



Press release

Clinical update: Dovitinib DRP data mining successfully completed and new LiPlaCis data continues to support an FDA breakthrough designation strategy

Hoersholm, Denmark and Cambridge, MA, US, February 7, 2019 – Oncology Venture A/S (“OV” or “the Company”) today provides a clinical update on its precision drug projects. Oncology Venture has finalized the data mining process for dovitinib and its companion DRP[®] in renal cancer and endometrial cancer. This datamining has given a precision improvement, and there is now, in both cases, an even stronger identification by the DRP[®] of the responders based on patient biopsy and gene expression data. The DRP gives dovitinib with a strong competitive edge. Further, Oncology Venture provides an up-date from the ongoing phase 2 study of LiPlaCis[®], showing continued strong data that supports an FDA breakthrough therapy designation. The updated data shows that the efficacy of LiPlaCis[®] is better than competitors – both in terms of response rate and time to progression. Response rates for LiPlaCis[®] are expected to fluctuate as the study progresses and the latest readout shows a decreased response rate compared to the November results. However, the response rate is higher than competitors and time to progression is significantly longer when LiPlaCis[®] is compared to the individual patient’s previous treatment. In addition to support the US FDA strategy this new data also supports a future marketing authorization application to the EMA.

Dovitinib

As previously announced, Oncology Venture is engaged in a data mining process based on documentation from more than 2,500 patients to further document the ability of its dovitinib DRP[®] to track, match and treat those patients where dovitinib is a relevant therapy.

Dovitinib (a multi tyrosine kinase inhibitor TKI) has been tested on 60 cancer cell lines from National Cancer Institute (NCI) in order to calibrate the DRP[®]. In November, Oncology Venture received good quality data from the NCI and were able to build a strong dovitinib DRP[®]. In connection with the licensing of dovitinib, Oncology Venture got access to biopsy and gene expression data from several of Novartis’ dovitinib studies. The data mining on dovitinib and its companion diagnostic DRP[®] is now finalized in renal cancer and in endometrial cancer, and in both cases the DRP[®] for dovitinib was able to identify the responders. This DRP result point towards a 2-4 fold higher response rates and gives dovitinib competitive advantage. This is a major step forward and supports further development of dovitinib as monotherapy and/or in combinations with different immune-oncology therapies.

“The whole immuno-oncology field is currently seeking the best therapy combinations for different patients and these recent positive data show that DRP can be a valuable tool in this development. DRP is a strong and maybe the only response predictor for combinations of immune-oncology drugs and tyrosine kinase inhibitors. This can pave the way for unleashing the full potential of dovitinib as a treatment for several forms of cancer,” **comments Peter Buhl Jensen, M.D., CEO of Oncology Venture.**

Drugs very similar to dovitinib (multityrosine kinase inhibitors) ,e.g. Eisai’s lenvatinib, have shown surprisingly strong data when used in combination with the new very successful immune-oncology products (IO) like Keytruda[®]. Lenvatinib has obtained breakthrough therapy designation in renal cancer and endometrial cancer when used with Keytruda[®], leveraging a significant deal with Merck. The huge initial success in the immuno-oncology space has led to a global race to develop new IO products, with many candidates underway. Several are showing efficacy, but they cannot all be winners and will need a competitive advantage.

The updated and more precise version of the DRP[®] gives dovitinib a strong competitive advantage and positions Oncology Venture as an attractive partner as the DRP[®] opportunity may be the only response predictor for IO – TKI combinations. Also, the regulatory pathway is expected to be strengthened by the DRP[®].

