Press release issued by Oncology Venture AB
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Press release

Successful DRP™ prediction of patients treated with 2X-121, the PARP inhibitor recently licensed from Eisai

Hoersholm, Denmark, August 1st, 2017 – Oncology Venture AB (OV:ST) announces that work on validating the Drug Response Predictor (DRP) for pipeline asset 2X-121 has been completed and that the developed DRP™ has been able to successfully identify responders and non-responders to treatment in 13 patients.

"Having worked with a number of the leading PARP inhibitors where clinical benefit is seen in all patients with high-grade serous ovarian cancer though highest benefit is seen in BRCA mutated population. The clinical benefit of available HRD tests is questionable as these tests are unable to separate responders from non-responders. It is of great interest to see the Drug Response Predictor work for 2X-121 and providing a 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 Mirza chief oncologist, Department of Oncology, Copenhagen University Hospital-Rigshospitalet, and lead investigator Tesaro's PARP inhibitor Niraparib

*HRD: Homolog Recombinant Deficiency is another biomarker commonly used

"This result from the 13 patient's biopsies are as good as we could hope for. The PARP race is on and we have a jumpstart with our DRP biomarker" said Peter Buhl Jensen, M.D., CEO of Oncology Venture

The market for Ovarian cancer drugs is according to Global Data expected to be worth $2.5bn in 2020 growing with an annual compound rate (CAGR) of 15.5% to $5.2bn in 2025. The majority of this growth will be attributed to the launch of anticipated pipeline agents, mainly the PARP inhibitor Zejula and the immune checkpoint modulators Bavencio and Tecentriq.

Zejula from Tesaro (TSRO – Market Cap $6.9bn) is expected to contribute the most to sales across the Ovarian Cancer market, reaching sales of $718.7M in 2025. Zejula's robust sales growth is expected to be due to its strong uptake as a first- and second-line therapy option for all patients regardless of their BRCA mutation status.

Rubraca from Clovis (CLVS – Market Cap $4.1bn) and Lynparza from Astra Zeneca are the other two PARP inhibitors currently on the market.

With the new precise DRP for 2X-121 it is expected, once the product reaches the market, that there will be significant market potential in patients irrespective of BRCA mutation status and in patients that develop resistance to other PARP inhibitors. In addition, 2X-121 is being developed to also treat breast cancer, more specifically breast cancer with metastasis, including metastasis in the brain where little or no treatment is available today.

The results

The DRP value show a significant separation between the patients who responded to treatment and those who did not respond to treatment. In the DRP predicted responder group 5 out of 7 patients survived (Overall Survival-OS) at 400 days from commencement of treatment, compared with only 1 out of 6 patients surviving at 400 days for those predicted by the DRP score to be non-responders. In other words, there is a four-fold difference in overall survival between the patients predicted to respond and those not predicted to respond to treatment.

The statistical findings are that the DRP in a blinded study correctly predicted response and overall survival with a p value of 0.07 and a hazard ratio on overall survival of 0.26.

2X-121 is being developed by Oncology Venture's 92% owned subsidiary in Boston, MA. 2X Oncology Inc.

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About the Drug Response Predictor (DRP™) Companion Diagnostic

Developed by and in-licensed from Medical Prognosis Institute A/S (MPI.ST), the DRP™ screening platform utilizes messenger RNA (mRNA) gene expression signatures from patient biopsies to identify patients with a high likelihood of responding to specific cancer-fighting therapies. 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. Specific DRP™s are developed for each pipeline product, which will enable Oncology Venture and its spin-out 2X Oncology to identify and predict which patients are most likely to respond and thereby benefit from a given pipeline product. This would enable likely responders to receive appropriate treatment while expediting the decision path for predicted non-responders, saving them critical time and money in their cancer fight.

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 will test and potentially develop the Novartis small molecule kinase inhibitor.

About 2X Oncology Inc.

The name 2X relates to the female XX-chromosomes and identifies 2X Oncology as a women's cancer company.
2X Oncology completed a series Seed investment round of $3.5M in Q1 2017 and is currently fundraising for a series A round of approximately $25M. 2X Oncology is, before a coming series A financing round a 92% owned subsidiary of Oncology Venture.
2X Oncology is utilizing the proprietary Drug Response Predictor (DRP™) biomarker technology to develop targeted therapeutics to address significant unmet needs in women's cancer. The DRP™ generates a precision mRNA-based companion diagnostic for each compound, enabling the identification of patients that are most likely to respond and benefit from treatment.
The 2X pipeline of 3 phase 2 compounds includes product candidates focused on breast and ovarian cancers and primary and secondary brain tumors. Our product candidates have been selectively in-licensed using strict criteria, including established clinical efficacy and safety and a known mechanism of action. It is expected that these programs be advanced through focused Phase 2 studies using a targeted DRP™ CDx with key data available in 2018. Learn more at 2xoncology.com.

This information is that Oncology Venture Sweden AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, on August 1st 2017.