Current Agreements

Dealdoc

Licensing option, manufacturing, supply and co-promotion agreement for TG4010 (MVA-MUC1-IL2)

Novartis
Transgene

Mar 10 2010

Licensing option, manufacturing, supply and co-promotion agreement for TG4010 (MVA-MUC1-IL2)

Companies:	Novartis Transgene
Announcement date:	Mar 10 2010
Amendment date:	Apr 29 2014
Deal value, US$m:	974.0 : sum of option and milestone payments

Details

Announcement date:	Mar 10 2010
Amendment date:	Apr 29 2014
Industry sectors:	Bigpharma Biotech Pharmaceutical
Therapy areas:	Oncology Oncology » Lung cancer
Technology types:	Biological compounds Vaccines
Deal components:	Co-promotion Collaborative R&D Licensing Option
Stages of development:	Phase III
Geographic focus:	Worldwide Asia » China Europe » France

Financials

Deal value, US$m:	974.0 : sum of option and milestone payments
Upfront, US$m:	10.0 : non-refundable option fee n/d : non-refundable licence issuance fee upon option
Milestones, US$m:	964.0 : successful development, regulatory and commercial milestones in various indications
Royalty rates, %:	n/d : royalties on global sales
Funding, US$m:	n/d : Transgene will fund and retain control over clinical development of TG4010

Termsheet

29 April 2014

Transgene announced that Novartis has informed the Company that it will not exercise its option for the global development and commercialization rights to TG4010 MUC1 targeted cancer immunotherapy.

Transgene retains all rights to the program.

Plans for the Phase 3 part of the TIME trial in MUC1+ patients with Stage IV non-small cell lung cancer (NSCLC) are well advanced.

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10 March 2014

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 entry1.

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.

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

Press Release

29 April 2014

TRANSGENE (ENX:TNG) Drops As Novartis AG (NVS) Decides To Pass On Bypass Drug; Stock Down -17.98% At Market Close (April 29, 2014)

Transgene Announces Option for TG4010 Not Exercised

STRASBOURG, France--(BUSINESS WIRE)--Regulatory News: Transgene SA (Paris:TNG) (NYSE-Euronext: TNG) today announced that Novartis has informed the Company that it will not exercise its option for the global development and commercialization rights to TG4010 MUC1 targeted cancer immunotherapy. As a result, Transgene retains all rights to the program.

"We regret that Novartis has chosen not to use its exclusivity period to opt-in and become our global partner for TG4010," said Philippe Archinard, Chairman and Chief Executive Officer of Transgene. He added: "We are committed to start a Phase 3 trial in advanced lung cancer as rapidly as possible as the data obtained with this cancer immunotherapy are compelling, and we are well financed to move our plans forward. In parallel, we will now be actively looking for a partner to co-develop and commercialize TG4010. A variety of global players active in the field of cancer immunotherapy have already expressed interest in the program."

Plans for the Phase 3 part of the TIME trial in MUC1+ patients with Stage IV non-small cell lung cancer (NSCLC) are well advanced, and Transgene is working to move into Phase 3 in the second half of this year, contingent on discussions with regulatory authorities.

The data from the Phase 2b part of the TIME trial continue to mature; Transgene expects detailed results to be presented at a major medical meeting later this year.

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10 March 2014

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 entry1. 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.

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.

Filing Data

Not available.

Contract

Not available.