Press release issued by Oncology Venture Sweden AB
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Press release

Oncology Venture enters development deal with Cadila Pharmaceuticals on LiPlaCis® and its Drug Response Predictor

Hoersholm, Denmark, September 20th, 2016 – Oncology Venture Sweden AB (OV:ST) and Cadila Pharmaceuticals Ltd., Ahmedabad, State of Gujarat, India today announce the entering of a co-development agreement to develop the anticancer product LiPlaCis® in combination with its Drug Response Predictor – DRP™. The aim is to evaluate the LiPlaCis efficacy in several different indications and perform a randomized phase 3 trial as corner stone and part of the data package study for marketing approval by the FDA, EMA, CDSCO (Central Drugs Standard Control Organization of India). The mutual goal is to sell or out license the product in combination with its Companion Diagnostic (DRP) when the clinical benefit has been documented. Cadila will perform four (4) phase 2 and one pivotal, randomized phase 3 trial over a period of three years. Initiation of individual studies will be announced separately. Cadila will invest in kind in research and drug development activities in 310 cancer patients and DRP screening of more than 1400 patients. In the consortium of owners now including Cadila Pharmaceuticals, LiPlasome, MPI and Oncology Venture - Oncology Venture owns 29% of the total value of the LiPlaCis project after Phase 3. Cadila has commercialization rights in India, Russia, Africa and South East Asia (ASEAN countries only). Oncology Venture has the commercialization rights in America, Europe and China and RoW. Oncology Venture is responsible for the manufacturing and will provide the product. Estimated costs for product in 2017-2018 is 0,6 MUSD. Cadila will in collaboration with an expert team in Oncology Venture set up a laboratory for the tissue handling in India. The DRP analysis will be paid by Cadila and Oncology Venture will provide the DRP evaluations. When developed, the parties may choose to market themselves in their own territories or out-license or sell to a third party. The potential of LiPlaCis sales in the two major indications alone in breast cancer in USA and EU is in excess of 700 MUSD annually and if successful LiPlaCis would compete in a market which currently has a value in excess of 5 billion USD in lung cancer in Europe and USA.
Around 310 cancer patients will according to the deal partake in clinical trials at a FDA and EMA quality level.
The agreement is entered between Cadila Pharmaceuticals Ltd. and Oncology Venture ApS which is 100% owned by Oncology Venture Sweden AB. Cadila Pharmaceuticals Ltd. is one of the largest privately held pharmaceutical companies in India.

"Cadila is one of the largest privately held pharma companies in India. The transformational partnership with Cadila places Oncology Venture in another league. Together with Cadila we aim to take LiPlaCis® and its Drug Response Predictor – DRP - through a strong and focused development program with the goal of receiving marketing approval. We will together with Cadila who invests heavily as an 'in kind' investment test LiPlaCis® in four promising indications: breast, head & neck, skin and esophageal cancer which gives the drug a really good chance to benefit patients who are likely to respond," ***says Peter Buhl Jensen, M.D., CEO of Oncology Venture.*** *"In this partnership OV has the opportunity to build a much larger value instead of selling it outright. Cisplatin is one of the most used drugs in cancer treatment and the potential sales with the improved LiPlaCis formulation is huge,"* ***Buhl Jensen further comments****.*

On this occasion, Dr. Rajiv Modi, Chairman and Managing Director, Cadila Pharmaceuticals Ltd., said, *"Cadila Pharmaceuticals believes in providing world-class healthcare products to improve quality of life of patients. This agreement with Oncology Venture is an affirmation of our commitment to develop novel treatment for those diseases in the realm of unmet medical needs. Cancer affects millions of people around the globe. We look forward to developing the product to benefit millions of patients who are affected by the deadly disease."*

The Partnership deal

The deal with Cadila Pharmaceuticals will finance and perform studies in a total of 310 cancer patients with highest likelihood of sensitivity to LiPlaCis. The deal covers the following:

1. Screening by the use of the LiPlaCis-DRP™ of 1 250 metastatic breast cancer patients to identify 250 patients with high likelihood to respond to LiPlaCis treatment and perform a randomized phase 3 trial in these 250 patients comparing standard therapy with LiPlaCis.
2. Through Cadilas strong network and Cadilas CRO run four (4) clinical Phase 2 trials in 20 patients (out of 100 screened) with Head & Neck cancer, 20 prostate cancer patients (out of 100 screened), and 10 skin cancer patients and 10 esophagus cancer patients – the two latter indications are in a high frequency sensitive to cisplatin – of which LiPlaCis® is an improved formulation – why the patients will not be screened.

