

Transgene Presents First Clinical Data Indicating that TG1050 Induces a Robust and HBV-Specific Cell-Mediated Immune Response in Patients with Chronic Hepatitis B

Data Featured in a Poster Presentation at AASLD Liver Meeting 2017

Strasbourg (France), October 17, 2017- 5:45 pm CET - Transgene (Euronext Paris: TNG), a biotech company that designs and develops viral-based immunotherapies, will be presenting a poster on TG1050 first promising clinical results at the American Association for the Study of Liver Diseases (AASLD) Meeting 2017, in Washington, DC, October 20-24.

TG1050 is a therapeutic vaccine, that is currently being evaluated in an international first-in-man Phase 1/1b trial in patients with chronic hepatitis B (or chronic HBV¹ infection) receiving nucleoside analogbased standard of care. The recruitment of the trial has been completed and the patients' follow up is ongoing.

During the poster presentation, Transgene will provide details on the good safety profile of the product, and will present preliminary results indicating that TG1050 induces a robust specific cell-mediated immune response in patients that have received a single dose of TG1050.

Poster title: *Phase 1b clinical trial of TG1050, a novel HBV-targeted immunotherapy, in NUC suppressed chronic hepatitis B patients: safety and early immunological data following single administration*

- Poster ID: 906
- Date, time, location: Poster Session II, Saturday, 21 October 2017, 5:30–7:30 pm, Hall D

The abstract published in *Hepatology* can be downloaded on the <u>AASLD website</u>.

Maud Brandely, Chief Medical Officer of Transgene, commented: "We are delighted to be presenting such encouraging data on HBV-specific immune responses induced by TG1050 in chronic HBV patients receiving standard-of-care. We have shown that a single injection of our therapeutic vaccine is able to generate a robust specific T cell mediated immune response against the different vaccine encoded HBV antigens, while demonstrating a good safety profile. These first results are very promising for the development of TG1050 and consistent with our preclinical data package."

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¹ HBV: hepatitis B virus

Notes to editors

About TG1050

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. Antiviral effects of TG1050have also been shown^{2 3.}

TG1050 is currently being evaluated in an international first-in-man Phase 1/1b trial in patients who are being treated for chronic HBV infection with standard-of-care antiviral therapy. This trial is randomized, multi-center, double-blind, and placebo-controlled. 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 correspond to the exploration of antiviral activity and immune responses to TG1050.

The technology of TG1050 is also being developed in China through Transgene's joint-venture with Tasly Biopharmaceutical Technology, where it is currently under SFDA evaluation and has been recently granted an IND number. The latest publications on TG1050 are available on: <u>www.transgene.fr</u>.

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 for their lifetime. Therefore, there is an urgent need to develop new therapeutic approaches to improve the cure rate.

About Transgene

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, 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 (chronic hepatitis B) and TG6002 (solid tumors). 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 <u>www.transgene.fr.</u>

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² Gut. 2015 Dec;64(12):1961-71. doi: 10.1136/gutjnl-2014-308041

³ J Hepatol, 2015, Vol 62 (Suppl N° 2), S205