

## **Transgene Announces Opening of First Clinical Site for its Phase II Trial of TG4040 for the Treatment of Chronic Hepatitis C**

**Parc d’Innovation, Illkirch, France, July 12, 2010** – Transgene S.A. (Euronext Paris: FR0005175080) announces the opening of the first clinical site for the phase II trial (named HCVac) of TG4040 (MVA-HCV) for the treatment of naïve genotype 1 hepatitis C infected patients in combination with standard of care (Pegylated-Interferon Alpha and Ribavarin).

HCVac is a phase II randomized, open-label, multi-site, international study that will enrol 140 patients chronically infected with HCV genotype 1 and who have not been previously treated for their infection. Forty clinical sites across seven countries in Europe, the United States and Israel will participate in the study.

HCVac has three arms: one control arm using standard of care alone and two experimental arms evaluating TG4040 at two different schedules of administration in combination with standard of care. In both experimental arms, TG4040 will be administered by subcutaneous injection at a dose of  $10^7$  pfu. The schedule of administration will consist of 6 injections in the first arm and 13 for the second arm.

The primary objective of HCVac is to evaluate the efficacy of TG4040, in combination with standard of care, as measured by the proportion of patients who achieve complete Early Virologic Response (cEVR). cEVR is defined as HCV RNA (ribonucleic acid) which is undetectable after 12 weeks of treatment.

The secondary objectives of the trial are: determine the effects on viral load over-time and up to 24 weeks after stopping therapy; determine the immunogenicity of TG4040 and identify molecular biomarkers related to TG4040 efficacy in combination with standard of care.

First results of the HCVac clinical trial are expected around the third quarter of 2011.

*“The size and nature of HCVac for TG4040 bear witness to our commitment towards the ongoing development of our infectious diseases franchise and we have high expectations of the future prospects offered by our product to help treat patients suffering from chronic HCV infection”* said Philippe Archinard, Chairman and Chief Executive Officer of Transgene, adding *“The entry of TG4040 into phase II clinical trials marks a further maturing of Transgene’s product portfolio, which promises to be rich in news-flow over the coming 18 months”*.

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### **About TG4040 clinical development program**

The results of a phase I trial in France, involving 39 treatment naïve patients with the genotype 1 HCV, were presented at the EASL (European Association for the Study of the Liver) conference on 23<sup>rd</sup> April 2009 (see press release 28<sup>th</sup> April 2009, on [www.transgene.fr](http://www.transgene.fr)) and at the AASLD (American Association for the study of Liver Diseases) meeting in November 2009.

Clinical results show that the product is safe and well tolerated by patients at all dose levels. Immunological analyses on 15 treatment naïve patients were very 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 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. 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 chronic hepatitis C**

Hepatitis C currently represents a major public health concern. The number of persons chronically infected with HCV in the world is estimated at 170 million 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 reasons 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 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 dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases. The company has four compounds in clinical development: TG4010 having completed phase II trials, TG4001/RG3484 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 with:

- Roche for the development of TG4001/RG3484 to treat HPV-mediated diseases, and
- Novartis for the development of TG4010 to treat various cancers.

Transgene has bio-manufacturing capacities for viral-based products.. Additional information about Transgene is available on the Internet at [www.transgene.fr](http://www.transgene.fr).

**Cautionary note regarding forward-looking statements**

*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 Transgene'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](http://www.transgene.fr).*

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