Cadila has commercialization rights in India, Russia, Africa and South East Asia (ASEAN countries only), Oncology Venture has the commercialization rights to America, Europe and China and RoW. Oncology Venture will be responsible for the manufacturing and pay for manufacturing of the product. Estimated costs for product in 2017-2018 is 0,6 MUSD. In the consortium of owners now including Cadila Pharmaceuticals, LiPlasome, MPI and Oncology Venture - Oncology Venture owns 29% of the total value of the LiPlaCis project after Phase 3. When developed parties may choose to market themselves in their own territories or out license or sell to a third party.

About the LiPlaCis license from LiPlasome Pharma and the DRP license from MPI

Oncology Venture has in-licensed LiPlaCis® from LiPlasome Pharma and the LiPlaCis DRP™ from MPI and has now entered a development partnership with Cadila Pharma. The financial impact is as follows:

In the consortium of owners now including Cadila Pharmaceuticals, LiPlasome, MPI and Oncology Venture - Oncology Venture owns 29% of the total value of the LiPlaCis project after Phase 3.

OV pays for the manufacturing of the product. Oncology Venture did not pay any upfront payment to LiPlasome but pays 2x9 MUSD in sales milestones to LiPlasome once LiPlaCis is commercialized either via a partner or sold on the market. (please see latest company prospectus).

Cost of clinical trials in oncology all phases per patient 59.500 USD (PhRMA 2013).

http://www.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-sponsored-clinical-trials-impact-on-state-economies.pdf

About Cadila Pharmaceuticals (www.cadilapharma.com)

Cadila Pharmaceuticals is one of the largest privately held pharmaceuticals companies in India, headquartered at Ahmedabad, Gujarat, India. Established in 1951, the company develops and manufactures pharmaceutical products and sells and distributes these in all major markets across the globe. It is an integrated healthcare solutions provider with a comprehensive therapeutic basket including oncology, pulmonology, neurology and cardiovascular.
Cadila Pharmaceuticals is a research and innovation driven company and has collaborations with premier academic and research-based organisations across the world.
Cadila Pharmaceuticals was the first Indian company to get IND approval by USFDA for clinical trials to be conducted in India. Subsequently, the company has filed 5 INDs with the USFDA.

About LiPlaCis

Cisplatin is one of the most widely used drugs in the treatment of cancer due to its documented efficacy in a number of tumour types. Cisplatin is used in the treatment of large indications as lung cancer Europe+US ≈ 673,000 new cases annually), head and neck cancer (500,000 cases annually worldwide) bladder cancer (EU+US ≈ 170,000 annually) and ovarian cancer

(EU+US ≈ 71,000 annually). The lipid formulation from LiPlasome is the answer to a well-established need for improving cisplatin therapy and improving the formulation of the drug, so that a more selective up-take of cisplatin administered takes place at the tumour sites. LiPlasome Pharma ApS has identified and incorporated a mechanism into their liposomes - called LiPlasomes - designed to trigger the release of an encapsulated drug specifically in the tumour tissue. An enzyme especially present on tumors called secretory phospholipase A2 (sPLA2), is utilised to break down the LiPlaCis once it has accumulated in the cancer tissue. The lipid composition of the LiPlasomes is tailored to be specifically sensitive to degradation by the sPLA2 enzyme and thereby for release of the encapsulated drug. The technology behind LiPlaCis® was originally developed by scientists from Danish Technical University -DTU.

More about LiPlaCis™ and the clinical testing

The Phase 1 study to evaluate the safety and tolerability of LiPlaCis in patients with advanced tumours is running at a two University Hospitals in Copenhagen and has included 21 patients and is now in its extension phase where patients with metastatic breast cancer screened for sensitivity to LiPlaCis by the DRP are included. LiPlaCis has demonstrated promising signs of good activity in a small number of patients in the ongoing study. LiPlaCis™ is administered intravenously in 3 weeks cycles on day 1 and day 8. Upon the investigator's judgement the patient may continue treatment for more than 3 cycles when benefiting from the study drug.

