Transgene Reviews Product Pipeline, Provides a Business Update and Outlines its Corporate Strategy

Parc d'Innovation, Illkirch, France, March 22, 2010 – Transgene (Euronext Paris: FR0005175080) details its major product milestones of 2009, provides a business update and outlines its corporate strategy.

Key Product highlights:

- ⇒ **TG4010 (MVA-MUC1-IL2)**, for the treatment of advanced non small cell lung cancer: confirmation of overall survival benefit of six months and FDA Fast Track status. In March 2010, Transgene granted Novartis an option for an exclusive worldwide license to the product.
- ⇒ **TG4001/RG3484 (MVA-HPV-IL2)**, in partnership with Roche, for the treatment of precancerous cervical lesions caused by the HPV virus entered a large international phase IIb trial in October 2009 enrolling over 200 patients.
- ⇒ **TG4023 (MVA-FCU1)** for the treatment of metastatic colorectal cancer and hepatocarcinoma entered phase I trial in October 2009.
- ⇒ **TG4040 (MVA-HCV)**, for the treatment of hepatitis C showed in phase I studies a good safety profile as well as a coincident viral load decrease with increasing vaccine-specific immune responses. Based on these results, the Company announced its decision to initiate a large phase II study.

"We have had a momentous 2009 and beginning of 2010", commented Philippe Archinard, Chief Executive Officer of Transgene. "The major clinical and regulatory milestones achieved last year with TG4010, our lung cancer product with substantial commercial potential, have led to the recent agreement with Novartis. We are proud of this partnership which supports Transgene's ambitions to become a fully integrated biopharmaceutical company within the next five years, and further validates our know-how and technology base", added Philippe Archinard.

Product Pipeline Review and Outlook

Products in Clinical Development

TG4010 (MVA-MUC1-IL2) for the treatment of advanced non-small cell lung cancer (NSCLC) in combination with chemotherapy: FDA grants Fast Track Status and an exclusive option agreement is signed with Novartis.

Major Developments in 2009: Positive clinical data from a controlled phase IIb trial in patients with advanced NSCLC was presented to the ASCO (American Society of Clinical Oncology) meeting on May 31, 2009 (see ASCO poster on www.transgene.fr) and formed the basis for the FDA's clearance to proceed to a pivotal phase III trial programme (see press release of June 9, 2009 on www.transgene.fr).

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On December 1, 2009 the FDA determined that TG4010 met the criteria for Fast Track designation (see press release on www.transgene.fr). The granting of Fast Track Status is a major achievement and a further validation of the quality of the clinical results obtained. It facilitates future development, expedites the FDA review process and allows for the TG4010 Biological Licence Application (BLA) to be considered for submission on a rolling basis, thus allowing the FDA to review sections of the BLA as they are completed.

Major Developments in Q1 2010: On March 10, 2010, the company announced an exclusive option agreement with Novartis for the development and commercialisation of TG4010 for the first-line treatment of NSCLC and other potential cancer indications (see press release on www.transgene.fr). Under the terms of the agreement, Novartis will pay Transgene a US$10 million (€7.4 million) non-refundable option fee. Contingent upon the exercise of the option by Novartis and the achievement of successful development, regulatory and commercial milestones in various indications, Transgene is eligible to receive up to a total of €700 million. In addition once the product is commercialised, Transgene will receive royalties on sales and revenues from the commercial supply of product to Novartis, and will benefit from co-promotion rights in certain countries including France and China.

Transgene will control and fund the phase IIb part of a pivotal, global, controlled phase IIb/III trial of TG4010 in patients with advanced (stage IV) NSCLC. This trial is expected to begin in the fourth quarter of 2010 and involve the overall recruitment of some 1,000 patients with MUC1-positive NSCLC and normal levels of activated NK cells at baseline. Interim results from this trial are expected during the first quarter of 2012 and Novartis will have 90 days to decide whether to exercise its option. Following exercise, Novartis will assume responsibility of the on-going phase III trial. Final results are anticipated for the fourth quarter of 2013.

Next Steps: A joint working group with Novartis has been established to oversee TG4010's overall development. Transgene is preparing the Special Protocol Application to the Food and Drug Administration and Scientific Advice to the European Medicine Agency, ahead of trial launch expected in the final quarter of 2010.

TG4040 (MVA-HCV) for the treatment of chronic hepatitis C: phase II launch expected in the second quarter of 2010

- **Major Developments in 2009**: Transgene has completed two phase I trials in France and in Canada. The French trial involved 42 treatment naïve patients with the genotype 1 HCV. The Canadian trial consisted of 24 patients with the same chronic HCV infection, but who had relapsed after standard of treatment.

The final results of the French trial were presented at the EASL (European Association for the Study of the Liver) conference on 23rd April 2009 (see press release April 28, 2009, on www.transgene.fr) and at the AASLD (American Association for the Study of Liver Diseases) meeting in November 2009.

