

# Transgene Announces Dosing of First Patient with TG1050 for Treatment of Chronic Hepatitis B Infection

**Strasbourg, France, November 4, 2015** - Transgene SA (Euronext: TNG) today announced that the first patient has been dosed in a clinical trial with its immunotherapy product candidate TG1050 for the treatment of chronic hepatitis B virus (HBV) infection. This first-in-humans trial is an international, randomized, multi-center, double-blind, placebo-controlled safety and dose-finding 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 to bring forward for further development. Secondary objectives include evaluating the antiviral activity of and immune responses to TG1050. Patients in the trial will continue to be treated with standard antiviral therapy. The Phase 1 part of this trial is planned to enroll up to 48 patients.

"We are pleased to advance another of our internally discovered and developed immunotherapy product candidates into the clinic, demonstrating the capabilities and productivity of our R&D organization," said Philippe Archinard, Chairman and Chief Executive Officer. "With our programs, we seek to address major unmet medical needs in oncology and infectious diseases. More effective treatments are urgently needed for chronic hepatitis B, which can lead to severe liver disease, including cirrhosis and liver cancer."

## 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-humans 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. 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 is resolved. Antiviral effects of TG1050, including seroconversion to the surface antigen (HBsAg), have also been shown.

## **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 Transgene:**

Transgene S.A. (Euronext: TNG), part of Institut Mérieux, is a publicly traded French biopharmaceutical company focused on discovering 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 satellite offices in China and the U.S. Additional information about Transgene is available at www.transgene.fr.

## **Disclaimer:**

This press release contains forward-looking statements about the 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. There can be no guarantee that the first-in-humans trial will have positive results or that, if positive, they will be predictive of future results with TG1050. 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).

## Contacts:

#### Transgene:

Elisabetta Castelli, Director Investor Relations +33 (0)3 88 27 91 21

Laurie Doyle, Director Investor Relations US & Corporate Communications +1 (339) 832 0752

investorrelations@transgene.fr

#### For media: MC Services

Raimund Gabriel +49 89 210 228 30 raimund.gabriel@mc-services.eu

Shaun Brown +44 207 148 5998 shaun.brown@mc-services.eu