

# Transgene Announces the Termination by Roche of the License Agreement on TG4001/RG3484 for the Treatment of Diseases Caused by the Human Papilloma Virus ("HPV")

- A strategic decision by Roche, not data driven
- Current Phase IIb trial in HPV-caused CIN2/3 interim data expected by end 2011 or early 2012
- At availability of these clinical data, Transgene will decide on Phase III development, potentially in co-development with a partner

**Parc d'Innovation, Illkirch (France), February 22, 2011** – Transgene (Transgene (NYSE Euronext Paris: FR0005175080)) announces today the termination by Roche (SIX: RO, ROG; OTCQX: RHHBY) of the 2007 agreement under which Transgene granted Roche exclusive global development and commercialization rights to TG4001/RG3484, a therapeutic vaccine candidate to treat notably high grade cervical intraepithelial neoplasia (CIN) lesions (CIN2/3) caused by Human Papilloma Virus infection. TG4001/RG3484 is currently in a Phase IIb clinical trial in this indication.

Roche has indicated to Transgene that its decision to terminate the license agreement is based on its own strategic reasons and is not data driven.

Transgene does not expect that the termination of the license agreement will have any impact on the ongoing Phase IIb trial involving 200 patients: with over 195 patients enrolled to date, recruitment in this trial is almost completed and interim data are expected by the end of 2011 or early 2012.

Upon effective termination this summer, Transgene will regain full and unencumbered development and commercialization rights to TG4001.

Transgene does not expect Roche's decision to have a significant financial impact for the company in the short term.

If clinical data in the ongoing Phase IIb trial is positive at the end of this year, Transgene currently intends to prepare the product for a first registration trial (Phase III) to be started in late 2012 or early 2013. In connection with the possible start of the Phase III, Transgene intends to look for a co-development partner for TG4001 so as to share the late stage development costs while retaining greater ownership rights than it had under its 2007 agreement with Roche.

"Although we are sorry to lose Roche as a corporate partner we remain committed to the product's development," stated Philippe Archinard, Chairman and CEO of Transgene. He added: "Moreover, in this new context, the value of TG4001 for Transgene increases significantly and will of course increase even further if clinical data of the ongoing Phase IIb trial are positive."

The company will host conference calls for analysts and investors in French and in English today, Tuesday, February 22nd. The conference call in French will begin at 6.30pm CET and the conference call in English will start at 7pm CET. The dial-in numbers for both are:

France Toll:+33 (0)1 70 99 42 77UK Toll:+44 (0)20 7136 2052US Toll:+1 212 444 0481Access code:**4585473** 

A listen only, live webcast can be opened using the following link: <u>http://www.thomson-webcast.net/uk/dispatching/?event\_id=768fbc400ec14b7515b18c47bca55099&portal\_id=3</u> <u>931a7cdcddca564ebb4cb3d2dad6baf&language=en</u>

The webcast will be available for consultation on our website: www.transgene.fr

## About TG4001

TG4001 HPV targeted immunotherapy is designed to target type 16 of the Human Papilloma Virus (HPV16) and HPV16-related genotypes, known to be a high risk factor for the development of precancerous cervical intraepithelial neoplasia and subsequently cervical cancer.

TG4001 is based on a non-propagative, highly attenuated vaccinia vector (MVA), which is engineered to express HPV16 antigens and an adjuvant. TG4001 is designed to have a twopronged 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 an adjuvant (interleukin 2).

In Phase II clinical trials, TG4001 demonstrated safety and promising clinical responses in HPV16 positive women with CIN2/3. Activity of the drug was demonstrated in a Phase II trial that was conducted in France in 21 women with HPV16 CIN2/3. No serious side effects were observed. Sustainability of the response was assessed by an examination at Month 12 of the patients who did not undergo surgical excision of CIN lesions at Month 6. No CIN2/3 relapse nor any HPV16 persistence or re-infection was observed in these women.

TG4001 is currently in a Phase II study for TG4001 HPV targeted immunotherapy involving 200 patients with high-grade cervical dysplasia (CIN 2/3), providing valuable additional clinical data that is expected to strengthen the product's profile and provide further proof of efficacy. Interim results from this study are expected by end 2011, beginning of 2012.

#### 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. 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.

Due to the wider use of HPV testing, HPV infection is being diagnosed in an increasing number of women, but no anti-viral treatment is currently available. Surgical resection, currently the only therapeutic solution for precancerous lesions, is effective but presents medical complications and relapses. Therefore, a therapeutic vaccine to clear precancerous lesions and the associated HPV infection could be an effective, non-invasive approach for the prevention of cervical cancer.

#### 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 five compounds in clinical development: TG4010 and JX-594/TG6006 having completed initial Phase II trials, TG4001 in Phase IIb trial, TG4040 in Phase II trial and TG4023 in Phase I trial. 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.
- an in-licensing agreement with US-based Jennerex Biotherapeutics, Inc., to develop and market JX-594/TG6006, an oncolytic product.

Transgene has bio-manufacturing capacities for viral-based products. Additional information about Transgene is available on the internet at <u>www.transgene.fr</u>.

#### Cautionary note for Transgene regarding forward-looking statements

This press release contains forward-looking statements referring to the clinical testing and development and commercial potential of TG4001. Clinical testing and successful product development and commercialization depend on a variety of factors, including the timing and success of future patient enrolment, the risk of unanticipated adverse patient reactions, regulatory approval and the level of demand for the product by the medical community. 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 success. In addition, forward-looking statements regarding product development, testing and marketing costs are by the nature subject to uncertainties as a result of unforeseen difficulties and expenses which may arise, and future product development costs may exceed current expectations. 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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