



Oncology Venture

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Press release
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Clinical up-date: Oncology Venture aims for approval of LiPlaCis® based on pivotal study in less than 200 patients

Hoersholm, Denmark and Cambridge, MA, US, November 1, 2018 – Oncology Venture A/S (“OV” or “the Company”), today announces its plans to aim for its first marketing approval of LiPlaCis® based on a single arm pivotal study. On the basis of current good data OV’s advisors and statisticians expect that a clinical study in 100-200 patients will be sufficient for a marketing approval of LiPlaCis® as a new treatment of breast cancer. The ongoing phase 2 study of LiPlaCis® may continue and bridge into such a pivotal trial. Recruitment timelines will be updated later. Furthermore, a status report is provided on the Company’s clinical stage projects 2X-121, dovitinib, Irofulven, 2X-111 and APO-010.

LiPlaCis®

Data from the ongoing Phase 2 LiPlaCis® study in patients with metastatic breast cancer shows:

- 50% response rate (five out of ten patients) in the upper one third of DRP® selected patients
- 24% response rate (6 out of 25 patients) in the upper two thirds of DRP® selected patients

These data should be compared with response rates to the established cancer drugs in metastatic breast cancer:

- 10-12% of eribulin, vinorelbine and gemcitabine and 10% of conventional cisplatin ⁽¹⁾

Oncology Venture has applied for a meeting with the FDA to discuss the filing of an IDE and IND application (the DRP® technology to track and match and the protocol for the LiPlaCis® treatment, respectively) with the intention to conduct LiPlaCis® breast cancer clinical trials also in the US. The aim is a first approval of LiPlaCis® by a single arm pivotal study. On the basis of current good data OV’s advisors and statisticians expect that a study in 100-200 patients will be sufficient for a marketing approval of LiPlaCis® as a new treatment of breast cancer. The ongoing phase 2 study of LiPlaCis® may continue and bridge into such a pivotal trial. Recruitment timelines will be updated later, following feedback from the FDA.

Oncology Venture’s regulatory strategy is firstly to obtain approval in the US, as the DRP® technology facilitates conduction of focused studies in a small number of patients to determine the efficacy of LiPlaCis®. The aim is then to run randomized pivotal studies in Europe and Greater China, provided necessary clearances from relevant regulatory bodies.

Patients with prostate cancer are also expected to respond to LiPlaCis®, and OV has recently been given clearance from the Danish health authorities to treat up to 15 DRP® selected prostate cancer patients with LiPlaCis®.

“Although the data sample from the ongoing LiPlaCis® study is still very limited, it should be pointed out that even a response rate of e.g. 30% in a larger population of heavily pretreated patients would give our drug candidate a huge competitive advantage. The US FDA has approved a range of pharmaceutical products based on clinical trials with only 70-120 patients where the efficacy readout is compared to

historical data. This would be a preferred regulatory route for projects like LiPlaCis[®], possibly followed by randomized post approval studies," **comments Peter Buhl Jensen, M.D., CEO of Oncology Venture.**

2X-121

PARP inhibitors are becoming an increasingly important class of drugs for treatment of breast cancer, with three drugs being approved in the USA for this indication. A study of metastatic breast cancer with Oncology Venture's PARP inhibitor 2X-121 was initiated in June 2018. A first efficacy read-out from the breast cancer study of 2X-121 will be reported once patients have been long enough in the study to demonstrate results (similar to the LiPlaCis[®] study).

In breast cancer all competitor approvals are linked to a subgroup of patients with BRCA mutated tumors. BRCA mutations counts for less than 10% of all breast cancers. PARP inhibitors are also active in ovarian cancer and breast cancer in patients with other types of non-BRCA mutated tumors. However, here the biology is complex with multiple mutations. In this space, Oncology Venture's patented DRP[®] technology is expected to be of particularly good help to track, match and guide treatment for susceptible patients. Patient inclusion to the 2X-121 study is based on our multi gene DRP[®] analysis; not on one single mutation as BRCA.

Clinical studies in ovarian cancer are planned to be conducted in Germany and the US. The US FDA has approved the initiation of such studies through the acceptance of IDE and IND applications (the DRP[®] technology to track and match and the protocol for the 2X-121 treatment, respectively). The ovarian cancer studies are expected to commence in Q1 2019.

Irofulven

In Q4 2018, OV started its phase 2 study aimed to demonstrate that its patented DRP[®] technology can be used to track, match and guide treatment of prostate cancer patients with Irofulven. Irofulven has previously shown a 10% response rate in prostate cancer. The aim is to raise the response rate to more than 20% to facilitate a marketing approval route. To speed up the inclusion OV will collaborate with German clinical centers. Results will be announced when prudent and relevant.

Dovitinib

As previously announced, OV is engaged in a data mining process based on documentation from more than 2500 patients to further document the ability of its dovitinib DRP[®] to track, match and treat those patients where dovitinib is a relevant therapy.

APO-010

A phase 1/2 trial is ongoing in Multiple Myeloma according to plan. No responders have so far been identified in the trial.

2X-111

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.

References

(1) [Link to reference](#)

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About Breakthrough therapy designation

Breakthrough therapy designation from the FDA (US Food and Drug Administration) is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. A breakthrough therapy designation conveys all of the fast track program features.

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 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 November 1, 2018.