Press release issued by Oncology Venture Sweden AB
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Press release

Status and Up-date on Oncology Venture & SPV pipelines

Hoersholm, Denmark January 31st 2017 – Oncology Venture Sweden AB (OV:ST) announces an update on its pipeline of anticancer drugs: with 3 products in OV, 2 signed term sheets and one in negotiation in 2X Oncology Inc. (2XO) and an agreed term sheet in OV-SPV2.
Specifically: *LiPlaCis®* is in Phase 2 – and ongoing as planned, *APO010* is in early clinical Phase 1/2 development– Clinical Trial Application has been submitted to the Danish authorities. Start of study is expected in Q1 2017 if existing product is approved as planned. *Irofulven* is in Phase 2. It was previously announced that treatment of first patient was expected in January 2017 now Clinical Trial Application is expected filed in Q2 2017. The postponement secures robust product manufacturing including optimization of production yield –sufficient Irofulven product will be manufactured for three phase 2 clinical trials instead of just one clinical trial. In Liver cancer, long lasting complete responders have been observed. Oncology Venture is in negotiation with potential collaborating partners in China to develop Irofulven for Liver Cancer.
Three public grants for Irofulven, APO010 and LiPlaCis now sum up to more than 38 mSEK.
The 2XO pipeline of phase 2 products has a *TOP2-inhibitor liposomal-GSH* for metastatic breast cancer patients and glioblastoma (brain cancer), a big pharma *PARP-inhibitor* for the development in metastatic breast cancer and a *TOP1-inhibitor* for development in patients with ovarian cancer.
OV-SPV2 is established to test the DRP™ in a Big Pharma *Tyrosine Kinase inhibitor* (TKI). Final deal terms are currently being negotiated. For financial information about the SPVs please refer to the Press release of 30 December 2016.

"Oncology Venture is now approaching ownership and control over 5-6 anticancer agents that all have demonstrated excellent effect in clinical trials and in all cases living up to OVs quality requirements with an exclusive Drug Response Prediction opportunity for each drug. With this OV will control a pipeline of phase 2 clinical products which is amongst the largest phase 2 oncology pipelines in Europe," **Said Peter Buhl Jensen, Adjunct professor, MD, PhD and CEO of Oncology Venture**. *"Initial financing for 2X Oncology Inc. and OV - SPV2 has been secured without OV cash and OV has secured a strong continued Medical Prognosis Institute (MPI) collaboration by a global exclusivity from MPI to OV allowing continued pipeline growth without fearing sudden product DRP™ competition for 3 years,"* **Peter Buhl Jensen further commented.**

LiPlaCis® Phase 2 for metastatic Breast Cancer (mBC)

LiPlaCis is an intelligent targeted liposomal formulation of cisplatin. LiPlaCis has finalized the dose escalation part of the trial in November 2016 and has demonstrated promising activity in patients already in the dose escalation part. LiPlaCis™ is administered intravenously in 3 week cycles on day 1 and day 8. Upon the investigator's judgement, the patient may continue treatment for more than 3 cycles when benefitting from the study. Response (confirmed PR = Partial Response) has been published for the first DRP-screened patient with a hard to treat metastatic Breast Cancer.
LiPlaCis has received status as a phase 2 study by the Danish authorities and 2 more (i.e. 3 out of 4 in total) Danish centers are now active in recruiting 12-15 metastatic Breast Cancer patients screened and expected to be highly likely responders to LiPlaCis. We expect to finalize the study in Q3 2017. The first regulatory approach has been to register LiPlaCis® together with its DRP™ companion diagnostic for an EU-marking. Next step in the regulatory strategy is building a data package for a 'Pre-Submission meeting' with the FDA. This is done in collaboration with US-experts.
Oncology Venture entered a collaboration agreement with Cadila Pharmaceuticals LTD in September 2016. Cadila invest in kind in research and development activities of 310 cancer patients and DRP screening of more than 1400 patients. Cadila will perform four (4) Phase 2 trials in Prostate, Head & Neck, Skin and Esophageal

cancers and a pivotal randomized clinical Phase 3 trial in metastatic breast cancer. 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. Further information about the development with Cadila is presented in a separate press release from 20 September 2016.
The phase 2 part of the OV trial will take approximately 12 months which is Q3 2017, with interim data expected during the period. Together with our CRO Smerud LiPlaCis obtained a EUROSTARS grant (EU grant) in December 2016 supporting the development of LiPlaCis with a total value of 18 mSEK.