Clinical results from both phase I trials show that the product is safe and well tolerated by patients at all dose levels. Immunological analyses on 15 patients involved in the French trial were very 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.

- **Next Steps**: Transgene expects to begin a phase II trial of TG4040, in combination with standard of care (Pegylated-Interferon Alpha plus Ribavarin), during the second quarter of 2010. The trial will recruit approximately 120 patients who are chronically infected with the genotype 1 HCV. The trial will involve around 40 clinical sites across some seven countries. Results are expected during the third quarter of 2011.

TG4001/RG3484 (MVA-HPV-IL2) for the treatment of precancerous cervical lesions caused by the HPV virus: Roche initiates phase IIb trial

- **Major Developments in 2009**: At the end of September 2009 Roche began a placebo controlled phase IIb trial on patients with HPV related CIN 2/3 lesions. The trial is being conducted in clinical centers in Europe and the United States, and aims to recruit some 200 patients. The first patient was recruited at the beginning of September 2009.

- **Next Steps**: Interim results are expected in the second quarter of 2011.

TG4023 (MVA-FCU1) for the treatment of metastatic colorectal cancer (mCRC) and hepatocarcinoma (HCC): phase I trial recruits first patient in September 2009

- **Major Developments in 2009**: On 4th November 2009, Transgene announced the enrolment of the first patient for the phase I trial of TG4023 (MVA-FCU1), its newest product to enter clinical trials.

  TG4023 is an MVA-based product that induces a targeted chemotherapy treatment in primary or secondary hepatic tumors, in particular metastatic colorectal cancer (mCRC) or hepatocarcinoma (HCC). TG4023 has a unique mechanism of action that converts a non-cytotoxic pro-drug, 5-FC, into 5-FU, a classic chemotherapeutic agent, resulting in high local concentrations of this agent.

  Transgene's phase I trial is taking place in six centers in France and involves the recruitment of approximately 20 patients. The primary endpoints are to assess the safety and maximum tolerated dose of TG4023.

- **Next Steps**: Final phase I results are expected in the first quarter of 2011.

TG1042 (Ad-IFNγ) for the treatment of relapsed cutaneous B-cell lymphoma (CBCL): Removal from the clinical pipeline.

- Since November 2008, the development strategy for TG1042 (see press release of November 21, 2008 on www.transgene.fr) has been placed on hold and a number of options assessed. Transgene has finally decided not to pursue the development of this product.

Corporate Strategy

"Our objective is to become a profitable biopharmaceutical company by 2015, establishing leadership in immunotherapy treatments for cancer and infectious diseases", Philippe Archinard declared. "Moving forward we adopted a three pillar based development strategy for our products: our well known MVA technology platform, and two innovative approaches: oncolytic virus and monoclonal antibodies. This balanced strategy constitutes an optimal way to create shareholder value", added Philippe Archinard.

Strategy: A Technology Platform Consisting of 3 Pillars

In addition to the well-known MVA platform, oncolytics and monoclonal antibodies issuing from Transgene's rich preclinical research have now become central to the broadening of the product portfolio going forward.

Therefore, the means by which we will attain our objective is through the concurrent development of these 3 pillars or product areas. In doing so we are maximising our chances of success and creating more options for the company to monetize potentially valuable R&D assets.

The 3 Pillars:

1. MVA franchise: Transgene intends to further organically grow its MVA franchise. Beyond our two existing partnered products (TG4001/RG3484 and TG4010), we are moving into phase II with TG4040, and will continue to invest in MVA-based products in the field of infectious diseases. As we recently announced in our agreement with Novartis on TG4010, Transgene is gradually retaining more rights over its products, which is fully consistent with the overall objective of becoming an integrated biopharmaceutical company.

2. Oncolytics: Oncolytic viruses are a novel class of cancer therapeutics. At Transgene we have been focusing historically on vaccinia viruses that have been engineered to attack and eradicate cancer cells selectively, without harmful impact on the surrounding normal cells. Unlike MVA-based products oncolytic products replicate themselves in cancer cells, leading to cancer cell destruction, while normal cells are left mostly unharmed. These products are activated by genetic pathways that are critical to the vast majority of human cancers. This mechanism of action is different from standard therapies such as chemotherapies, small molecule tyrosine kinase inhibitors, antibodies and radiotherapy, and thus oncolytic products could potentially be used in combination with those treatments or even alone in case of cancers that are resistant to these treatments.

Furthermore these viruses could be "armed" for instance with suicide genes like FCU1 in order to further potentiate their activity, or targeted to improve their specificity.

From a manufacturing perspective this platform is totally synergistic with the MVA platform.

