



VBL Therapeutics Announces Top-Line Data from Phase 3 OVAL Trial of Ofra-Vec in Patients with Platinum-Resistant Ovarian Cancer

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- Trial Did Not Meet Statistical Significance on Improvement in Primary Endpoints of Progression Free Survival (PFS) or Overall Survival (OS) -

TEL AVIV, Israel and NEW YORK, July 19, 2022 (GLOBE NEWSWIRE) -- VBL Therapeutics (Nasdaq:VBLT), a biotechnology company developing targeted medicines for cancer and immune-inflammatory diseases, today announced top-line data from the Phase 3 OVAL clinical trial of ofra-vec (ofranergene obadenovec; VB-111) in platinum-resistant ovarian cancer. The trial did not meet the primary endpoints of achieving a statistically significant improvement in progression-free survival (PFS) or overall survival (OS).

The OVAL trial demonstrated that patients randomized to the combination of ofra-vec and paclitaxel had a median PFS of 5.29 months, versus 5.36 months for the paclitaxel control arm (HR=1.03). The interim overall survival analysis was also not significantly different between the two study arms (median OS 13.37 months in the treatment arm versus 13.14 months in the control arm; HR= 0.97) and did not support study continuation.

"Given the urgent unmet need for those fighting platinum-resistant ovarian cancer, we are deeply disappointed that the top-line data indicate that ofra-vec did not improve progression free survival or overall survival," said Prof. Dror Harats, M.D., chief executive officer of VBL Therapeutics. "Based on this outcome, we plan to discontinue the OVAL trial and will review the data from our ongoing Phase 2 trials in metastatic colorectal cancer and recurrent glioblastoma multiforme to determine next steps with the ofra-vec program. We extend our deepest gratitude to all the patients, families and healthcare professionals who participated in this trial."

As VBL evaluates next steps with the ofra-vec program, it continues to move the VB-601 program forward towards a first-in-human clinical trial, expected to begin in the fourth quarter of 2022. The Company anticipates that its current cash on hand will be sufficient to fund planned operations for at least the next 12 months.

About the OVAL Phase 3 Clinical Trial

OVAL (VB-111-701/GOG-3018) was an international, Phase 3, randomized, double-blind, placebo-controlled, clinical trial comparing a combination of ofra-vec (ofranergene obadenovec; VB-111) plus paclitaxel to placebo plus paclitaxel in 409 adult patients with recurrent platinum-resistant ovarian cancer. The two primary endpoints of the trial were progression free survival (PFS) and overall survival (OS). OVAL was conducted in collaboration with the GOG Foundation, Inc., an independent international non-profit organization with the purpose of promoting excellence in the field of gynecologic malignancies. For more information, refer to Clinicaltrials.gov NCT03398655.

About VBL Therapeutics

VBL Therapeutics (Nasdaq: VBLT) is developing targeted therapies for cancer and immune-inflammatory diseases. Lead oncology product candidate ofra-vec combines vascular disruption to starve the tumor's blood supply with an immuno-oncology approach that brings T-cells to the tumor; it is being evaluated in Phase 2 trials in recurrent glioblastoma multiforme and metastatic colorectal cancer. VBL's lead immunology product candidate VB-601 is a targeted antibody for immune-inflammatory applications expected to enter Phase 1 this year that has shown disease-modifying activity across multiple preclinical models including multiple sclerosis, rheumatoid arthritis and inflammatory bowel disease. To learn more about VBL, please visit vblrx.com or follow VBL on LinkedIn, Twitter, YouTube or Facebook.

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 discontinuation of the OVAL trial, review of data for other trials in the ofra-vec program, timing of the initiation of a first-in-human trial for VB-601, and expectations regarding cash on hand, among others. 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 the development of pharmaceutical product candidates, and include risks associated 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 VBL's financial resources do not last for as long as anticipated, and that VBL may not realize the expected benefits of its intellectual property protection. A further list and description of these risks, uncertainties and other risks can be found in VBL's regulatory filings with the U.S. Securities and Exchange Commission (SEC), including in its annual report on Form 20-F for the year ended December 31, 2021, 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 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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