LiPlaCis[®]

In the ongoing phase 2 part of the LiPlaCis[®] study in patients with metastatic breast cancer, Oncology Venture's companion diagnostic tool DRP[®] is used to identify the patients most likely to respond to LiPlaCis. The results are measured by response rate (number of patients with reduced tumor volume), time to progression (time from treatment start until the disease starts to worsen or spread) and time to progression compared to the individual patient's previous therapy results. Only patients with a LiPlaCis[®] DRP[®] above the bottom 33% are included in the trial. When comparing the middle 33% with the top 33% there are significant differences. Only patients in the top group responded, i.e. had partial remissions. Likewise, time to progression in the LiPlaCis[®] treated patients depended highly on the level of DRP[®]. Median time to progression in the top 33% group is 18 weeks but only 7 weeks in the middle group. Thus, the DRP[®] continues to be strong tool for selecting patients who will benefit from LiPlaCis[®].

Response data from the study shows:

- 33% response rate (4 out of twelve patients) in the upper one third of DRP[®] selected patients and
- 40% in the upper 20% of DRP[®] selected patients that have not previously been treated with cisplatin. One patient who was previously deemed a partial responder (PR) is now deemed a stable disease (SD+24) for more than 29 weeks, i.e. showing good clinical benefit.

In the latest clinical update (November 2018) the reported response rate was 50% in the upper one third of DRP[®] selected patients and 24% in the upper two thirds. Even if the updated data show a lower response rate, the results are strong compared with response rates to the established cancer drugs in metastatic breast cancer: 10-12% for eribulin, vinorelbine and gemcitabine and 10% for conventional cisplatin ⁽¹⁾.

Response data is further substantiated by data showing with statistical significance ($p=0.05$, one sided) that the DRP[®] works in everyday practice: **Time to Progression** (TTP) compared to the physician's previous choice (the patient is its own control):

- 18 weeks on LiPlaCis compared to
- 12 weeks on physician's previous choice

In the top 20% DRP[®] score:

- 19 weeks on LiPlaCis compared to
- 11 weeks on physician's previous choice

On the basis of continued good data, Oncology Venture's advisors and statisticians expect that a study in less than 200 patients will be sufficient for a marketing approval of LiPlaCis[®] as a new treatment of breast cancer. The ongoing phase 2 study may continue and bridge into such a pivotal trial. Recruitment timelines will be updated later, following feed-back from the regulatory authorities.

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% of heavily pretreated patients would give the 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.

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

“The new data analysis from the ongoing phase 2 study of LiPlaCis shows a lower response rate than what was observed in November 2018 but is still deemed high enough to motivate an FDA breakthrough therapy designation. This is also supported by good data showing that time to progression is significantly improved which also opens up for a potential EMA approval. Further, LiPlaCis shows a clear advantage in terms of for how long patients are benefiting from the treatment, compared to their previous treatment of choice,” **comments Peter Buhl Jensen, M.D., CEO of Oncology Venture.**

2X-121

Seven patients are ongoing in a study of metastatic breast cancer with Oncology Venture’s PARP inhibitor 2X-121. A first efficacy read-out from the breast cancer study of 2X-121 will be reported once patients have been treated long enough to demonstrate results.

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

Four patients with prostate cancer are currently being treated with Irofulven at two Danish University Hospitals. To further speed up the inclusion, Oncology Venture will collaborate with German clinical centers. Results will be announced when prudent and relevant.

APO-010

A phase 1/2 trial is ongoing in Multiple Myeloma (MM) according to plan. 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. Oncology Venture is currently comparing these collection methods to get the right calibration. 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 Oncology Venture plans to initiate further development of this product once contract negotiations on product manufacturing are completed.

References

- (1) [Link to reference](#)

For further information, please contact:

For investor inquiries
Ulla Hald Buhl, IR & Communications
E-mail: uhb@oncologyventure.com
Telephone +45 21 70 10 49

For media inquiries
Thomas Pedersen, Carrotize PR &
Communications
E-mail: tsp@carrotize.com
Telephone +45 60 62 93 90

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%.

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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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Certified Adviser: Sedermera Fondkommission, Norra Vallgatan 64, 211 22, Malmö, Sweden

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 February 7, 2018.