Transgene’s New Therapeutic Vaccine Candidate (TG1050) to Treat Chronic Hepatitis B (“CHB”) Reaches Pre-Clinical Proof of Concept

- Long-term control of hepatitis B remains a major unmet medical need
- Positive pre-clinical data supports future clinical development
- Poster presentation at EASL, Barcelona, April 19, 2012

Strasbourg, France, April 19, 2012 - Transgene (Euronext Paris: FR0005175080) today announced that it has achieved pre-clinical proof of concept with a new therapeutic vaccine candidate, TG1050, aiming at treating chronic infection by the hepatitis B virus (“HBV”).

Positive pre-clinical data supports further development of the product. These data include:

- Robust and broad immune (T cell) response in pre-clinical models after one or more injections;
- Potent *in vivo* cytolysis\(^1\) against several epitopes\(^2\); and
- Genetic stability of the vaccine.

Despite the introduction in the past decade of efficacious new drugs (Nucleoside analogs - “NUCs”- and PEG-IFNα) to treat CHB, these drugs result only rarely in the resolution of the infection, which is defined by the disappearance of circulating hepatitis B virus surface antigen (“HBsAg”) and a measurable antibody response against this same antigen, or HBsAg seroconversion\(^3\).

In combination with standard of care, TG1050 has the potential to increase the level of seroconversion in comparison to current treatments, and thus could provide a new option for the cure of the infection.

The product is expected to enter clinical development in 2014.

“The promising preclinical proof of concept on this new vaccine candidate, together with the clinical efficacy data obtained with TG4040, our therapeutic vaccine against hepatitis C, proves again the excellence of Transgene’s research in the field of infectious diseases” said Philippe Archinard, Chairman and CEO of Transgene. He added: “Although the management of CHB has significantly improved over the past decade, the long-term control of the infection is very rarely achieved and patients have to endure decades-long treatments. We believe that a combination of TG1050 with the standard of care could potentially help to cure the infection, providing relief to millions of patients”.

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\(^1\) Cytolysis is the cell death induced by a rupture in the cell’s membrane following the action of cells from the immune system.

\(^2\) An epitope, also known as antigenic determinant, is the part of an antigen that is recognized by the immune system, specifically by antibodies, B cells, or T cells.

\(^3\) Seroconversion is the development of detectable specific antibodies to microorganisms in the blood serum as a result of infection or immunization.
Transgene’s HBV research program will be presented today in a poster at the EASL congress (European Association for the Study of Liver), in Barcelona, Spain. During the same EASL congress (on April 21, 2012), Pr. Heiner Wedemeyer, MD, of the Department of Gastroenterology, Hepatology and Endocrinology at Hannover Medical School (Germany), will give a “late breaker” oral presentation and present follow up data from the randomized Phase 2b clinical trial with TG4040, a therapeutic vaccine against chronic hepatitis C infection for which initial proof of concept data were released at AASLD in November 2011.

About HBV:

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’s HBV vaccine:

Transgene’s therapeutic CHB vaccine is based on a recombinant non-replicative human adenovirus serotype 5, expressing multiple specific HBV antigens (Core, Envelope and Polymerase) from genotype D. The vaccine has been designed to prime de novo and/or stimulate functional T-cells expected to control the HBV replication and to elicit viral clearance.

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 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.com). 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.
Contacts:

Transgene

Philippe Archinard, Chairman & CEO
Phone: +33 (0)3 88 27 91 22

Stéphane Boissel, Executive Vice President & CFO
Phone: +33 (0)3 88 27 91 02

Elisabetta Castelli, Director IR
Phone: +33 (0)1 44 08 55 05

MC Services

Raimund Gabriel
Phone: +49 89 210 228 30

Shaun Brown
Phone: +44 207 148 5998