating the safety and tolerability of TG1050 in patients who are currently being treated for chronic HBV infection with standard-of-care antiviral therapy. The technology of TG1050 is also being developed in China, where it is currently under SFDA evaluation and has been recently granted an IND number. In China, Transgene operates a joint-venture with Tasly Biopharmaceutical Technology.
The latest publications on TG1050 are available on: www.transgene.fr.

About Transgene

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biopharmaceutical 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 two lead clinical-stage programs are: TG4010, a therapeutic vaccine for non-small cell lung cancer and Pexa-Vec, an oncolytic virus for liver cancer. The Company has several other programs, including TG4001, in clinical and preclinical development. Transgene is based in Strasbourg, France, and has additional operations in Lyon, as well as a joint venture in China. Additional information about Transgene is available at www.transgene.fr.

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