Transgene has different oncolytic products in pre-clinical development. The intention is to continue clinical development in-house whilst remaining open to any in-licensing opportunities aimed at complementing the existing portfolio or shortening development timelines. The preferred indications for oncolytic products are HCC (hepatocellular carcinoma), other solid tumors like metastatic colorectal cancer or head and neck cancer, and also onco-haematological indications. TG6002, our most advanced oncolytic candidate is expected to enter clinical trials before the end of 2011.

3. Monoclonal antibodies: Monoclonal antibodies represent the most successful new bio-product class with a strong commercial franchise in oncology and auto-immune diseases. Over the past two years, Transgene has developed a humanised monoclonal antibody (TG3003), targeting CD115 (Colony Stimulating Factor 1 Receptor or CSF1-R), which is now in late pre-clinical development.

CD115 is a transmembrane Tyrosine kinase receptor of type III subfamily which includes for instance VEGF-R. CD115 is expressed on phagocytes and is involved in the proliferation of bone marrow hematopoietic stem cells and the ontogeny of myeloid lineage cells. It is also implicated in the proliferation and recruitment of blood monocytes and the differentiation of macrophages and osteoclasts.

CD115 is expressed in a large variety of human tumors **(**breast, ovaries for instance**).** CD115 and CSF1 are frequently co-expressed at late / metastatic stages. Furthermore, tumor cell invasion is controlled by autocrine CSF-1/CD115 loop.

TG3003 is aimed at blocking the CD115 / CSF-1 pathway and at having a cytotoxic effect on CD115-positive cells either directly (CD115-positive cancer cells) or indirectly through CD115-positive Tumor infiltrated Activated Macrophages (TAMs). TG3003 is expected to enter clinical trials before the end of 2011.

The Transgene Business Model

Transgene's business model based on these three technological pillars is fundamental to achieve our aim to become an integrated biopharmaceutical company.

Our strategy will trigger long term investment in the following critical areas:

⇒ Commercial bio-manufacturing capacity
⇒ Late clinical stage know-how
⇒ A dedicated marketing and sales force for specific territories

The agreement with Novartis is exemplary in the way it supports this business model, regarding our products based on **MVA** and **oncolytics**. The model emphasizes organic development in key indications and greater vertical integration so that in the future Transgene can retain more of the value chain. This does not exclude the possibility of pursuing in-licensing or out-licensing opportunities in order to strengthen our portfolio and/or cashflow.

Our business model for **monoclonal antibodies** is different because they represent somewhat flexible "cash in" options rather than being a vector of integration like the MVA or oncolytics products. Our strategy is to continue development until early proof of concept as it leverages our core competencies in development, but thereafter we are likely to seek out-licensing opportunites or co-development partnerships. Since this product area is highly attractive to the pharmaceutical industry we prefer to exploit the potential cash generation capacity of our know-how in monoclonal antibodies and re-invest the proceeds in other areas.

About Transgene

Transgene is a France-based biopharmaceutical company dedicated to the development of therapeutic vaccines and immunotherapeutic products in oncology and infectious diseases. The company has four compounds in clinical development: TG4010 having completed phase II trials, TG4001/RG3484 in phase IIb trial, TG4040 having completed phase I studies and TG4023 in phase I trial. Transgene has concluded strategic agreements for the development of two of its immunotherapy products with:

- Roche for the development of TG4001/RG3484 to treat HPV-mediated diseases, and
- Novartis for the development of TG4010 to treat various cancers.

Transgene has bio-manufacturing capacities for viral-based products.. Additional information about Transgene is available on the Internet at www.transgene.fr.

Cautionary note regarding forward-looking statements

This press release contains forward-looking statements referring to the planned clinical testing and development of Transgene's therapeutic vaccine candidates and to the anticipated development and commercialisation of one of Transgene's therapeutic product candidates pursuant to a recently entered into option agreement with Novartis, as well as to future payments and other matters provided for under the agreement. Clinical testing and successful product development depend on a variety of factors, including the timing and success of future patient enrolment and the risk of unanticipated adverse patient reactions. Results from future studies with more data may show less favorable outcomes than prior studies, and there is no certainty that product candidates will ever demonstrate adequate therapeutic efficacy or achieve regulatory approval or commercial use. Except for the US$10m option grant payment, all other payments to Transgene by Novartis under the agreement are subject to (i) the exercise by Novartis of the option to license the product, which will be decided upon following the release of the results from the phase IIb part of the phase IIb/III trial currently expected in the first quarter of 2012, and (ii) the occurrence of certain events that are dependent on regulatory approvals, demonstrated product efficacy and success in broad clinical studies, and effective commercialisation, market demand and sales levels, none of which can be assured at this time. For further information on the risks and uncertainties involved in the testing and development of Transgene's product candidates, see Trangene's Document de Référence on file with the French Autorité des marchés financiers on its website at http://www.amf-france.org and Transgene's website at www.transgene.fr .

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