

# Transgene Presents Promising Pre-Clinical Data on TG1050 to Treat Chronic HBV at EASL 2013

- Initiation of a Phase I study in 2014
- New first in class immunotherapeutic to treat CHB

**Strasbourg, April 29th, 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 pre-clinical data obtained with its novel immunotherapeutic, TG1050, to treat chronic hepatitis B infection (CHB). These results were presented in an oral session (Hepatitis B and D Experimental) at this year's European Association for the Study of the Liver Conference (Amsterdam, Netherlands, April 24-28, 2013).

Philippe Archinard, Chairman and Chief Executive Officer of Transgene, stated: "We are excited that TG1050 was selected for an oral presentation at EASL. We hope that this presentation will trigger interest in the scientific community as well as discussions with potential partners. We expect to start a first-in-human/phase 1 clinical trial in 2014 and we believe that TG1050 is currently the most promising direct active immunotherapeutic in development for the treatment of CHB, an area of unmet medical need and high worldwide prevalence."

The selection process from 32 promising product candidates of TG1050 was endorsed and approved by different panels of key opinion leaders in the viral hepatitis field. TG1050 is based on a nonreplicative Adenovirus 5 vector that encodes three HBV (Hepatitis B Virus) antigens or related domains. The clinical candidate has demonstrated potent immunogenicity in pre-clinical mouse models as well as genetic stability. Immunogenic properties include induction of potent, multispecific, functional and cross-reactive T cell responses, including both cytokines production (IFN $\gamma$ /TNF $\alpha$ ) and *in vivo* cytolysis; all important characteristics that have been associated with viral clearance during natural infection.

Today's presentation provided updated and more recent data that demonstrated the capacity of TG1050 to induce long-lasting HBV-specific memory T cells. Experiments in two murine models based on hepatic expression of the full length HBV genome, a HBV transgenic mouse model (University of Ulm) and a model using a recombinant adenovirus associated virus encoding HBV (AAV-HBV, Institute Pasteur) showed that a single injection of TG1050 had the capacity to educate HBV-specific functional T cells within a tolerant environment without inducing liver inflammation, whilst displaying antiviral activities, which were particularly shown in the AAV model.

"TG1050 is to my knowledge the most comprehensive HBV immunotherapeutic currently under development that will be delivered by a single vector. Viral vectors and adenovirus-based vectors in particular, remain today the most efficient delivery platform when it comes to inducing strong cellular immune responses which play a central role in the control of HBV infection. A strong inverse correlation exists between HBV specific functional T-cells and control/eradication of viremia; immunotherapeutic for the treatment of CHB may provide a significant increased cure rate to the existing antiviral drugs" stated Dr Fabien Zoulim, Medical Director of the Liver Department at the Hospices Civils de Lyon and Scientific Director of the Hepatitis Research Laboratory at INSERM Unit 1052. He added further: "This type of approach provides new hope towards the development of a treatment with limited duration either alone or in combination with nucleoside analogues."

### About TG1050

The novel immunotherapeutic product TG1050 developed by Transgene to treat chronic infection by hepatitis B is based on a recombinant non-replicative human adenovirus serotype 5, expressing multiple specific HBV antigens (Core, Polymerase and Envelope) from genotype D. The product has been designed to prime *de novo* and/or stimulate functional T cells expected to control the HBV replication and to elicit viral clearance.

According to the World Health Organization's ("WHO") estimates, 350 million people are chronic carriers (WHO, 2009) of HBV. Hepatitis B is more common in some parts of the world than others. In China and other parts of Asia, up to 10% of the population is believed to be chronically infected. In addition to the significant burden of disease, CHB is responsible for 1 million deaths each year due to related complications such as liver failure, cirrhosis or hepatocellular carcinoma (liver cancer).

## **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 <u>www.transgene.fr</u>.

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

This press release contains forward-looking statements notably referring to the future development of TG1050 as a treatment against chronic hepatitis B. Such anticipated development is based on the results obtained in preclinical models. These results are not necessarily predictive of the results that we may obtain in future clinical testing on Man. We could never be able to develop, manufacture or sell TG1050 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.amffrance.org and on Transgene's website at www.transgene.fr.

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