About the Drug Response Predictor - DRP™ screening tool

Oncology Venture uses the MPI multi gene DRP™ to select those patients that by the gene signature in their cancer is found to have a high likelihood of response to the drug. The goal is to develop the drug for the right patients and by screening patients before treatment the response rate can be significantly increased.
This DRP™ method builds on the comparison of sensitive vs. resistant human cancer cell lines including genomic information from cell lines combined with clinical tumor biology and clinical correlates in a systems biology network. The DRP™ is based on messenger RNA from the patients biopsies.
The DRP™ platform i.e. the DRP™ and the PRP™ tools can be used in all cancer types, and is patented for more than 60 anti-cancer drugs in the US. The PRP™ is used by MPI for Personalized Medicine. The DRP™ is used in Oncology Venture for drug development.

About LiPlaCis sales potential in breast cancer and lung cancer

Provided that LiPlaCis has activity in the same diseases as cisplatin the below serves as examples of two major indications where conventional cisplatin is frequently used. LiPlaCis sales potential in breast cancer in USA and EU is more than 700 MUSD annually (please see below). For comparison eribulin sales for late stage breast cancer was 390 MUSD in 2013.
http://www.eisai.com/pdf/eannual/epdf2014an.pdf

Breast Cancer (BC) in the USA

http://www.breastcancer.org/symptoms/understand_bc/statistics

- 246.600 new cases expected in 2016
- 40.450 deaths
- 2.8 million with a history of BC

The 40.450 women who died of BC would be candidates to better treatment. If ½ of these are amenable for treatment and 20% would receive LiPlaCis there would be. 4045 women treated – 6 months average treatment of 10.000 USD per month = 242 MUSD.

Breast Cancer in Europe

http://eu-cancer.iarc.fr/eucan/CancerOne.aspx?Cancer=46&Gender=2
Europe 2012: 458.337 new cases and 131.258 deaths.
EU

- 358.967 new cases
- 90.665 deaths
- 9067 women treated – 6 months average treatment 10.000 USD per months = 544 MUSD

http://www.wcrf.org/int/cancer-facts-figures/data-specific-cancers/breast-cancer-statistics

Globally 1.7 million new cases annually.

LiPlaCis in lung cancer

Lung cancer USA

http://www.cancer.net/cancer-types/lung-cancer-non-small-cell/statistics

- 224.390 new cases in 2016
- 158.080 deaths

Cisplatin is the most important agent in this disease. If LiPlaCis is preferred and given by DRP in

- 20% of cases
- 44.880 patients treated 4 months average 10.000 USD per month = 1.795 billion USD

Lung cancer Europe

http://www.lungcancereurope.eu/wp-content/uploads/2015/11/LuCE-EU-Policy-Position-Paper-2015-IMPAGINATO.pdf

449.000 new cases in 2015.

89.800 patients treated 4 months average 10.000 USD per month = 3.59 billion USD

AND: * Head and Neck * Esophagus * Ovarian * Bladder are all potential indications for LiPlaCis.

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About Oncology Venture Sweden AB

Oncology Venture Sweden AB is engaged in the research and development of anti-cancer drugs via its wholly owned Danish subsidiary Oncology Venture ApS. Oncology Venture has a license to use Drug Response Prediction – DRP™ – in order to significantly increase the probability of success in clinical trials. DRP™ has proven its ability to provide a statistically significant prediction of clinical outcomes from drug treatment in cancer patients in 29 of the 37 clinical studies that were examined. The Company uses a model that alters the odds in comparison with traditional pharmaceutical development. Instead of treating all patients with a particular type of cancer, patients' tumors genes are screened first and only those who are most likely to respond to the treatment will be treated. Via a more well-defined patient group, the risk and costs are reduced while the development process becomes more efficient.

The current product portfolio: LiPlaCis for Breast Cancer, Irofulven developed from a fungus for prostate cancer and APO010 – an immuno-oncology product for Multiple Myeloma.