

Transgene Reports Positive Follow Up Phase 2 Data on its HCV Therapeutic Vaccine TG4040

- **Primary endpoint (efficacy at week-12) met**
- **Both faster effect on viral load decrease and significant improvement of viral response over time (week-24) in TG4040 pre-vaccination arm**
 - **Late-breaker oral presentation at EASL in Barcelona**

Strasbourg, France, April 23, 2012 – Transgene S.A. (Euronext Paris: FR0005175080) announces today the presentation, during the EASL (*European Association for the Study of Liver*) congress in Barcelona, Spain, of follow up interim data showing both a more rapid response as well as an improved long term effect on viral load decrease in a combination of TG4040 with PEG-IFN α (pegylated interferon alpha) and ribavirin (the current standard of care) in patients chronically infected with genotype 1 hepatitis C virus.

These data were observed in a randomized phase 2 trial that has enrolled 153 patients (the “HCVac” study). HCVac had three treatment arms: one control arm (Arm A) with the current standard of care alone and two arms (B and C) with a combination of this standard of care and TG4040 delivered in two different administration schedules, including one schedule (Arm C) with pre-vaccination by TG4040 (i.e. TG4040 injected prior to the introduction of PEG-IFN α and ribavirin).

As reported in November 2011 at the AASLD meeting in San Francisco, the primary endpoint of the HCVac study was met in the pre-vaccination arm C with 64% (34/53) evaluable patients having achieved a complete early viral response¹ (“cEVR”) at week-12 after initiation of treatment with the standard of care compared to 30% (9/30) in the control arm A ($p=0.003$).

The positive effect of TG4040 pre-vaccination was observed as early as one week after initiation of treatment with the standard of care: the slope of mean viral load decrease was significantly steeper in Arm C (1.4 log₁₀ IU/ml) compared to Arms A and B (respectively 0.9 and 1.0 log₁₀ IU/ml) ($p=0.04$), meaning a faster viral response in Arm C than in other arms.

When following the viral response at week-24 after the initiation of treatment with the standard of care in the patients evaluable for cEVR (week-12), the responses continue to improve as expected in all arms: 70% in the control Arm A, 67% in the Arm B (initiation of treatment with the standard of care before introduction of TG4040) and 79% (vs. 64% at week-12) in the Arm C.

Preliminary End-of-Treatment Response measurement (“ETR”, or viral response measured at the end of 48 weeks of standard of care), is respectively 64% and 56% in Arm A and B. In arm C, 19 out of 19 patients analysed so far are undetectable.

“These data are important for TG4040 as they confirm the efficacy profile of our therapeutic vaccine. As far as we know, they are unheard of for an immunotherapy in HCV and this is one of the reasons why we were invited for a late breaker oral presentation in such a prestigious event” said Philippe

¹ Limit of detection for the HCV RNA quantification test: 10IU/ml.

Archinard, Chairman and CEO of Transgene. He added: *"The benefit seen at week-12 in the pre-vaccination arm is further confirmed at week-24 and the preliminary data of ETR in this arm are also very encouraging"*.

Data were presented on Saturday April, 21, at the annual meeting of the European Association for the Study of Liver (EASL) in Barcelona, by Pr. Heiner Wedemeyer, MD, of the Department of Gastroenterology, Hepatology and Endocrinology at Hannover Medical School (Germany) and principal investigator of the HCVac study.

Pr. Wedemeyer said: *"The data accumulated so far in the HCVac study illustrate the importance of immunity in the treatment of chronic hepatitis C"*. He added: *"The assessment of TG4040 in a combination with directly acting agents (DAA) should be the next development step"*.

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 1

Phase 1 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. Phase 1 data were published in the journal *Gastroenterology* and reported in *Nature Reviews* in 2011.

Phase 2

153 patients in the HCVac study were recruited in five countries in Europe, in the United States and in Israel, and were randomized in one control arm (Arm A) or one of the two experimental arms (Arms B and C). In the Arm B, the TG4040 dosage was administered 6 times and the standard of care was given 4 weeks prior to the initiation of TG4040. In the Arm C, the TG4040 dosage was administered 13 times and the standard of care was introduced 12 weeks after the initiation of treatment with TG4040. The HCVac study is investigating 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 SAEs:

The three cases of severe haematological adverse events, one aplastic anemia and two cases of thrombocytopenia, reported in October 2011, all recovered within 1 to 4 months. A fourth case corresponding to a thrombocytopenia was recorded recently. Of interest, the three cases of thrombocytopenia share all a same class 2 Human Leukocyte Antigen ("HLA") allele. This association is statistically significant and, as these HLA types could be excluded *a priori* in a new clinical trial, this will be taken into account in future developments of the therapeutic vaccine, should it be combined

with standard of care including PEG-IFN α . These adverse events should also have no impact in future developments without PEG-IFN α .

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 2 clinical development: TG4010 and JX594/TG6006 having already completed initial phase 2 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 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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