

Transgene to Continue Phase 1/1b Study with TG1050 in Chronic Hepatitis B Patients on the Recommendation of the Trial's Safety Review Committee

Strasbourg, France, July 21, 2016, 6:00 pm 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 Safety Review Committee of the Phase 1/1b trial with TG1050, Transgene's immunotherapy product candidate for the treatment of chronic hepatitis B virus (HBV) infection, has recommended that the study should continue.

Maud Brandely, Chief Medical Officer of Transgene, said: *"We are pleased to be continuing the development of our internally discovered and developed immunotherapy TG1050. The Phase 1/1b trial is progressing well with no severe adverse events observed. We are now moving ahead with the enrollment of the multiple dose cohorts of this study. Chronic hepatitis B is a major unmet medical need, and with TG1050, we are 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."*

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

TG1050 is a targeted immunotherapy candidate for the treatment of chronic hepatitis B, based on a viral vector expressing 3 HBV antigens. Pre-clinical 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 resolved¹. Antiviral effects of TG1050, including seroconversion to the surface antigen (HBsAg), have also been shown^{1,2}.

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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 diagnosed and treated for their disease. 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. TG1050 is also being developed in China, where Transgene operates a joint-venture with Tasly Biopharmaceutical Technology, TG1050 has been recently granted an IND number.

The latest publications on TG1050 are available on [Transgene's website](http://www.transgene.fr): 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 for non-small cell lung cancer and Pexa-Vec for liver cancer. The Company has several other programs in clinical and pre-clinical 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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Disclaimer

This press release contains forward-looking statements about the future development of TG1050. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements 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 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 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, which is available on the AMF website (<http://www.amf-france.org>) or on Transgene's website (www.transgene.fr).