



## **VIDAC PHARMA PHASE 2 STUDY OF VDA-1102 IN ACTINIC KERATOSIS MEETS INTERIM ANALYSIS CRITERION**

Jerusalem, Israel, December 12, 2016 – Vidac Pharma, a clinical-stage oncology-focused pharmaceutical company, today announced that the ongoing Phase 2 study with VDA-1102 ointment, a potent selective VDAC/HK2 modulator, in actinic keratosis (AK) met a pre-determined interim analysis criterion. The drug candidate is being developed by Vidac as a first-in-class treatment for actinic keratosis, an early form of cutaneous squamous cell carcinoma (cSCC), featuring potency, safety, and tolerability at the same time.

The interim futility analysis was performed on the primary efficacy endpoint, which is reduction in the number of lesions on day 56 relative to placebo, following completion of the day 56 visit by the first 40 subjects enrolled in the trial. The interim analysis was performed by a single unblinded statistician who determined, according to a pre-defined criterion, that at least one of the treatment arms could achieve statistical significance by the end of the study. The study remains blinded and is continuing as planned.

Dr. Oren M. Becker, Vidac's President and Chief Executive Officer said, “we are pleased with the interim analysis results and are looking forward to the completion of the study in Q2 of 2017.”

### **About the Phase 2 Study**

The Phase 2 clinical trial is multiple-center randomized, double-blind, placebo-controlled, parallel-cohorts study to evaluate the efficacy, safety, tolerability, and pharmacokinetics of once-daily application of topical VDA-1102 ointment for 28 days in subjects with actinic keratosis. Subjects will be followed for two months after they complete treatment (through day 84). The primary and secondary efficacy endpoints for the study are reduction in the number of lesions on days 56 and 84, respectively. Subjects are randomly assigned in a double-blind fashion to one of three parallel treatment cohorts (5%, or 10% VDA-1102, or placebo) at a ratio of 1:1:1. To qualify for the study, subjects aged 18 (inclusive) or older must have 4-8 discrete Grade 1 or 2 AK lesions within a 25-centimeter squared area of skin on the scalp or face. The study is expected to enroll 90 subjects in the US and Israel. The first 15 subjects enrolled in the trial were part of a "nested Phase 1b safety sub-cohort" and underwent extensive safety evaluation on Day 7. Earlier in the trial, a safety committee consisting of 3 physicians, Board-certified in internal medicine and a medical subspecialty,

reviewed the safety data from this Phase 1 sub-cohort and found no safety signals or concerns. Local skin reactions were mild to absent.

### **About VDA-1102 ointment**

VDA-1102 is a novel, potent selective modulator of the VDAC/HK2 complex in cancer cells. The drug triggers the dissociation of this HK2 from VDAC leading, among other effects, to apoptosis and death of the malignant cells. The selective nature of VDAC/HK2 dissociation targets only cancer cells without affecting the surrounding healthy tissue. VDA-1102 is being developed as a topical ointment for treatment of pre-malignant and malignant skin conditions, such as AK, cutaneous squamous cell carcinoma (cSCC), and cutaneous T-cell lymphoma (CTCL). VDA-1102 ointment has successfully completed a Phase 1 study in healthy volunteers, and is now ongoing a Phase 2 study in subjects with AK. VDA-1102 is also being developed as an injectable for treatment of solid tumors.

### **About Actinic Keratosis**

Actinic keratosis (AK) is one of the most common dermatologic conditions worldwide. It affects an estimated 58 million people in the United States alone. In 2015 the global AK market was estimated at \$6.6 billion. This skin disease occurs predominantly in older males with fair skin and most often begins as a rough red patch that may progress to a thicker, scaly, and unsightly skin lesion. AK is considered by many as an early form of cSCC. Thus treatment is most commonly recommended by physicians in order to prevent cSCC. Current therapies are inadequate and pose significant disadvantage to public health. The limited tolerability of current treatment options greatly decrease the willingness of patients to be retreated and/or compliant. AK is a chronic disease for which patients often require repeat treatments. As a result patients with this prevalent condition elect to avoid treatment, seeking medical help only later, after their lesions have become esthetically intolerable or have advanced to malignant cSCC tumors.

### **About Vidac Pharma**

Vidac Pharma is an innovative clinical-stage oncology-focused pharmaceutical company, developing novel drugs to help people suffering from a range of oncologic and dermatologic diseases. Vidac's breakthrough technology targets the VDAC/HK2 system that is unique to malignant cells. The mechanism-of-action of these drugs leads to selective apoptosis of cancer cells without affecting the surrounding healthy tissue, offering well-tolerated efficacious treatments. Its lead drug VDA-1102 is in Phase 2 testing in Ak. Vidac is also developing VDA-1102 injections as a systemic treatment for solid tumors. For more information regarding Vidac Pharma, please visit [www.vidacpharma.com](http://www.vidacpharma.com).

Contact: Shelly Majar +972-2-5952090

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