VBL Therapeutics Announces the Launch of a New Clinical Trial of VB-111 Combined with the Checkpoint Inhibitor, Nivolumab, in Metastatic Colorectal Cancer

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- ***This clinical trial will investigate for the first time a combination of VB-111 with a checkpoint inhibitor.***
- ***Pathology readouts are expected to shed light on the potential of VB-111 to turn "cold" colorectal tumors "hot."***

TEL AVIV, Israel, Feb. 20, 2020 (GLOBE NEWSWIRE) -- VBL Therapeutics (Nasdaq: VBLT) today announced the launch of a phase 2 clinical trial of VB-111 in combination with nivolumab (Opdivo®), an immune checkpoint inhibitor, in the treatment of metastatic colorectal cancer. **The National Cancer Institute (NCI) will serve as the Investigational New Drug (IND) sponsor for this study and the IND application has been approved by the U.S. Food and Drug Administration (FDA).** This new study will investigate if priming with VB-111 can drive immune cells into the tumor and turn the colorectal tumor from immunologically "cold" to "hot." The addition of nivolumab to VB-111 may further boost the anti-tumor immune response.

"This phase 2 study is part of our strategy to broaden the potential indications for VB-111 and to explore its activity as part of combination therapies," said Dror Harats, M.D., Chief Executive Officer of VBL Therapeutics. "We look forward to collaborating with NCI on this clinical trial, as we continue to generate data which adds to our understanding of VB-111's mechanism of action and therapeutic potential. We were particularly encouraged by results in ovarian cancer demonstrating the recruitment of infiltrating T cells into a tumor following treatment with VB-111, turning the tumor 'hot'. This important finding suggests that VB-111 may be applied to other 'cold' tumors, in which checkpoint inhibitors show limited or no efficacy, including colorectal cancer, for which there remains a major unmet need."

VBL and the NCI have entered into a Cooperative Research and Development Agreement (CRADA) under the direction of Tim F. Greten, M.D., Deputy Branch Chief & Senior Investigator of the Thoracic and GI Malignancies Branch (TGMB) and Co-Director of the NCI Center for Cancer Research (CCR) Liver Cancer Program. The goal of this open-label, single-arm phase 2 study is to evaluate VB-111 in combination with an anti-PD-1 inhibitor, nivolumab, in patients with metastatic colorectal cancer. In addition to safety and tolerability, this study will evaluate efficacy endpoints including Best Overall Response, as well as immunological and histologic readouts from tumor biopsies. For additional information refer to https://clinicaltrials.gov/show/NCT04166383.

For patients interested in enrolling in this clinical study, please contact NCI's toll-free number 1-800-4-Cancer (1-800-422-6237) (TTY: 1-800-332-8615) and/or the Web site: **https://trials.cancer.gov**

About VBL
Vascular Biogenics Ltd., operating as VBL Therapeutics, is a clinical stage biopharmaceutical company focused on the discovery, development and commercialization of first-in-class treatments for cancer. VBL's lead oncology product candidate, ofranergene obadenovec (VB-111), is a first-in-class, targeted anti-cancer gene-therapy agent that is being developed to treat a wide range of solid tumors. It is conveniently administered as an IV infusion once every two months. It has been observed to be well-tolerated in >300 cancer patients and demonstrated activity signals in a VBL-sponsored "all comers" phase 1 trial as well as in three VBL-sponsored tumor-specific phase 2 studies. Ofranergene obadenovec is currently being studied in a VBL-sponsored phase 3 potential registration trial for platinum-resistant ovarian cancer.

Forward Looking Statements
This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "look forward to," "may," "plan," "potential," "predict," "project," "should," "will," "would" and similar expressions. These forward-looking statements include, but are not limited to, statements regarding our programs, including VB-111, including their clinical development, such as the timing of clinical trials and expected announcement of data, therapeutic potential and clinical results, and our financial position and cash runway. These forward-looking statements are not promises or guarantees and involve substantial risks and uncertainties. Among the factors that could cause actual results to differ materially from those described or projected herein include uncertainties associated generally with research and development, clinical trials and related regulatory reviews and approvals, the risk that historical clinical trial results may not be predictive of future trial results, that our financial resources do not last for as long as anticipated, and that we may not realize the expected benefits of our intellectual property protection. A further list and description of these risks, uncertainties and other risks can be found in our regulatory filings with the U.S. Securities and Exchange Commission, including in our annual report on Form 20-F for the year ended December 31, 2018, and subsequent filings with the SEC. Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. VBL Therapeutics undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

INVESTOR CONTACT:

Michael Rice
LifeSci Advisors
mrice@lifesciadvisors.com
(646) 597-6979


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