TG1050 is well tolerated and induces a strong specific immune response in patients with chronic hepatitis B

Data presented at AASLD Liver Meeting 2017

Strasbourg, October 23, 2017- 7:30 am - Transgene (Euronext Paris: TNG), a biotech company that designs and develops viral-based immunotherapies, announces that **the analyses conducted on patients with chronic hepatitis B receiving standard antiviral therapies and a single dose of TG1050 in the Phase 1/1b trial, confirm the good tolerability profile and demonstrate the immunogenicity of this novel therapeutic vaccine.**

Transgene presented a poster describing the first promising clinical data of TG1050 on October 21, 2017, at the annual meeting of the AASLD (*American Association for the Study of Liver Diseases*) that is currently taking place in Washington, DC.
These **results were obtained from the first cohort of patients included in the Phase 1/1b trial**; patients that are currently treated with standard antiviral therapy also received a single dose of TG1050. **The data presented further strengthen the first elements communicated in 2016**[1], *i.e.* **a very satisfying tolerability profile** of TG1050. They also **confirm the product's mechanism of action**.

The immunologic analyses show that **TG1050 induces a specific immune response in the patients**:

- Strong **immune responses against the different HBV antigens that are vectorized by TG1050** (core protein, polymerase and envelop protein – HbsAg) have been shown in the patients who received the two highest doses (10^{10} vp et 10^{11} vp);
- A **dose-effect relationship** was observed in terms of number of patients developing responses against the different viral antigens, with a higher intensity of responses in the groups receiving the two highest doses (10^{10} vp et 10^{11} vp).

The abstract published in *Hepatology* can be downloaded on the AASLD website. The poster is accessible from Transgene's website: www.transgene.fr.

Prof Fabien Zoulim, MD, PhD, principal investigator of the trial and head the gastro-enterology service of the Croix-Rousse Hospital (Lyon, France), commented: *"Patients with chronic hepatitis B are currently treated over very long periods. They live with the risk of developing severe complications due to the disease and are expecting therapies that can cure them. The results obtained after a single injection of TG1050 are very promising and confirm the expected mechanism of action of this novel therapeutic vaccine. We are looking forward to presenting the full results of the trial at upcoming major international conferences dedicated to liver diseases."*

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Contacts

Transgene:

Lucie Larguier
Director Corporate Communications & IR
+33 (0)3 88 27 91 04
investorrelations@transgene.fr

Media contacts:

Citigate Dewe Rogerson
David Dible/Marine Perrier
+ 44 (0)20 7638 9571
transgene@citigatedr.co.uk

[1] Press release distributed on July 21, 2016

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 therapies. 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: www.transgene.fr.

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 www.transgene.fr.

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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*