Transgene: First Patient enrolled in Phase I Trial of TG4023 for the Treatment of Liver Tumours

Strasbourg, France, November, 4th, 2009 – Transgene S.A. (Euronext Paris: FR0005175080) today announced the enrolment of the first patient in the Phase I trial of TG4023 (MVA-FCU1), its newest product to enter clinical trials.

Transgene is developing TG4023, a Modified Vaccinia Ankara (MVA) based product, as a targeted chemotherapy treatment for patients with primary or secondary hepatic tumours mainly related to metastatic colorectal cancer (mCRC) or hepatocellular carcinoma (HCC). TG4023 has a unique mechanism of action that converts a non-cytotoxic pro-drug, 5-FC, into 5-FU, a classic chemotherapeutic agent.

Transgene's Phase I trial will take place in six centres in France and should enrol 20 patients. The primary endpoints are to assess the safety and maximum tolerated dose of TG4023.

Eligible patients will have at least one unresectable tumour in the liver and no other option for treatment or care. Each patient will receive one percutaneous injection into the hepatic tumour followed by the administration of 5-FC. Several dose levels of TG4023 will be administered in successive cohorts in order to define the maximum tolerated dose. Transgene expects to report preliminary safety data in the third quarter of 2010, with complete data planned by the first quarter of 2011.

"We are pleased to bring this new product to clinic and to expand our clinical portfolio with this innovative approach" said Philippe Archinard, Chief Executive Officer of Transgene. "The pre-clinical data for TG4023 has been very promising and there is a clear market need for an alternative treatment of hepatocellular carcinoma and liver metastasis for the thousands of patients for whom transplant is not possible."

About TG4023

TG4023 mechanism of action: TG4023 is injected into the tumour and delivers FCU1 to tumoral liver cells. FCU1-transduced liver cells are then able to locally convert the 5-FC pro-drug given systemically to the patients, into 5-FU, a well-known chemotherapeutic drug. The passive diffusion of the 5-FU agent ensures in preclinical models an impressive bystander effect with the ability to kill 100% of a tumour cell population comprising only 1% of FCU1-transduced cells. As the 5-FU is produced locally by the FCU1-transduced cells, this approach should reduce the toxicity and increase the local concentration of 5-FU compared to standard systemic delivery of 5-FU based chemotherapy.

The TG4023 project is based on promising pre-clinical results for a targeted chemotherapy approach. Data from these studies show:

- A concentration of 5-FU 20 times higher has been observed in tumours treated with TG4023 as compared to 5-FU standard chemotherapy.
- Tumour growth control has been shown *in vivo* in several models: colorectal cancer, hepatocellular carcinoma, head and neck cancer, glioblastoma.
- A prolonged conversion of 5-FC into 5-FU in tumours has been observed for at least two weeks after TG4023 administration.

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About Liver tumours

***Primary tumours*: Hepatocellular carcinoma (HCC)**

- HCC is one of the most common malignancies in the world, accounting for about 500,000 deaths per year. Most HCC tumours occur in patients with cirrhosis of the liver (80% of diagnosed HCC) either due to alcohol consumption or chronic infection with the hepatitis B or C virus.

- It is estimated that about 360,000 patients per year worldwide are not eligible for resection or transplantation surgery; in these cases, local palliative treatments are proposed, aiming at destroying the tumour by percutaneous procedures, using radiology or ultrasound imaging guidance.

***Secondary tumours:* Liver metastases of colorectal cancer (CRC)**

In 2000, 2.4 million people worldwide were affected by CRC and 950,000 new cases were observed. CRC accounts for over 500,000 annual deaths and is the second cause of cancer-related deaths in industrialized countries, after lung cancer.

Up to 70% of patients with CRC eventually develop liver metastasis. Liver resection has been recognized as the only option for possible cure in patients with colorectal cancer metastasis confined to the liver at the time of diagnosis. Of these patients, only 20% are actual surgical candidates due to size, distribution or accessibility of the tumour(s), leaving the remaining 80% with palliative treatments (about 130,000 patients per year in the US and EU).

About Transgene

Transgene is a France-based biopharmaceutical company dedicated to the development of immunotherapeutic products in oncology and infectious diseases. The company has three compounds in Phase II trials (TG4001/R3484, TG4010 and TG1042) and two compound in Phase I studies (TG4040 and TG4023). Transgene has concluded a strategic partnership agreement with Roche for the development of its TG4001/R3484 immunotherapeutic product to treat HPV-mediated diseases. Transgene has bio-manufacturing capacities for viral-based vectors. 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 one of Transgene's targeted chemotherapy treatment product candidates. However, 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. 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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