APO010 in Phase 1/2 for Multiple Myeloma (MM)

APO010 is a Fas receptor immuno Oncology product. Kills cancer cells via the same mechanism as our T-cells. Four i.e. all planned Danish hematology sites are open and recruiting patients to the screening part of the APO010 project for Multiple Myeloma. So far, >35 patients have consented to have their tumors DRP screened for sensitivity to APO010.
APO010 drug is on stock from the previous drug owner and a Clinical Trial Application including an updated Investigational Medicinal Product Dossier (IMPD) has now been sent to the Danish authorities - DKMA - with new stability data for approval in order for OV to use the drug at hand for the planed Phase 1/2. Start of study is expected in Q1 2017 if existing product is approved as planned. In June 2016 OV announced a total value of a EUROSTARS grant and SMERUDS investment in the development of APO010 sums up to a total value of approximately 13.5 MSEK.

Irofulven for Prostate, Ovarian and potentially Liver Cancers

Irofulven is an alkylating agent derived from the lantern fungus. Irofulven has been in Phase 2 and Phase 3 studies and has shown a 10% response rate in patients with prostate cancer previously treated with docetaxel and 13% in ovarian cancer patients relapsing between 6 and 12 months after standard treatment with carboplatin and paclitaxel. This is not sufficient to obtain marketing approval why a method - i.e. the Drug Response Predictor DRP - to enrich the patient population is needed. Screening for Irofulven DRP™-positive prostate cancer patients has been initiated at two Danish sites and one Swedish.
In Liver cancer, long lasting complete responders have been observed. Oncology Venture is in negotiation with potential collaborating partners in China to develop Irofulven for Liver Cancer.
As previously announced – first patient was initially expected in January 2017 now Clinical Trial Application is expected filed in Q2 2017. The postponement secures robust product manufacturing including optimization of production yield –sufficient Irofulven product will be manufactured for three phase 2 clinical trials instead of just one clinical trial including a potential proof of concept trial in China instead of just one clinical trial. Irofulven has received a grant of 800,000 USD from Massachusetts Life Science Center and Medicon Valley for the development of the product in prostate cancer.

The 2X Oncology Inc. pipeline of three promising, novel Phase 2 products

2X Oncology Inc. (2XO) is a US spinout of Oncology Venture. The spinout will work in close collaboration with Oncology Venture, utilizing OV's Nordic network for clinical trial testing.
The 2XO pipeline of products has 2 signed term sheets and one in negotiation: a TOP2-inhibitor liposomal-GSH for metastatic breast cancer patients and glioma (brain cancer), a big pharma PARP-inhibitor for the development of metastatic breast cancer and a TOP1-inhibitor for development in patients with ovarian cancer.

OV-SPV2 – project Tyrosine Kinase inhibitor (TKI), Phase 3

OV has incorporated a Danish spin-out for development of a specific TKI drug for the treatment of cancers using DRP™. OV-SPV2 will run a quick test of the usability of the DRP and potentially develop an oral Tyrosine Kinase inhibitor from a Big Pharma. Final deal terms are currently being negotiated.
The drug candidate has been run in Phase 2 and 3 and biopsies as well as results are available from these trials. OV has the unique possibility to run a fast and blinded proof of concept DRP™ test on the available patient biopsies to assess if the DRP™ tool can identify responders from the clinical trials. If positive a risk reduced development program can take place.

About the Drug Response Predictor - DRP™ screening tool

Oncology Venture uses the MPI multi gene DRP™ to select those patients that by the genetic 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 70 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.

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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 in collaboration with Cadila Pharmaceuticals, Irofulven developed from a fungus for prostate cancer and APO010 – an immuno-oncology product for Multiple Myeloma.
Oncology Venture has spun out two companies in Special Purpose Vehicles: 2X Oncology Inc. a US based company focusing on Precision medicine for women's cancers with a pipeline of three promising phase 2 product candidates and Danish OV-SPV 2 will test and potentially develop an oral phase 2 Tyrosine Kinase inhibitor.