ASX Announcement (380)

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# Virax Co-X-Gene™ Technology Licence with Transgene
# Trangene's TG4010
# Exclusive Option Agreement with Novartis

Virax Holdings Limited (ASX:VHL) advises that Transgene SA of Strasbourg, France have announced that they have entered into an exclusive option agreement with Novartis for TG4010, a treatment for Non-small-cell-lung cancer (NSCLC). TG4010 has previously successfully completed Phase IIb testing for the first-line treatment of advanced non-small cell lung cancer (NSCLC) in combination with chemotherapy. TG4010 has also potential applications in other epithelial cancers including prostate, breast, kidney, pancreatic and colorectal cancers.

Under the terms of the agreement Novartis will pay a non-refundable option fee of $US10 million.

Also Transgene is eligible to receive up to € 700 million (AUD 1.04 billion) upon achievement of development, regulatory and commercial milestones in various indications, in addition to royalties on global sales.

TG4010 utilises Virax's Co-X-Gene™ technology which Transgene access under a Licence Agreement with Virax. Under the terms of this agreement, Virax will benefit from milestone and royalty payments upon Transgene achieving relevant development milestones and sale of product.

Virax's CEO, Dr. Larry Ward stated: "This is an extremely exciting development for Virax. Through the Transgene sub-licence and the Transgene/Novartis Option agreement, we now have the potential to benefit from milestone and royalty payments for TG4010. This is in addition to the previously announced partnership between Roche and Transgene for the HPV therapeutic vaccine, TG4001. The advancement of both Transgene products into late stage development exemplifies the intrinsic value of the Co-X-Gene™ technology intellectual property and the Transgene Sub-licence."

This is a significant transaction in the area of immunotherapeutic vaccines, and in particular validates the value and technology that Virax's VIR201 utilises – currently in clinical testing in South Africa for HIV.

Virax's Co-X-Gene™ sub licence provides that a percentage of milestone moneys received by Transgene are payable to Virax.

The Transgene press release is attached.

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## Additional information about Virax

Virax, based in Melbourne, Australia, is a biopharmaceutical company engaged in the discovery and development of novel immunotherapeutic products for the treatment of chronic infectious diseases and cancer. The Company's lead product, VIR201, a HIV/AIDS immunotherapeutic (therapeutic vaccine) utilising Co-X-Gene™ technology, has been tested successfully in two clinical trials in Australia. A further Trial of VIR201 has commenced in South Africa. Funding for the Southern African Trial is via contributions from a consortium of global and Southern African resource companies led by BHP Billiton.

Transgene (Eurolist Paris: FR0005175080) has a Licence Agreement with Virax for access to Co-X-Gene™ technology for use in two of Transgene's immunotherapeutic products. These are TG4001 - a treatment for pathologies relating to human papilloma virus (HPV) infection that can lead to cervical cancer - and TG4010 - a treatment for non-small cell lung cancer (NSCLC).

- TG4001 is in advanced development with a completed Phase II trial showing promising safety and efficacy. A Phase IIb trial has commenced so as to optimise the product profile. Transgene has licensed TG4001 to the pharmaceutical company Roche for treatment of HPV related pathologies.

- TG4010 is also in advanced development with successful Phase IIb testing in NSCLC achieved. Transgene reported that the FDA had supported the approach for further development of TG4010 in Phase III trials and has granted Fast Track development designation for TG4010.

Additional information about Virax is available at www.virax.com.au

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**TRANSGENE SIGNS AN EXCLUSIVE OPTION AGREEMENT FOR THE DEVELOPMENT AND COMMERCIALISATION OF ITS IMMUNOTHERAPY PRODUCT TG4010**

**Parc d'Innovation d'Illkirch, France**, March 10, 2010 – Transgene S.A. (Euronext Paris: FR0005175080) today announced the signing of an exclusive option agreement with Novartis for the development and commercialisation of Transgene's targeted immunotherapy product, TG4010 (MVA-MUC1-IL2), for the first-line treatment of non-small cell lung cancer (NSCLC) and other potential cancer indications.

Pursuant to the agreement, Transgene has granted Novartis an option to acquire an exclusive worldwide license for TG4010 and Novartis will pay Transgene a $10 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 approximately €700 million.

According to the agreement, Transgene will initially fund and retain control over the next clinical development phase of TG4010, which is a pivotal, global phase IIb/III clinical trial that Transgene currently anticipates starting by the end of 2010. This study will involve approximately 1,000 patients with MUC1-positive NSCLC who have normal levels of activated Natural Killer (NK) cells at time of trial entry[1]. The final results are expected to become available by the end of 2013.

