



TRANSGENE PUBLISHES PHASE I CLINICAL DATA OF ITS HCV IMMUNOTHERAPY PRODUCT IN JOURNAL *GASTROENTEROLOGY* AND ANNOUNCES FUTURE COMMUNICATION AT AASLD

- **Detailed Phase I clinical results (Good safety and early antiviral efficacy)**
- **Phase II (HCVac study) data will be presented at AASLD in early November**

Strasbourg (France) – 23rd August 2011: Transgene (NYSE Euronext: TNG) today announces that detailed results of its Phase I open-label, dose-escalating study performed in France with its therapeutic vaccine TG4040 (MVA-HCV) in patients infected with chronic hepatitis C (HCV) are published in the September issue of *Gastroenterology*, which is now available online. It also announces that the initial Phase II data of the HCVac study will be presented at the upcoming AASLD (American Association for the Study of Liver Diseases) liver meeting to be held in San Francisco on November 3rd to 8th, 2011.

The published Phase I results, also highlighted in the August issue of *Nature Reviews Gastroenterology and Hepatology*, give a thorough analysis of safety data together with analysis of vaccine-induced immunogenicity and early antiviral efficacy, giving Hepatologists and Gastroenterologists the opportunity to view in more detail the results of this first clinical trial.

TG4040 is currently undergoing a large Phase II trial (the “HCVac” study) in patients with chronic HCV in combination with the standard of care, peg-IFN alpha and ribavirin. The initial primary end-point data, i.e. complete early virologic response (“cEVR”), have been selected for presentation at the next AASLD.

“We are encouraged by the increasing interest shown in TG4040 as a potential innovative treatment for chronic HCV infection. The good safety profile coupled with the novel mechanism of action, which is complementary to those currently exploited by small antiviral agents such as anti-proteases and anti-polymerases, make TG4040 a very attractive, innovative candidate to improve treatment of chronic HCV infection”, said Philippe Archinard, Chairman and CEO of Transgene, adding further *“We are now looking forward to presenting the HCVac primary end-point data at the upcoming AASLD meeting”.*

About TG4040

Transgene's TG4040 vaccine candidate is a recombinant vector-based on the MVA virus carrying and expressing three of the major non-structural proteins (NS3, NS4 and NS5B) of the hepatitis C virus ("HCV"). The MVA vector is a highly attenuated strain of vaccinia virus, which has been tested extensively in humans as a vaccine against smallpox and is known to strongly stimulate innate and adaptive immune responses to antigens.

About TG4040 clinical development program

Phase I clinical results in 39 treatment naïve genotype 1 HCV patients showed that the product is safe and well tolerated at all dose levels tested. Immunological analyses on 15 treatment naïve patients were encouraging and supported the expected mechanism of action of TG4040 which aims at inducing an effective HCV-specific T cell-based immune response, able to control viral replication.

Enrolment of patients for the Phase II HCVac trial was completed at the end of March 2011. One hundred and fifty three treatment naïve patients chronically infected with genotype 1 hepatitis C virus were recruited in 5 countries in Europe, the U.S. and Israel. Patients were randomized in the 3 arms of the study: one control arm without TG4040 and two experimental arms exploring the combination of TG4040 with standard of care (Pegylated-Interferon Alpha2a and Ribavirin). The HCVac trial investigates the efficacy and safety of two different schedules of administration of TG4040 and will measure the proportion of patients who achieve complete Early Virologic Response (cEVR) and Sustained Virologic Response (SVR) as well as the product's ability to elicit an immune response.

Primary end-point data i.e. complete early viral response ("cEVR") for all patients is expected by the fourth quarter of 2011, with final data (sustained virological response, "SVR") expected for the fourth quarter of 2012.

About chronic hepatitis C

Hepatitis C currently represents a major public health concern. The population chronically infected with HCV in the world is estimated at 170 to 200 million and hepatitis-C-related deaths at approximately 470,000 annually. Peak of prevalence of HCV-related diseases is expected to occur in 2025-2030 in developed countries.

HCV infection leads to liver diseases such as fibrosis, cirrhosis and liver carcinoma, which are the prime indications for liver transplants. The current standard of care for patients infected with the HCV genotype 1 (a combination of Pegylated Interferon Alpha and Ribavirin) is lengthy, often poorly tolerated and effective in only approximately 50% of patients completing therapy. In addition, a substantial number of patients never receive therapy. Therefore, there is a strong medical need for new alternative approaches, including combination therapies.

About Transgene (www.transgene.com)

Transgene, a member of the Institut Mérieux Group, is a publicly traded French bio-pharmaceutical company dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases, and has five compounds in clinical development: TG4010 and JX594/TG6006 having completed initial Phase II trials, TG4001 in Phase IIb trial, TG4040 in Phase II trial and TG4023 in Phase I trial. Transgene has concluded strategic agreements for the development of two of its immunotherapy products, an option agreement with Novartis for the development of TG4010 to treat various cancers, and an in-licensing agreement with US-based Jennerex Biotherapeutics, Inc., to develop and market JX594/TG6006, an oncolytic virus.

Transgene has bio-manufacturing capacities for viral-based products. Additional information about Transgene is available on the internet at www.transgene.fr.

Cautionary note for Transgene regarding forward-looking statements

This press release contains forward-looking statements referring to the clinical testing, development, and manufacturing of our products. Clinical testing and successful product development, manufacturing and commercialization depend on a variety of factors, including the timing and success of future patient enrolment, the risk of unanticipated adverse patient reactions, the capacity to manufacture products efficiently in accordance with Good Manufacturing Practices standards, regulatory approval and the level of demand for the product by the medical community. In addition, forward-looking statements regarding product development, testing, manufacturing and marketing costs are by their nature subject to uncertainties as a result of unforeseen difficulties and expenses which may arise, and future product development costs may exceed current expectations. For further

Contacts

Transgene

Philippe Archinard, Chairman & CEO
+33 (0)3 88 27 91 22

Stéphane Boissel, Executive Vice President & CFO
+33 (0)3 88 27 91 02

Elisabetta Castelli, Director IR
+33 (0)1 44 08 55 05

MC Services

Raimund Gabriel
+49 89 210 228 30

Shaun Brown
+44 207 148 5998