



## VBL Therapeutics Receives FDA Fast Track Designation for Ofra-Vec for the Treatment of Platinum-Resistant Ovarian Cancer

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- FDA grants Fast Track designation to facilitate development and expedite the review of therapies with potential to treat serious unmet medical needs. The purpose of this designation is to bring important new drugs to patients earlier
- OVAL Phase 3 top-line progression free survival (PFS) primary endpoint data for ofra-vec expected in 2H 2022; with positive results, VBL anticipates submitting a Biologics License Application (BLA) in 1H 2023

TEL AVIV, Israel and NEW YORK, April 26, 2022 (GLOBE NEWSWIRE) -- VBL Therapeutics (Nasdaq: VBLT), a late-clinical stage biotechnology company focused on developing first-in-class therapeutics for difficult-to-treat malignant solid tumors and immune or inflammatory indications, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for ofra-vec (ofranergene obadenovec or VB-111) in combination with paclitaxel for the treatment of platinum-resistant ovarian cancer.

"We are pleased to receive FDA Fast Track designation for ofra-vec in platinum-resistant ovarian cancer. The Fast Track designation can facilitate the process towards potential registration and, importantly, may help expedite the time to market for ofra-vec, if approved," said Prof. Dror Harats, M.D., chief executive officer of VBL Therapeutics. "The readout of the progression free survival primary endpoint in the OVAL trial will be an important milestone for VBL in the second half of this year. We believe that, if positive, this will support a Biologics License Application submission to the FDA."

Ofra-vec is VBL Therapeutics' investigational anti-cancer, gene-based agent in development to treat a wide range of solid tumors. The lead clinical program for ofra-vec is the OVAL Phase 3 registration-enabling trial in recurrent platinum-resistant ovarian cancer patients. VBL recently completed patient enrollment of 409 patients in this global trial being conducted at centers in the United States, Europe, Israel and Japan. In addition, the Independent Data Safety Monitoring Committee (DSMC) unanimously recommended to continue the trial as planned, following review of unblinded data from 370 randomized patients.

### About the OVAL Trial

OVAL (VB-111-701/GOG-3018) is an international Phase 3 randomized, pivotal registration-enabling clinical trial comparing a combination of ofra-vec (ofranergene obadenovec or VB-111) and paclitaxel to placebo plus paclitaxel, in adult patients with recurrent platinum-resistant ovarian cancer. The OVAL trial has two primary endpoints: progression free survival (PFS) and overall survival (OS). Successfully meeting either primary endpoint has the potential to support a Biologics License Application (BLA). Meeting the PFS endpoint, with a top-line readout anticipated in the second half of 2022, could accelerate BLA submission by approximately one year, subject to discussions with the U.S. Food and Drug Administration. A top-line readout of the OS primary endpoint is anticipated in 2023. OVAL is being 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](https://Clinicaltrials.gov/NCT03398655).

### About Ofra-Vec (ofranergene obadenovec; `VB-111`)

Ofra-vec is an investigational anti-cancer, gene-therapy agent in development to treat a wide range of solid tumors. Ofra-vec is a unique biologic agent designed to use a dual mechanism to target solid tumors. Its mechanism combines the blockade of tumor vasculature with an anti-tumor immune response. Ofra-vec is administered as an IV infusion once every 6-8 weeks. It has been observed in past clinical research to be generally 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 trials. Ofra-vec has received orphan designations for the treatment of ovarian cancer and for the treatment of glioma by the European Commission. The FDA granted ofra-vec orphan designation for the treatment of malignant glioma and fast track designation for the treatment of rGBM and the treatment of platinum-resistant ovarian cancer. Ofra-vec demonstrated proof-of-concept and survival benefit in Phase 2 clinical trials in radioiodine-refractory thyroid cancer (NCT01229865) and platinum-resistant ovarian cancer (NCT01711970).

### About VBL Therapeutics

Vascular Biogenics Ltd., operating as VBL Therapeutics (VBL), is a late-clinical stage biopharmaceutical company focused on the discovery, development, and commercialization of first-in-class treatments for difficult-to-treat malignant solid tumors and immune or inflammatory indications. VBL's novel VTS™ gene-based platform and antibody-based monocyte targeting technology enable the creation of a pipeline of programs that are designed to harness the body's innate biological processes to provide unique solutions for significant unmet medical needs. VBL's lead oncology product candidate, ofra-vec (ofranergene obadenovec; `VB-111`), is an investigational targeted anti-cancer gene-based agent in development to treat a wide range of solid tumors. Ofra-vec is currently being studied in a Phase 3 registration-enabling clinical trial (NCT03398655) for platinum-resistant ovarian cancer. To learn more about VBL, please visit [vblrx.com](http://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 include, but are not limited to, statements regarding timing of topline data from the OVAL trial and its potential to support BLA submission, the benefits of Fast Track designation, including its ability to expedite commercialization, as well as statements regarding the therapeutic benefit of ofra-vec (VB-111) and its ability to obtain regulatory approval, 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, including risks associated with conducting 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, and other risks, which risks may be compounded by the ongoing COVID-19 pandemic. 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, 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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