

## Promising Final Data from the Phase 2 HCVac Trial of TG4040 Presented at EASL 2013

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**Strasbourg, April 29<sup>th</sup>, 2013** - Transgene SA (Euronext Paris: FR0005175080), a biopharmaceutical company that develops targeted immunotherapy products to treat major unmet medical needs in cancer and chronic infectious diseases, announced final data of the Phase 2 HCVac trial of TG4040 for the treatment of genotype 1 chronic hepatitis C (CHC) at an oral presentation of the European Association for the Study of the Liver (EASL) Congress in Amsterdam, the Netherlands.

Professor Heiner Wedemeyer, University of Hanover, Germany and Principal Investigator of the HCVac trial, today presented the final data at EASL and stated: *“This trial is unique in the field of hepatitis C, representing one of the largest randomized studies ever investigating an immunotherapeutic product against a persistent infection. It is remarkable that TG4040 induced a decline in HCV viral load and that early response rates of standard therapy with peg-interferon alpha and ribavirin were increased. In addition, very important general findings were made that will help Transgene optimize the future clinical development of TG4040.”*

This open label study evaluated in 153 randomized patients two schedules of TG4040 in combination with PegIFN $\alpha$ 2a (P) and ribavirin (R) versus P/R alone (Arm A): Arm B with six TG4040 injections initiated 4 weeks after P/R and pre-vaccination Arm C with thirteen TG4040 injections initiated 12 weeks before P/R.

The positive effect of TG4040 was seen with pre-treatment of TG4040 in Arm C. The benefit of pre-treatment was observed as early as one week after initiation of PEG-IFN $\alpha$ /RBV with a 40% improvement in decline of mean HCV RNA viral load. The primary endpoint was met in Arm C with a complete early viral response (cEVR) of 64% as compared to 30% in the control arm ( $p=0.0037$ ).

The virologic response was sustained over time with a SVR24 of 58% in Arm C, compared to 48% in the control arm.

The key immunologic findings were that induction of MVA and HCV specific T-cell responses were essentially seen in Arm C before the addition of PEG-IFN $\alpha$ /RBV. The viral response seen in Arm C was observed in spite of the development of anti-MVA responses.

Overall, safety was similar across the three arms (percentage of adverse events and grade). The investigation of the four cases of severe blood toxicity led to the conclusion of an exacerbation of IFN-known immune side effects in patients with autoimmune predisposition (see press release of 23<sup>rd</sup> April 2012).

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Philippe Archinard, Chairman and Chief Executive Officer of Transgene, stated: *“Today’s oral presentation at EASL once again verifies the high level of scientific and medical interest in Transgene’s immunotherapy products. The final results of the HCVac study demonstrated that a specific vectored immunotherapeutic can improve treatment of CHC. While new treatment paradigms are currently emerging, and are likely to enter the market as early as 2014, Transgene is examining different opportunities for TG4040’s future clinical development. Given the results of our Phase 2 study, immunotherapy with TG4040 may warrant further evaluation in combination with IFN-free direct-acting antivirals treatment regimens once they are approved.”*

### **About TG4040**

Transgene’s TG4040 immunotherapeutic product 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**

In this Phase 2 HCVac study, a total of 153 treatment-naïve patients were enrolled in 28 sites from Europe, the United States and Israel. Patients were randomized in three arms: one control arm (48 weeks of Peg-IFN/RBV) or one of the two experimental arms. In one experimental arm, the TG4040 dosage (subcutaneous injections at the dose of  $10^7$  pfu) was administered six times and Peg-IFN/RBV was given as a 4 week lead-in prior to the initiation of TG4040. In the other experimental arm, the same TG4040 dosage was administered 13 times and Peg-IFN/RBV was introduced twelve weeks after initiation of pre-treatment with TG4040. The HCVac trial evaluated the efficacy and safety of these two different schedules of TG4040 administration in combination with Peg-IFN and RBV as compared to Peg-IFN/RBV alone.

### **About Transgene**

Transgene (NYSE-Euronext: TNG), a member of the Institut Mérieux Group, is a biopharmaceutical company. We create, develop and manufacture targeted immunotherapeutics for the treatment of cancers and infectious diseases. Our products are major technological breakthroughs that use well tolerated viruses to indirectly or directly kill infected or cancerous cells. Our four most advanced products have generated proof of concept data in randomized clinical studies: in lung cancer (TG4010), liver cancer (Pexa-Vec), hepatitis C (TG4040) and HPV-related cervical lesions (TG4001). We have concluded strategic agreements for the development of three of these products: an option agreement with Novartis for the development of TG4010, an in-licensing agreement with US-based Jennerex, Inc. to develop and market Pexa-Vec and a strategic collaboration with EORTC to develop TG4001 in cancer of the oropharynx. We also have a non-exclusive agreement with Sanofi/Genzyme for the future commercial production of our products. Most of our 280 employees are based in Strasbourg, France, and we have operations in Lyon, China and the USA. Additional information about Transgene is available at [www.transgene.fr](http://www.transgene.fr).

### ***Transgene Forward Looking Statements***

This press release contains forward-looking statements notably referring to plans for the future development of TG4040 as a treatment against chronic hepatitis C, in combination with new treatments. These plans are subject to changes and uncertainties and we could never be able to develop, manufacture or sell TG4040 in the future. 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 on Transgene's website at [www.transgene.fr](http://www.transgene.fr).

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