

# Transgene Announces Completion of Enrolment in HCVac (Phase II Trial) of TG4040 for the Treatment of Chronic Hepatitis C

**Parc d'Innovation, Illkirch, France, March 31, 2011** – Transgene S.A. (Euronext Paris: FR0005175080) announces that, with 154 patients randomized and treated, the enrolment of patients in the phase II HCVac trial is now complete. This study explores the combination of TG4040 (MVA-HCV) with standard of care (Pegylated-Interferon  $\alpha$ 2a and Ribavarin) in treatment naive patients with chronic genotype 1 hepatitis C.

The patients were recruited in five countries in Europe, in the United States and in Israel, and were randomized in the three arms of the study (one control arm without TG4040 and two experimental arms). HCVac investigates the efficacy and safety of two different schedules of administration of TG4040 administered in subcutaneous injections at the dose of  $10^7$  pfu in combination with the standard of care.

HCVac will measure the proportion of patients who achieve complete Early Virologic Response (cEVR), i.e. have no detectable viral load 12 weeks after the beginning of the treatment. These data will be available during the fourth quarter of 2011.

The study will also measure the patients' Sustained Virologic Response (SVR), i.e. the treatment's long term effects on the viral load, up to 24 weeks after the end of the treatment, as well as TG4040's ability to elicit an immune response. An additional expected outcome of the study is to identify molecular biomarkers related to TG4040 efficacy in combination with the standard of care. Final data are expected in the fourth quarter of 2012.

"We look forward to obtaining the first results of the study in order to begin preparing the next steps of the development of this promising product candidate for the treatment of patients suffering from chronic hepatitis C, a disease with a growing incidence and which is becoming a public health concern even in the most economically developed countries." stated Philippe Archinard, Chairman and CEO of Transgene.

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# 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.

# 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

Transgene is a France-based biopharmaceutical company focused on the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases. The Company has four compounds in Phase II clinical trials: TG4010, JX594/TG6006, TG4001/RG3484 and TG4040 and one compound in Phase I clinical trial: TG4023. Transgene has entered into strategic collaborative agreements for the development of two of its immunotherapy products:

- An option agreement with Novartis for an exclusive license to develop TG4010 for the treatment of various cancers, including non small cell lung cancer (NSCLC)
- An in-licensing agreement with US-based Jennerex Biotherapeutics, Inc., to develop and market JX594 (JX594/TG6006), an oncolytic product.

Transgene has bio-manufacturing capacities for viral-based vectors. Additional information about Transgene can be found at <u>www.transgene.fr</u>.

## **Disclaimer:**

This press release contains forward-looking statements referring to the clinical testing and development of Transgene's product candidates. Clinical testing and successful product development depend on a variety of factors, including the timing and success of future patient enrolment and the risk of unanticipated adverse patient reactions. Results from future studies with more data may show less favorable outcomes than prior studies, and there is no certainty that product candidates will ever demonstrate adequate therapeutic efficacy or achieve regulatory approval or commercial use. For further information on the risks and uncertainties involved in the testing and development of Transgene's product candidates, see Trangene's Document de Référence on file with the French Autorité des marchés financiers on its website at http://www.amf-france.org and Transgene's website at www.transgene.fr.

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