



## Company Announcement

# Oncology Venture publishes Interim Report for the period January – June 2019

Hoersholm, Denmark – August 30, 2019 – Oncology Venture A/S (OV:ST) (“Oncology Venture”) today announces the Interim Report for the period January – June 2019. The report is available as an attached document and on the company’s website ([www.oncologyventure.com](http://www.oncologyventure.com)).

### Comment from CEO Peter Buhl Jensen

*“We have a rich pipeline of seven mature drug candidates, and data that show us which projects are closest to the next value inflection points. Our priorities now are to continue planning the pivotal study of LiPlaCis to compile the marketing application for dovitinib and its DRP® and to prepare a pivotal study that can be the base for marketing authorization of ixabepilone”.*

### Summary of the Half Year Report

- Consolidated group revenue amounted to 0.5 MDKK (1.6 MDKK).
- Consolidated group loss before depreciation amounted to -28.1 MDKK (-6.4 MDKK).
- Consolidated group loss before net financials amounted to -28.6 MDKK (-6.4 MDKK).
- Consolidated net result amounted to -36.9 MDKK (3.6 MDKK).
- Consolidated earnings per share (EPS) amounted to -0.65 DKK (0.15 DKK).

2019 numbers reflect the merged entity and 2018 numbers (in brackets) reflect Medical Prognosis Institute A/S only.

### Highlights during Q2 2019

- On June 24, Oncology Venture announced that the European Patent Office will grant Oncology Venture a patent on LiPlaCis DRP®, which covers 205 genes and predicts the response in individual patients based on a pre-treatment biopsy.
- On June 13, Oncology Venture acquired an additional 8% ownership in the dovitinib project from Sass & Larsen ApS at a purchase price of DKK 5.4 million. Following the transaction, Oncology Venture’s ownership amounts to 63%. Further, Oncology Venture has negotiated an option to acquire Sass & Larsen’s remaining ownership in dovitinib at a price of DKK 0.7 million per percent of the ownership. The current deal replaces a previous deal which allowed Oncology Venture to obtain 85% ownership. There is currently no time limit to this option.
- On June 4, it was announced that an e-abstract has been published in Journal of Clinical Oncology – an ASCO Journal –, describing that DRP® (Drug Response Prediction) is able to predict which breast cancer patients will be high likelihood responders to neoadjuvant (before surgery) treatment with doxorubicin.
- On June 3, Oncology Venture announced that the US FDA had provided its initial response to the IND application and proposed pivotal Phase 3 study of LiPlaCis® in the US. The FDA has requested some additional testing of LiPlaCis® related to the product characterization. Oncology Venture expects to have these additional tests completed in good time before initiation of the study. The study design will be adapted to accommodate FDA’s recommendation for the pivotal study.

- On May 16, Oncology Venture confirmed that its rights issue had been successfully executed, raising a gross amount of approximately DKK 56 million. None of the commitments from guarantors were utilized. The capital increase is a result of DKK 48.7 million paid in cash and DKK 7.7 as a debt conversion. In the event that the investor warrants allocated to the new shares issued are exercised in full during the 12-month exercise period, the company expects to receive additional net proceeds from the offering of approximately DKK 105 million.
- On May 5, it was announced that members of Oncology Venture's management team had decided to participate in the rights issue.
- On April 30, Oncology Venture provided news on DRP<sup>®</sup> based analyses of biopsies from clinical trials with dovitinib. In addition to renal, endometrial and GIST tumors, Oncology Venture has now also shown in two new indications - liver cancer and breast cancer - that DRP<sup>®</sup> can predict the responding patients. Moreover, it was announced that the first patient has been dosed with 2X-121 (PARPi) at the Dana Farber Cancer Institute, Boston, US for the treatment of advanced ovarian cancer. Also, Oncology Venture disclosed that it had submitted an Investigational New Drug Application for LiPlaCis<sup>®</sup> and its DRP<sup>®</sup> to the FDA, with the intention to start a pivotal study in metastatic breast cancer.
- On April 10, a supplement to the rights issue prospectus from April 5, 2019 was published. The reason for the supplement was that the company had obtained additional subscription undertakings from investors, raising the total undertaking to (DKK 56 million), and that the exercise periods for the Investor Warrants had been extended. Finally, a correction had been made in the terms for the Investor Warrants with regards to the exercise price.
- On April 5, the Board of Directors of Oncology Venture decided to conduct a rights issue of shares supported by an authorization granted at the Annual General Meeting on April 4, 2019. The rights issue comprised of up to 25,155,639 offer units, each consisting of one new share at a subscription price of SEK 4/DKK 2.87 and one warrant at an exercise price of SEK 7.50.
- On April 4, the Company announced that it has obtained an exclusive option to in-license the European rights to IXEMPRA<sup>®</sup> (ixabepilone) from the pharmaceutical company R-Pharm U.S., LLC. In July 2015, R-PHARM U.S., LLC acquired global rights to IXEMPRA<sup>®</sup> 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<sup>®</sup> companion diagnostic in order to accomplish a market approval in Europe.
- On April 3, it was announced that Oncology Venture intends to submit a new drug application to the FDA for marketing approval of dovitinib based on existing Novartis data in renal cancer. Also, the development of a new combination biomarker – PD1 - PD-L1/Dovitinib DRP<sup>®</sup> has been completed. This gives a strong competitive edge in the immuno-oncology field. Oncology Venture has appointed US based Destum Partners to support its out-licensing activities.

### Highlights after the period

- On August 15 Oncology Venture informed that the US Food & Drug administration (FDA) had approved an IDE (Investigational Device Exemption) application for use of the company's drug response predictor LiPlaCis DRP<sup>®</sup> in a planned pivotal Phase 3 study. And in parallel, the FDA is evaluating Oncology Venture's IND (Investigational New Drug) application for the drug substance LiPlaCis<sup>®</sup>, which is primarily being developed as a potential new treatment of metastatic breast cancer in heavily pre-treated patients.

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### **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; irofulven, 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 84% in Oncology Venture US Inc. and 63% of dovitinib with an obligation to buy additional 12% and opportunity to acquire the final 25%.

Learn more at [oncologyventure.com](http://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 undertakes 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 August 30, 2019.