



Press release

Oncology Venture obtains option to in-license the European rights to the FDA approved ixabepilone

Hørsholm, Denmark and Cambridge, MA, US, April 4, 2019 – Oncology Venture A/S (“OV” or the Company) today announced that the company has obtained an exclusive option to in-license the European rights to IXEMPRA® (ixabepilone) from the pharmaceutical company R-Pharm U.S., LLC. In July 2015 R-PHARM U.S., LLC acquired global rights to IXEMPRA® from Bristol-Myers Squibb (BMS). The drug is approved in the USA for the treatment of breast cancer. Oncology Venture will evaluate ixabepilone together with its drug-specific DRP® companion diagnostic in order to accomplish a market approval in Europe.

Oncology Venture has, based on prior treatment results and tumor gene data published by BMS in scientific literature, evaluated the ability of its DRP® companion diagnostic to identify which patients will most likely benefit from ixabepilone. The analysis indicates that patients benefitting from Ixabepilone can be identified by using our ixabepilone-specific DRP® companion diagnostic. Oncology Venture is confident that it can succeed in gaining EMA approval to market ixabepilone in Europe for the treatment of metastatic breast cancer.

According to the agreement, Oncology Venture will evaluate IXEMPRA® (ixabepilone), together with its DRP® companion diagnostic, in European clinical trials in patients with metastatic breast cancer. If the results are convincing Oncology Venture has the option to exclusively in-license the commercial rights for the European Union (EU) market. The broadened pipeline is not expected to increase Oncology Venture’s cost base since the clinical development of ixabepilone will be financed through a special purpose vehicle/joint venture to be offered to interested investors while Oncology Venture will continue to control the program.

Oncology Venture’s strategy is to make use of its proprietary Drug Response Prediction (DRP®) biomarker platform to progress its broad pipeline of late-stage oncology drug candidates. The company in-licenses drug candidates that have previously shown good clinical efficacy and where the DRP® technology is expected to add value for cancer patients as a companion diagnostic to the drug. The DRP® companion diagnostic enables identification of the patient population most likely to benefit from the drug and then only treating those patients. After conducting clinical studies that prove a better efficacy of its drug candidates, Oncology Venture can apply for market approval or out-license the drug candidate at a higher value inflection point.

The cancer drug ixabepilone was originally developed by the pharmaceutical company Bristol-Myers Squibb (BMS) and was approved for treating metastatic breast cancer by the FDA in the US in 2007 but was not approved by The European Medicines Agency’s (EMA) for use in Europe. R-Pharm U.S. acquired ixabepilone from BMS in July 2015 and the product is today marketed by R-Pharm in the USA, as well as certain countries in South America, Switzerland, and Lichtenstein.

“This is a great opportunity to apply our value increasing process. Ixabepilone is a top-quality FDA approved product and we believe that our DRP technology can bring the product to an European approval. Ixabepilone has all the features that we seek for and we are looking forward to pinpoint the patients that truly benefit from ixabepilone, with the ultimate goal to bring a new efficacious drug to the European/EU cancer patients,” **comments Peter Buhl Jensen, M.D., CEO of Oncology Venture.**

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About the Drug Response Predictor – DRP® Companion Diagnostic

Oncology Venture uses its multi gene DRP® to select those patients who by the genetic signature of their cancer are found to have a high likelihood of responding to the drug. The goal is developing the drug for the right patients, and by screening patients before treatment the response rate can be significantly increased. The 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. DRP® is based on messenger RNA from the patient's biopsies.

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 and is currently demonstrating promising results in an ongoing phase 2 study prospectively using LiPlaCis and its DRP® to track, match and treat patients with metastatic breast cancer.

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 Oncology Venture for Personalized Medicine. The DRP® is used by Oncology Venture for drug development.

About Oncology Venture A/S

Oncology Venture A/S is engaged in the research and development of anti-cancer drugs via its wholly-owned subsidiary, Oncology Venture Product Development ApS. Oncology Venture uses 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 and is currently demonstrating promising results in an ongoing phase 2 study prospectively using LiPlaCis and its DRP® to track, match and treat patients with metastatic breast cancer. The DRP® 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 OV product portfolio includes: LiPlaCis®, a liposomal formulation of cisplatin in an ongoing Phase 2 trial for breast and prostate cancer; 2X-121 a PARP inhibitor in an ongoing Phase 2 for breast cancer; dovitinib, which will enter Phase 2 trials for indications dependent on further Dovitinib-DRP retrospective/prospective analysis of studies completed by Novartis. 2X-111, a liposomal formulation of doxorubicin under manufacturing for Phase 2 in breast cancer; irifolven, a Phase 2 is ongoing for prostate cancer; and APO010, an immuno-oncology product in Phase 1/2 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 on developing 2X-121 and 2X-111, and OV-SPV 2, a Danish company that will test and develop dovitinib. Oncology Venture A/S has an ownership of 92% in Oncology Venture US and 55% of dovitinib with an opportunity to acquire further 30%.

Learn more at oncologyventure.com

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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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This information is information that Oncology Venture A/S is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication on April 4, 2019.