
Strong LiPlaCis Treatment Results in DRP-Selected Breast Cancer Patients Collaborative LiPlaCis Regulatory Meeting with DKMA

Oncology Venture Provides Clinical and Business Update

Hoersholm, Denmark, 02 July 2018 – Oncology Venture Sweden AB (SPOTLIGHT: OV.ST) (“OV” or “the Company”) and MPI announce the third interim report from the ongoing LiPlaCis® Phase 2 study in hard-to-treat metastatic breast cancer patients and outcomes of a recent meeting with the Danish Medicines Agency (DKMA).

Regulatory:

In this constructive meeting, the Company discussed the interim Phase 2 LiPlaCis data with the DKMA along with a proposed design of a pivotal (*i.e.* aimed for marketing approval) randomized trial of LiPlaCis for metastatic breast cancer. Importantly, there was a mutual agreement that the product could meet a significant medical need if success rates demonstrated to date in the ongoing Phase 2 trial are confirmed in a pivotal study. For the European market, [it is generally suggested that the primary endpoint of an oncology clinical trial should be patient overall survival, with progression free survival as a parallel endpoint. DKMA suggested that we narrow the LiPlaCis comparator arm to include just three specific comparator products. Furthermore, DKMA indicated that the planned clinical trial will be considered a pivotal Phase 2 study if it is accepted for the [EMA PRIME program](#).

For the ongoing Phase 2 study, the DKMA advised that we increase the patient cohort to strengthen the statistics around the DRP cut-off level. Solid data on the cut-off is of high importance for a subsequent study, since the level evaluated will be included in the final label, assuming approval. Accordingly, OV plans to expand this study to enroll ten additional patients for a total of 30 metastatic breast cancer patients.

With continued strong data from our most advanced clinical program LiPlaCis this together with OV's two recently inlicensed products from big pharma - PARPi from Eisai and dovitinib from Novartis –are our highest prioritized programs.

PARP Inhibitor 2X-121:

PARP inhibitors have revolutionized the treatment of ovarian cancer and have proven highly effective against multiple cancer changes that are common in ovarian cancer. While PARP inhibitors can also effectively fight other cancer types, including breast cancer and prostate cancer, response rates in these diseases is not as high as in ovarian cancer.

The DRP® method is distinguished by its ability to analyze a large amount of complex data to identify the patients who can benefit from the drug. With our gene DRP method, we can look for the same significant cancer changes that enable PARPs to effectively combat ovarian cancer in e.g. breast cancer and treat those patients most likely to benefit. The DRP technology can translate between cancer types, look for similarities in biology, and predict benefit no matter the origin of the tumor.

This biology approach is a new wave of thinking and has led to approval of the first pan-oncologic product by the U.S. FDA: a completely different drug the immunotherapy Keytruda®, which is indicated for treatment of all cancer types that demonstrate a specific biochemistry. Our DRP method is different, but the road is being paved.

We are initially developing 2X-121 for metastatic breast cancer. Data from an earlier clinical trial of this novel tankyrase and PARP inhibitor were selected for an oral presentation at this year's largest cancer conference, ASCO.

Dovitinib:

This very large program includes data from more than 2500 patients. OV has commenced data mining using our DRP technology. Dovitinib has shown identical activity as sorafenib in a randomized phase 3 study in renal cancer and in a randomized phase 2 study in liver cancer. Sorafenib is the gold standard in liver cancer and also approved in renal cancer. Dovitinib has also shown activity in several Phase 2 studies in cancer types including lung, prostate, endometrial and thyroid cancers as well as GIST and acute myelocytic leukemias. Due to its complex mechanism of action, similar to PARP and cisplatin, development of dovitinib will benefit from use of the drug-specific DRP to better identify the patients who will benefit.

LiPlaCis:

Cisplatin is one of the most effective anticancer drugs ever developed. Many new chemotherapy drugs have arrived on the scene over the past few decades, but cisplatin still finds wide use. Even when it is not the sole or primary drug given to the cancer patient, it can be a valuable part of a combination chemotherapy regimen. Look at the regimens given to patients and you will often see cisplatin as one of the drugs. Even with the advent of the so-called targeted therapies in the past ten years, cisplatin use remains strong. Someone actually called cisplatin the penicillin of cancer (<http://www.cisplatin.org/>).

LiPlaCis is a third-generation liposomal formulation of cisplatin enabling direct delivery of this known oncologic agent to cancerous sites. It combines this technology with a proven response predictor to cisplatin. LiPlaCis is initially being developed for metastatic breast cancer. We believe the product could have a place also in early breast cancer treatment as well, since adjuvant therapy still lacks efficacy with many patients dying of breast cancer in spite of early aggressive chemotherapy treatment.

LiPlaCis may also be useful in other cancers such as lung, head and neck, and prostate. We are working with Cadila Pharmaceuticals to expedite clinical trials with studies in India. Because the Indian regulatory authorities do not see a liposomal deep-frozen product as approvable in India, we are exploring alternate solutions such as freeze drying to potentially enable cancer patients in India access to LiPlaCis.

Detailed enrolment status

To date, a total of 21 patients have been included in the Phase 2 part of the study. 19 of these have been followed sufficiently long for evaluation of efficacy.

To be included in the study patients had to be in the best 2/3 group with regard to DRP score whereas the 1/3 of patients with lower DRP scores were not included in the study.

