VBL Presents Positive Interim Data from the OVAL Phase 3 Pivotal Study in Ovarian Cancer at the ASCO20 Annual Meeting, Showing 58% or Higher Objective Response Rate

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- *OVAL independent Data Safety Monitoring Committee (DSMC) reviewed un-blinded data and determined that the study has met the interim pre-specified criterion of an absolute percentage advantage of 10% or higher in CA-125 response in the VB-111 treated arm compared to control. The DSMC recommended that the study proceed without modification.*
- *Overall CA-125 response rate in the first 60 randomized evaluable patients is 53%. Assuming a balanced randomization, the response rate in the treatment arm (VB-111 in addition to weekly paclitaxel) is 58% or higher.*
- *In patients with post-treatment fever, the CA-125 response is 69%. Fever is frequently observed after VB-111 treatment.*
- The next interim analysis in the OVAL study is expected in 3Q 2020.

TEL AVIV, Israel, June 01, 2020 (GLOBE NEWSWIRE) -- VBL Therapeutics (Nasdaq: VBLT), today announced the presentation of the positive outcome of pre-planned interim analysis results from the OVAL Phase 3 pivotal clinical trial in platinum-resistant ovarian cancer at the American Society of Clinical Oncology (ASCO) 2020 virtual annual meeting.

The analysis compared the CA-125 objective response rate (ORR) according to GCIG criteria in the treatment and control arms among the first 60 evaluable patients. The CA-125 ORR in those patients was 53%. Assuming a balanced randomization, the response rate in the treatment arm (VB-111 in addition to weekly paclitaxel) was 58% or higher. In patients who had post-dosing fever, which is a marker for VB-111 treatment, the response rate was 69%.

The CA-125 response rate observed in the Phase 3 interim analysis is at least as good as the response rate seen in the prior Phase 2 study, which enrolled a similar patient population and showed overall survival benefit. In the previously reported Phase 2 study of VB-111 in platinum resistant ovarian cancer, 58% of the patients treated with VB-111 and paclitaxel demonstrated a CA-125 response. Those patients with a CA-125 response demonstrated a median overall survival of 808 days, versus 351 days for those patients without a CA-125 response.

“The OVAL interim data are very encouraging as they demonstrate the potential benefit of VB-111 over standard-of-care in a randomized-controlled setting,” said Tami Rachmilewitz, M.D., Vice President Clinical Development of VBL Therapeutics. “With over 25% of the patients already enrolled in the study, we look forward to further advancing the OVAL study by expansion to Europe and Japan later this year.”

For VBL's presentation at ASCO see: *Link*

About the OVAL (VB-111-701/GOG-3018) study (NCT03398655)
OVAL is an international Phase 3 randomized, double-blind, placebo-controlled potential registration clinical trial that compares a combination of VB-111 and paclitaxel to placebo plus paclitaxel, in patients with platinum-resistant ovarian cancer. The study is planned to enroll approximately 400 patients. OVAL is conducted in collaboration with the GOG Foundation, Inc., an independent international non-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies.

About VB-111 (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. VB-111 is a unique biologic agent that uses a dual mechanism to target solid tumors. Its mechanism combines blockade of tumor vasculature with an anti-tumor immune response. VB-111 is administered as an IV infusion once every 6-8 weeks. It has been observed to be well-tolerated in >300 cancer patients and demonstrated activity signals in an “all comers” Phase 1 trial as well as in three tumor-specific Phase 2 studies. VB-111 has received an Orphan Designation for the treatment of ovarian cancer from the European Commission. VB-111 has also received orphan drug designation in both the US and Europe, and fast track designation in the US for prolongation of survival in patients with rGBM. VB-111 successfully demonstrated proof-of-concept and survival benefit in Phase 2 clinical trials in radioiodine-refractory thyroid cancer and recurrent platinum-resistant ovarian cancer (NCT01711970).

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 areas of unmet need in cancer and immune/inflammatory indications.

About The GOG Foundation, Inc.
The GOG Foundation, Inc. (GOG-F) is a not-for-profit organization with the purpose of promoting excellence in the quality and integrity of clinical and basic scientific research in the field of gynecologic malignancies. The GOG-F is committed to maintaining the highest standards in clinical trials development, execution, analysis and distribution of results. The GOG-F is the only group in the United States that focuses its research on women with pelvic malignancies, such as cancer of the ovary, uterus, and cervix. The GOG-F is multi-disciplinary in its approach to clinical trials, and includes gynecologic oncologists, medical oncologists, pathologists, radiation oncologists, nurses, statisticians, basic scientists, quality of life experts, data managers, and administrative personnel.

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 may include, but are not limited to, statements regarding our programs, including VB-111, including their clinical development, therapeutic potential and clinical results. 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, the impact of the COVID-19 pandemic on our business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines and clinical 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. In particular, the DSMC recommendation that the OVAL trial proceed is not assurance that the trial will meet its primary endpoint of overall survival once completed. 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, 2019, 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.

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