# Transgene's Therapeutic HCV Vaccine TG4040 Combined with Commonly Used Treatment Achieves Substantial Viral Suppression in Randomized Phase II trial

- **64% cEVR in one experimental arm vs. 30% in the control arm**
- **Multiple options for further clinical development**

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**Strasbourg, France, November 7, 2011 –** Transgene S.A. (Euronext Paris: FR0005175080) announces today the publication, during the AASLD congress (*American Association for the Study of Liver Diseases*), of interim data showing a substantial viral suppression at 12 weeks by using the combination of its therapeutic vaccine TG4040 with the commonly used treatment regimen in patients with chronic hepatitis C. These data were observed in a randomized Phase II trial that has included 153 patients (the "HCVac" study).

*"The magnitude of improvement in early viral suppression observed in the HCVac trial is unheard of in the immunotherapy of this pathology"* said Philippe Archinard, Chairman and CEO of Transgene. He added: *"We will immediately start discussing with possible partners so as to envisage the future development of TG4040. Among the options, there is a strong rationale to go to treatment regimens without interferon".*

The HCVac study is a three-arm (one control and two experimental arms with different schemes of administration) randomized Phase II trial evaluating the safety and efficacy of TG4040, a therapeutic vaccine, in combination with ribavirin ("RBV") and pegylated alpha interferon ("Peg-IFN"), the commonly used treatment regimen in the indication.

The study evidenced activity of the therapeutic vaccine in the two experimental arms with a substantial early viral suppression in arm C, with 64% of patients who achieved complete Early Virologic Response ("cEVR"), the primary endpoint of the study, compared to 30% in the control arm. The cEVR patients had no detectable viral load 12 weeks after the beginning of the treatment with Peg-IFN and RBV. The detection limit of the blood hepatitis C virus in the study was set at 10 IU/ml (using the Roche COBAS® HCV TaqMan® assay). The table below summarizes these findings:

| Arm | Number of evaluable patients | cEVR (% of patients) |
|---|---|---|
| A (control) | 30 | 30% |
| B (experimental) | 61 | 46% |
| C (experimental) | 53 | 64%* |

*p=0.003

The experimental arms tested the same dosage of the therapeutic vaccine ($10^7$ pfu) injected subcutaneously under two different schemes of administration: in the arm B, the TG4040 dosage was administered 6 times and Peg-IFN and RBV were given 4 weeks prior to the initiation of TG4040 while in arm C the TG4040 dosage was administered 13 times and the Peg-IFN and RBV were introduced 12 weeks after the initiation of treatment with TG4040.

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Two of the three adverse events reported on October 11, 2011 occurred in the experimental arm B, while one occurred in the experimental arm C. These adverse events are still under investigation. However, it could already be noted that: (i) TG4040 was administered at ten times higher dosage in the previous clinical trial (Phase I) without any of such adverse events reported, (ii) the 56 patients treated in the experimental arm C have received TG4040 in monotherapy (7 injections over 12 weeks) before Peg-IFN and RBV introduction and no such adverse events were observed during this monotherapy phase of the treatment and, finally, (iii) the three adverse events occurred in patients who received co-medications which could possibly have induced hematological toxicities independently of those usually documented with the usage of Peg-IFN and RBV.

Data were reported in a poster presented today at AASLD that can be consulted at www.transgene.fr.

Transgene will host a conference call for analysts on November 8, 2011 (Tuesday) at 8am CET. The dial-in numbers are as follows:

| | | |
|---|---|---|
| France: | +33 1 72 00 14 02 | – toll free: 0805-638852 |
| United Kingdom: | +44 207 7509903 | – toll free: 0808-2381771 |
| United States: | +1-347-6377291 | – toll free: 1-866-9286050 |

Pin code: **29598380#**

**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**

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 naive 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. Phase I data were published in the journal *Gastroenterology* and reported in *Nature Reviews* in 2011.

**Phase II**

The 153 patients in the HCVac study 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 Peg-IFN and RBV.

**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 commonly used treatment regimen for patients infected with the HCV genotype 1 (a combination of Pegylated Interferon α 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, a member of the Institut Mérieux Group, is a publicly traded French biopharmaceutical company dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases and has four compounds in Phase II clinical development: TG4010 and JX594/TG6006 having already completed initial Phase II trials, TG4001 and TG4040. 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, 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 at www.transgene.fr.

***Disclaimer:***

*This press release contains certain forward-looking statements. 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. In particular, the Company's ability to commercialize its first product depends on the continuing success of clinical studies, ongoing financing for further product developments and marketing launch, a positive response from the medical community regarding the product's costs and effectiveness. 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 Reference prospectus, which is available on the AMF website (http://www.amf-france.org) or on Transgene's website (www.transgene.fr). This press release and the information contained herein do not constitute an offer to sell or a solicitation of an offer to buy or subscribe to shares in Transgene in any country.*

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