

Transgene Reports Randomized Phase 2b Data with its Therapeutic HPV Vaccine TG4001 in Women with CIN2/3 Intraepithelial Cervical Neoplasia

Robust clinical and virological proof-of-concept for the activity of the therapeutic vaccine in monotherapy

Strasbourg, France, May 9, 2012 – Transgene S.A. (Euronext Paris: FR0005175080) announces today that it has received from Roche, the former exclusive licensee of the product¹, 6-month headline results of the placebo-controlled study of TG4001 (RG3484) in women with CIN2/3 intra-epithelial neoplasia of the cervix due to infection with high-risk HPV (as defined by the Roche Linear-Array[®] test).

This ongoing study conducted in the US and Europe enrolled 206 patients and aims at demonstrating the safety and activity of TG4001 in terms of histological resolution² and viral clearance³. The primary endpoint of the study is the histological resolution rate at 6 months in the sub-group of women with HPV16 mono-infection.

The main efficacy results of the study in terms of histological and anti-viral efficacy at 6 months (6 months after treatment) are summarized in the following table:

	HPV16 mono-infected			All genotypes		
	TG4001	Placebo	<i>p value</i>	TG4001	Placebo	<i>p value</i>
Histological resolution	11/55 (20%)	1/27(4%)	0.0498	32/129 (25%)	6/63 (10%)	0.0126
Viral clearance	20/52 (38%)	2/23 (9%)	0.009	45/121 (37%)	8/58 (14%)	0.0013

Results in the modified Intent-To-Treat (mITT) population: Patients who received at least one dose of study drug and had baseline diagnosis of CIN2/3 confirmed by central pathology review.

Histological resolution and viral clearance in both groups (HPV16 mono-infected and all genotypes) are significantly higher in the experimental arm than in the placebo arm, with notably a fourfold difference between the arms in the HPV16 mono-infected patients group, all this with high significant statistical value⁴.

Given the short dosing schedule (only three administrations of the therapeutic vaccine) and the fact that TG4001 was, unlike in other clinical trials conducted by Transgene with its other MVA products,

¹ Roche terminated its exclusive license agreement in February 2011 (announcement dated February 22, 2011) but is still the sponsor of the ongoing study.

² Histologic resolution: complete disappearance of CIN lesions.

³ Viral clearance: disappearance of the high-risk HPV genotypes present at baseline.

⁴ As demonstrated by low *p* value numbers (below 0.05 by the Chi²) based on post-hoc analyses done by Transgene.

only injected in monotherapy, such data represent a strong proof-of-concept for the activity of the therapeutic vaccine, and are therefore extremely encouraging for TG4001 and the MVA platform.

TG4001 has shown a similarly good safety profile as in the previous trials, with non-serious injection site reactions being the most frequent adverse events associated with the product.

To move the product into phase 3 clinical trials and towards registration in CIN 2/3, it was expected, in addition to at least a doubling of the resolution rate compared to placebo (which was attained), a 60% resolution rate in the HPV16 mono-infected population. This latter objective, not reached, was set in light of the well-established high efficiency of conization, the existing surgical option for CIN 2/3 patients. As a consequence, Transgene does not expect to further develop TG4001 in this indication and would rather address higher unmet medical needs, such as certain head and neck cancers and cervical cancer related to infection by HPV. Indeed, for these latter indications, the market potential is far greater than for CIN 2/3 and the product could efficiently be combined with chemotherapy (as it has been demonstrated that MVA therapeutic vaccines synergize the effect of chemotherapy).

Further analysis of the data is necessary and will be conducted. Transgene expects to receive follow up data (notably on safety and viral clearance) on this trial within the next two years.

“The study conducted by Roche has clearly demonstrated that TG4001 is active, which obviously is a positive sign for the product as well as for the whole MVA platform” said Dr. Jean-Marc Limacher, CMO of Transgene S.A. He added: *“We are not going to move this product into phase 3 in CIN 2/3 but we believe that its clinical development in other HPV-induced malignancies, such as head and neck cancer or cervical cancer, particularly in combination with chemotherapy, makes sense”*.

“Given the effective existing surgical treatment, CIN 2/3 is an indication with a very high entry bar for any novel therapeutic approach.” said Philippe Archinard, Chairman and CEO of Transgene S.A. He added: *“We have other development options for TG4001, but in the short term Transgene wants to focus its resources on its most advanced developments with TG4010 (lung cancer), JX594/TG6006 (liver cancer) and TG4040 (hepatitis C). Hence, development of TG4001 in other indications is more likely to be conducted through partnerships. In the short term, these results will have a limited impact on our portfolio which only marginally factored in the CIN2/3 development.”*

About TG4001:

TG4001 is a therapeutic vaccine based on a non-propagative, highly attenuated vaccinia vector (MVA), which is engineered to express HPV16 antigens (E6 & E7) and an adjuvant (IL-2). TG4001 is designed to have a two-pronged anti-viral approach: to alert the immune system specifically to HPV16-infected cells that have started to undergo precancerous transformation (cells presenting the HPV16 E6 and E7 antigens) and to further stimulate the infection-clearing activity of the immune system through interleukin 2.

About HPV-mediated diseases:

HPV infection is recognized as the necessary cause of precancerous cervical lesions and cervical cancers and is the most common sexually transmitted disease affecting about 400 million women worldwide. HPV participates also in the development of a substantial and increasing proportion of head and neck cancers. Most infections are spontaneously eliminated in less than one year. In the remaining cases, persistent HPV infection can lead, after several years or decades to precancerous lesions of the cervix - called cervical intraepithelial neoplasia of grades 2 and 3 (CIN 2/3) - and eventually to cervical cancer. In the United States and in Europe, some 580 000 new cases of CIN 2/3 are reported yearly, of which over 80% are linked to HPV16 and HPV16 related genotypes. The HPV16 genotype, along with HPV18, 31 and 33 genotypes, have the highest risk of transforming infected cervical cells into cancerous cells.

HPV16 and related HPV are also associated with a subset of head and neck cancers, especially those arising from the oropharynx, the most incident, and the larynx. The incidence of HPV16-related oropharyngeal squamous cell cancer has significantly increased among white men and at younger ages, over the last past years (+1.5% CAGR expected) and is estimated to reach ~35 000 patients by 2020 in the US and the five major countries in Europe. The global market value of head and neck cancer indications amounted to 1B\$ in 2010, with chemotherapies as the most widely used options.

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 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

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