Results from the phase IIb portion of this combined phase IIb/III clinical trial are expected to be available in the first quarter of 2012. In accordance with the option agreement, Novartis will have up to 90 days after receiving results from Transgene for this phase IIb portion to exercise its option.

If the option is exercised:

- Novartis will assume all development, regulatory and commercialisation costs related to TG4010 across all indications.
- Transgene will receive a non-refundable licence issuance fee and further milestones contingent upon successful development for various indications and the achievement of longer-term commercialisation targets.
- Transgene will receive royalties on global sales.
- Transgene will retain co-promotion rights in certain countries including France and China.
- Transgene will retain primary manufacturing rights for TG4010 to supply Novartis' clinical and commercial requirements.

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[1] The selection criteria was determined thanks to Transgene's biomarker programme, which retrospectively identified in a controlled phase IIb study, completed in 2009 in NSCLC, that patients with normal levels of activated NK cells survived significantly longer in the experimental arm than in the control arm (Phase IIb detailed clinical data of TG4010 are available at www.transgene.fr).

Transgene and Novartis will now form a joint working group to oversee the implementation of the TG4010 global development program.

”We are delighted to have reached this agreement with Novartis and believe they will be an excellent partner for TG4010, given their broad expertise, experience and resources in oncology and their long standing world-class research and development capabilities in cancer immunology,” commented Philippe Archinard, Chief Executive Officer of Transgene. “We believe this agreement represents the best way to accelerate development and create long term value for our shareholders. It is also consistent with the company’s goal of becoming a fully integrated biopharmaceutical company as under this agreement Transgene will maintain certain commercialisation and manufacturing rights. We now look forward to closely working with Novartis in order to rapidly advance the Phase IIb/III development of TG4010 so that cancer patients may benefit from a new treatment option," Philippe Archinard added.

**About TG4010**

TG4010 (MVA-MUC1-IL2) uses the Modified Vaccinia Ankara virus vector, a poxvirus that combines distinguishing advantages for an optimized systemic vaccination:

- MVA is a highly attenuated strain which has been tested extensively in humans as a smallpox vaccine and is known to strongly stimulate innate and adaptive immune responses to antigens.

- MUC1 is a major tumor-associated antigen that provides a viable target for immunotherapy.

- TG4010 expresses the entire MUC1 gene sequence and has the potential to generate an immune response to all antigenic epitopes of MUC1.

- The sequence coding for the cytokine Interleukin 2 (IL2) is included to help stimulate specific T-cell response.

**About Non-Small-Cell Lung Cancer (NSCLC)**

Lung cancer is a major public health issue with over 1 million new cases a year across the world, and accounts for some 450,000 deaths per year in Europe and the United States alone. Around 80% of lung cancer patients are diagnosed with non-small-cell lung cancer. Of these, some 60% over-express MUC1, which is the target for TG4010. The efficacy of current treatments for NSCLC is limited, and TG4010 is targeting first line treatment of metastatic NSCLC in combination with chemotherapy.

**About NK Cells**

Natural Killer cells (NK cells) are effector lymphocytes of the innate immune system that control several types of tumors and microbial infections by limiting their spread and subsequent tissue damage. Recent research highlights the fact that NK cells are also regulatory cells engaged in reciprocal interactions with dendritic cells, macrophages, T cells and endothelial cells. NK cells can thus limit or exacerbate immune responses.

**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 three compounds in phase II trials (TG4001/R3484, TG4010 and TG1042) and two compounds in phase I studies (TG4040 and TG4023). Transgene has concluded strategic agreements for the development of two of its immunotherapy products with:

- Roche for the development of TG4001/R3484 to treat HPV-mediated diseases, and
- Novartis for the development of TG4010 to treat various cancers.

Transgene has bio-manufacturing capacities for viral-based vectors and technologies available for out-licensing. 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 anticipated development and commercialisation of one of Transgene's therapeutic product candidates pursuant to a recently entered into option agreement, as well as to future payments and other matters provided for under the agreement. 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. 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 broad commercial use. For further information on the technical, regulatory and competitive risks and uncertainties involved in the development and commercialisation of product candidates, see Transgene's Document de référence on file with the French Autorité des marchés financiers at http://www.amf-france.org and Transgene's website at www.transgene.fr.*

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