Oncology Venture

Hoersholm, Denmark, August 23rd 2017
Press Release

Pipeline update

Hoersholm, Denmark -- August 23rd 2017 – Oncology Venture Sweden AB:s (OV:ST) announces a pipeline update:
At the inception of the Company, we promised five products in three years. In just two years, we now have six products secured – ahead of plan – with a seventh on the horizon. We believe that our strong oncology pipeline positions us as a very strong global player in anti-cancer drug development.
We have global rights to six products and global rights to their corresponding Drug Response Predictors (DRP™) - a cutting-edge advantage for development of precision medicine for cancer patients.

LiPlaCis has shown activity in skin cancer, esophageal cancer, head and neck cancer, and breast cancer. We have shown and published that the LiPlaCis DRP prediction works – we can in fact identify responding patients. We continue to expect data from the Phase 2 part with our -80 degree C product from the ongoing clinical trial to be published in *late Q3 this year*. Following this, we look forward to initiating the international, multicenter, randomized Phase 2 study in Europe; preparations are ongoing. As previously announced, we received non-dilutive Eurostars funding for this randomized Phase 2 study.

Our partner in India, Cadila Pharmaceuticals, has the option per our agreement to obtain 1/3 drug value ownership if Cadila can evaluate LiPlaCis in 320 patients in a clinical trial conduced to FDA/EMA quality standards, and provide the clinical outcomes, within a certain time frame. Cadila will be using refrigerated product and stability studies for this product version has taken some time. Phase 2 trials is expected to start soon in head and neck, prostate, skin, and esophageal cancers. We also look forward to the initiation of a Cadila Phase 3 clinical trial in metastatic breast cancer.

We are in the process of finding commercial partners in the OV territories which include USA, Europe, Japan and China.

At the widely-attended annual meeting of the American Society for Clinical Oncology (ASCO) in Chicago in June, we showed that we could predict response to epirubicin. This directly validates our second liposomal product, 2X-111, which targets tumors and metastases in the brain and is being developed in the pipeline of our US-based spin-off, 2X Oncology.

During summer, we were very pleased to announce deals for two products from two different Big Pharmas– a PARP inhibitor (EISAI) and TKI (Novartis). Both drugs have clearly demonstrated excellent responses in sensitive patients. We have tablets and capsules available for the projects allowing a jump start AND in both cases with biopsies from trials.

For the PARP inhibitor now called 2X-121, we now know that we can identify the responding patients. Professor Knudsen's DRP analysis showed that the DRP, in a 13-patient blinded study, correctly predicted response and overall survival with a p-value of 0.07, meaning that there is only a risk of 7% that the result is random.

"It is of great interest to see the Drug Response Predictor work for 2X-121, and the clear separation between responders and non-responders. This bodes well for the future role of 2X-121 in the treatment of cancer," **stated Dr. Mansoor R. Mirza, chief oncologist, Department of Oncology, Copenhagen University Hospital-Rigshospitalet** and lead investigator Tesaro's PARP inhibitor Niraparib.

The set up for the analysis of data from previous studies of the Phase 3 TKI product is ongoing. We are in the process, together with FDA and EMA regulatory experts, of evaluating the possibility of discussions with the regulatory authorities of data for a potential fast approval. Date from previous trials of the drug was highly interesting in both liver and renal cancer.

For Irofulven, we had to go back to restart manufacture and all methods had to be reinvented or new. Dr. Bruce Pratt, who is responsible for this project, successfully identified vials with fungus for fermenting - the initial steps of irofulven has been more time consuming than originally expected *this put us three months behind schedule*. However, irofulven has now been successfully manufactured and filled into vials for clinical trials. The last quality check (QA) before vials are released is ongoing, and we are finalizing a sufficient number of vials to run our planned trial in metastatic prostate cancer. We expect to *submit to authorities in September* to commence the trial in Denmark and Sweden for which we have screened >70 patients with Prostate cancer.

The APO-010 trial in multiple myeloma *is on time and recruiting patients*. APO010 is a Fas receptor immuno Oncology product which 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, >60 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 been approved by the Danish authorities - DKMA – for use in the Phase 1/2 study which *was initiated in Q1 2017 according to plans*. 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.

TOP1 inhibitor - Term sheet under negotiation.

Oncology Venture has engaged with the professional CRO Smerud Medical Research as a clinical and financial partner to appropriately dimension the clinical development process in multicenter, multinational trials.

We are setting up umbrella trials, *i.e.* screening patients' tumors for possibility to enter into OV and 2X Oncology studies with the drug in our collective pipelines that has the highest likelihood of effect for the individual cancer patient.

In metastatic breast cancer, treatment options are:

- LiPlaCis
- PARP inhibitor (2X-121*)
- Liposomal doxorubicin (2X-111*)

In ovarian cancer, treatment options are:

- Irofulven
- PARP inhibitor (2X-121*)
- Topoisomerase 1 inhibitor (2X-131*).

The focused Phase 2 trials in Ovarian cancer are planned to run in Germany.

**Represents 2X Oncology pipeline product candidates*

During July, we continued to conduct business development activities in the USA for 2X Oncology. Meetings have been nourished by the deal with Eisai for 2X-121 and especially the successful response prediction.

Furthermore, as previously announced we are working with British and Chinese partners for a China strategy for clinical trials in liver cancer as well as product manufacture and licensing.

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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 an exclusive license to use the Drug Response Predictor (DRP™) technology 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 with DRP™ 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 which will test and potentially develop the Novartis small molecule kinase inhibitor. Oncology Venture currently owns 92% of 2X Oncology Inc. and 40% of OV-SPV2 ApS.