

Oncology Venture in-licenses 2-BBB's Phase 2 product 2B3-101 for 2X Oncology's pipeline

Hoersholm, Denmark; Leiden, the Netherlands, March 28th 2017 – Oncology Venture Sweden AB (OV:ST) and 2-BBB Medicines BV announce today to have entered into an exclusive global license agreement on 2-BBB's Phase 2 lead product 2B3-101 – now called 2X-111. The drug is a liposomal formulation of doxorubicin utilizing the so-called G-Technology, which enables the drug to pass the Blood-Brain Barrier to enhance treatment of brain metastases and primary brain tumors. 2X-111 has demonstrated clinical activity in a phase 2 study in metastatic Breast Cancer patients and in patients with Glioblastoma (primary brain cancer), both hard to treat cancers with a huge unmet medical need. 2X-111 will be combined with its Drug Response Predictor (DRP™) as a companion diagnostic in DRP™ focused Phase 2 trials for selected, high-likelihood responder patients. The drug will be developed as a 2X Oncology Inc. pipeline drug. 2X Oncology Inc. is a spinout of Oncology Venture developing Precision medicine for Women's cancers.

The active anticancer drug in 2X-111, doxorubicin, is an almost identical molecule to epirubicin, for which it was recently announced that the DRP™ biomarker can, with certainty, identify those patients who benefit from treatment with the drug. A retrospective-prospective validation (i.e. the highest validation level) has been achieved for the epirubicin DRP™, and 2X-111 therefore has a similar risk-reduced profile (as is also the case with LiPlaCis in the Oncology Venture pipeline).

Under the terms of the agreement, Oncology Venture will be responsible for the development and commercialization of 2X-111 in oncology. Further terms of the agreement were not disclosed. Oncology Venture will, through 2X Oncology, fund and execute the mutually agreed upon clinical development plan.

"I'm excited for the opportunity to in-license the liposomal doxorubicin compound from 2-BBB. I believe that the cutting-edge science and compelling clinical data behind the drug (now called 2X-111) in combination with our unique Drug Response Predictor (DRP™) biomarker technology gives an exceptional risk-reduced opportunity to develop effective treatments for hard to treat cancers," says Adjunct Professor Peter Buhl Jensen, M.D., CEO of Oncology Venture. "2X-111 will be developed in two focused Phase 2 trials in metastatic Breast Cancer and in Glioblastoma in 2X Oncology Inc. a precision medicines company for Women's Cancers – a spinout from Oncology Venture," Peter Buhl Jensen further commented.

Pieter Gaillard, CEO of 2-BBB says: "Combining 2B3-101 with the DRP™ biomarker technology will enhance the efficacy by screening patients who are likely to respond to ultimately deliver a new treatment option for such devastating diseases. The license deal further validates 2-BBB's technology and development strategy through crucially improving medicines for patients in need."

"We are proud to see 2B3-101 move into the next phase of clinical development with Oncology Venture's spinout 2X Oncology Inc. as the right partner for the product," adds Sijme Zeilemaker, Head of Business at 2-BBB.

About 2X-111 (previously 2B3-101)

2-BBB has applied its proprietary G-Technology to its lead product 2B3-101 now 2X-111 to enhance the delivery of doxorubicin to the brain and enable better treatment of metastatic cancer types and primary brain tumors.

In preclinical studies, 2-BBB has shown that conjugation of glutathione to the tips of PEGylated liposomes can provide a five-fold increased delivery of doxorubicin to the brain compared to untargeted liposomes. 2B3-101 has been studied in a phase 1/2a clinical trial in 10 clinical sites in the Netherlands, Belgium, France and the United States, confirming its tolerable safety profile in 85 patients and showing encouraging signs of anti-tumor activity in amongst others metastatic Breast Cancer and Glioblastoma (primary brain tumor).

About the Drug Response Predictor (DRP™) biomarker technology

Oncology Venture (OV) and 2X Oncology Inc. use the multi gene DRP™ from MPI (Medical Prognosis Institute A/S; MPI.ST) to select those patients that by the genetic signature in their cancer is found to have a high likelihood of response to a given drug. The goal is to develop the drug for the right patients and by screening patients with a drug-specific DRP™ biomarker before treatment the response rate can be significantly increased. 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. The DRP™ is based on messenger RNA from the patients' biopsies. 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 MPI for Personalized Medicine. The DRP™ is used in Oncology Venture and 2X Oncology Inc., a spinout of OV for drug development.

About 2-BBB Medicines BV

2-BBB is created to develop medicines for the treatment of devastating brain diseases. We believe that we can transform the lives of those affected faster and more successful by combining known disease targets and compounds with established drug delivery systems united with safe targeting technology. This has led to two programs in clinical development: 2B3-101 for brain cancer and 2B3-201 for neuro-inflammatory diseases. 2-BBB is based in the Netherlands on the Leiden Bio Science Park, and its subsidiary to-BBB Taiwan Ltd. is based in Taipei, Taiwan.

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™) platform 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 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 (OV currently owns 92% of the shares in 2X Oncology) and Danish OV-SPV 2 will test and potentially develop an oral phase 2 Tyrosine Kinase inhibitor.

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