LiPlaCis efficacy given to patients with the highest likelihood of response (the top 1/3 with highest DRP scores) was compared to the patients with intermediate sensitivity (middle 1/3) patients. This demonstrated a clear benefit to the top 1/3 patients. Time to progression was 25 weeks in the top group compared to only 8 weeks in the middle 1/3. The difference was statistically significant and clearly demonstrates how the DRP can transform to clinical benefit.

Data from Top third DRP® level and excluding patients previously treated with platin drugs

- 7 of 7 heavily pretreated patients, with a median of seven previous treatments, had clinical benefit (SD, long term SD or PR)
- Time to progression in the top third (10 patients, 3 not evaluable for response) was in median 25 weeks on LiPlaCis versus 14.5 weeks of their latest prior treatment ("Doctors prior Choice")
- 5 of 7 patients experienced better response or longer effect duration (3 with PR and 1 SD+ 24 weeks and 1 SD 21 weeks) than all prior medical treatments against their advanced disease including combination- and hormone therapies.

All in all, 19 have finished treatment or are still on treatment but evaluable for response, whereof three had a Partial Remission (PR), three had long-term stable disease (>24 weeks) and four had Stable Disease (SD). Five had Progressive Disease (PD) and four patients are not evaluable for response, one for early renal toxicity and three due to early death – two deaths deemed unrelated to study drug by the Data Committee - One death was deemed possibly related to toxicity of LiPlaCis. This was a small patient and a safety change in the administration of LiPlaCis has been agreed with the authorities so that patients are now treated according to their size. The toxicity is a known rare side effect of cisplatin and other chemotherapies and is expected to be prevented by the individually adapted dosing.

We continue to screen and enroll patients in this clinical trial and based on input from the DKMA we will expand the target cohort to approximately 30 patients.

2X-111:

2X-111 is a liposomal formulation technology that provides an excellent doxorubicin delivery method and in addition provides enhanced delivery of doxorubicin to the brain aimed for better treatment of metastatic cancer like breast cancer and primary brain tumors.

Based on the prospective validation of a consecutive cohort of breast cancer patients, the DRP is clearly able to identify patients benefitting from treatment with the product.

2X-111 is not only an anthracycline but also passes the blood brain barrier and has the potential to treat cancers in the brain. This is a very unusual opportunity. There is a robust manufacturing procedure in place, and we look forward to developing this product once contract negotiations on product manufacturing are in place.

Irofulven:

Irofulven is a synthetically-improved natural product that exploits cancer cells' deficiency in DNA repair mechanisms, similar to PARPi products.

With this unique target we have very limited competition. We were allowed to include patients in a phase 2 study in DRP selected prostate cancer patients in December. There have been many competing studies in the prostate cancer field. In the mean time we have screened more than 70 patients and we are now first in line to initiate our study protocol and to dose the first patient after the end of summer holidays. In previous studies, irofulven has demonstrated efficacy in ovarian, prostate and liver cancers conducted without the DRP. We look forward results of this first DRP-guided trial of the drug.

APO-010:

Our immuno-oncology (IO) product APO-010 is in the Phase 1 part of a Phase 1/2 study in multiple myeloma (MM) patients. In MM, the tumor cells are only available by laboratory separation from other bone marrow cells. The APO-010 DRP result is influenced by the tumor cell collection procedure, which varies across hospitals. We are currently comparing these collection methods to get the right calibration. In the meantime, during the dose escalation Phase 1 part of the study, patients are enrolled and treated without a known DRP score.

The IO opportunity differs considerably from using APO-010 as a direct anticancer agent. The product may prove to be an interesting companion product with PD-1 products like Keytruda. Developed as an IO product, the DRP may not be necessary.

Business:

Oncology Venture and Medical Prognosis Institute [have now merged into one company](#). This union forms a cutting-edge cross-over company bridging pharma and genomic profiling to see through a large complexity of cancer and find the patients who most likely will benefit from our drugs.

We see the same business strategy behind Roche's acquisition of worldwide rights to Foundation Medicine last month – they write: "Roche and Foundation Medicine... to accelerate broad availability of comprehensive genomic profiling in oncology. Together, the companies will leverage expertise in genomics and molecular information to enhance the development of personalized medicines and care for patients with cancer."

Similarly, with OV's gene DRP method we can look for the significant cancer changes that enable drugs to effectively treat those patients most likely to benefit regardless of cancer type. The DRP technology can translate between cancer types and look for similarities in biology and predict benefit no matter the tumor origin. This biologic method is a new wave of thinking. OV's method is different - the road is being paved.

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About Oncology Venture 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® –to significantly increase the probability of success in clinical trials. DRP® has proven its ability to provide a statistically significant prediction of the clinical outcome from drug treatment in cancer patients in 29 out of 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 first screened, and only the patients most likely to respond to the treatment will be treated. Via a more well-defined patient group, risks and costs are reduced while the development process becomes more efficient.

The current product portfolio includes: LiPlaCis® for breast cancer in collaboration with Cadila Pharmaceuticals; irofulven for prostate cancer; and APO010, an immuno-oncology product for multiple myeloma.

Oncology Venture has spun out two companies as Special Purpose Vehicles: Oncology Venture U.S. Inc. (previously 2X Oncology Inc.), a US-based precision medicine company focusing developing two promising phase 2 product candidates, and OV-SPV 2, a Danish company that will test and potentially develop a Phase 2 oral Tyrosine Kinase inhibitor.

Forward-looking statements

This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of OV's control and which could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning OV's plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. OV undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

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