VIDAC PHARMA REPORTS POSITIVE RESULTS FROM PHASE 2A PROOF-OF-CONCEPT TRIAL OF VDA-1102 OINTMENT IN ACTINIC KERATOSIS

- **Establishes that VDA-1102 ointment is well-tolerated, non-irritating and safe**
- **Demonstrates reduction of number of actinic keratosis lesions in treatment field**

Jerusalem, Israel, October 12, 2017 – Vidac Pharma, a clinical-stage dermatology- and oncology-focused biopharmaceutical company, today announced positive results from a Phase 2a Proof-of-Concept (POC) clinical trial for its investigational topical drug, VDA-1102 ointment, in subjects with actinic keratosis (AK), an early form of cutaneous squamous cell carcinoma (cSCC). These results establish VDA-1102 ointment as a potential first-in-class non-irritating treatment for AK.

According to Dr. Mark Lebwohl, Professor and Chairman of Dermatology at the Icahn School of Medicine at Mount Sinai and an investigator in this trial, "the results of this trial are exciting because, until now, all the treatments we have available for actinic keratoses are irritating. We need nonirritating AK treatments that don't cause crusting and scabbing on the face."

“There is a high unmet need for an effective treatment of actinic keratoses without unpleasant skin reactions. Based on the results of this first study, VDA-1102 ointment appears to successfully go in this direction," said Professor Kristian Reich, Founder of *Skin*flammation™, Hamburg, Germany.

“This proof-of-concept study established VDA-1102 ointment's safety and tolerability, demonstrating that it is completely non-irritating,” said Dr. Chaim M. Brickman, Chief Medical Officer at Vidac. “The study also confirmed VDA-1102 ointment’s efficacy in AK and paves the way for a higher dose, longer duration confirmatory Phase 2b study, which is planned for 2018.”

The randomized, double-blind, placebo-controlled, parallel-cohort Phase 2a clinical trial investigated the efficacy, safety, tolerability, and pharmacokinetics of once-daily application of topical VDA-1102 ointment for 28 days in subjects with actinic keratosis on

their face or scalp (25 cm^2 treatment area with 4-8 discrete Grade 1 or 2 AK lesions at baseline). Study endpoints were evaluated on Day 56. The study enrolled 93 subjects, at 8 clinical sites in the U.S. and Israel. Subjects were randomized to three treatment cohorts (5%, or 10% VDA-1102 ointment, or placebo). The mean age of the enrolled subjects was 66.5 (ranging from 37 to 93 years), and the majority of subjects (75.3%; 70 subjects) were treated for AK lesions on the face.

Safety – There were no treatment-emergent serious adverse events (AEs) or severe AEs related to the study drug. None of the subjects on the active study drug withdrew consent, discontinued treatment, or applied an emollient to the treatment field. Only 2 treatment-emergent AEs were deemed related to the study drug in the active treatment arms. Both AEs were mild and occurred in the 5% treatment group; none were reported in the 10% group. There were no clinically significant findings in vital signs, physical examinations, clinical laboratory results, or ECGs.

Tolerability – VDA-1102 ointment treatment resulted in no local skin irritation as measured by a Local Skin Reaction (LSR) score that ranges from 0 to 4 for 9 possible findings including erythema, edema, scaling, itching, and pain. On this 36-point LSR scale, the mean maximal scores for the VDA-1102 ointment treatment groups were 1.1±2.0 and 0.9±1.5 for the 5% and 10% doses, respectively, compared to 0.8±1.3 in the placebo treatment group. There was no statistical difference in the mean composite LSRs between the three treatment groups at any time (p= 0.7821).

Efficacy –The primary efficacy endpoint of the study was reduction in the total number of AK lesions (of all Grades) in the treatment field on Day 56. The 10% VDA-1102 ointment demonstrated statistically significant reduction in the total number of AK lesions vs. placebo for subjects treated on their face (p=0.023; 70 subjects), showing 50% median reduction with 10% VDA-1102 ointment (mean 38.8%±36.4%) compared to a median reduction of 20% in the placebo group (mean 29.0%±32.5%). The mean reduction in AK lesion count was greater in the 10% VDA-1102 ointment group than in the placebo group for the combined face or scalp population as well (32.1%±34.1% and 27.8%±30.6%, respectively) although the difference was not statistically significant.

The 10% VDA-1102 ointment treatment also demonstrated a statistically significant (p=0.0004) effect in an additional efficacy endpoint, reduction in the number of the more advanced lesions (only Grade 2 or 3; not counting Grade 1 lesions) for subjects treated on their face, with a median reduction of 64.6% (mean 59.9%±38.6%) compared with a median reduction of 0% in the placebo group (mean 19.9%±72.0%). This effect was even more prominent in the Per-Protocol population (N=83) where the median reduction of Grade 2 (or 3) AK lesions on the face was 80% in the 10% VDA-1102 ointment group compared to a median reduction of 0% in the placebo group. Reduction in Grade 2 (or 3) AK lesions was also statistically significant in the combined face and scalp populations (p=0.029), demonstrating a median reduction of 56.3% for the 10% VDA-1102 ointment group (mean 53.1%±41.9%) compared to a 0% median reduction in the placebo group (mean 25.9%±69.8%).

No Grade 3 lesions developed during the study in the two VDA-1102 ointment treatment groups, while 2 subjects in the placebo treated groups developed at least one Grade 3 lesion, despite having no Grade 3 lesions at baseline. A confirmatory Phase 2b study for VDA-1102 ointment in AK is planned for 2018.

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 HK2 (hexokinase 2) from mitochondrial VDAC (voltage dependent anion channel) 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 actinic keratosis (AK), cutaneous squamous cell carcinoma (cSCC), and cutaneous T-cell lymphoma (CTCL). VDA-1102 ointment has successfully completed a Phase 2a proof-of-concept study in subjects with AK, demonstrating efficacy, safety, and tolerability. 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 on the face, scalp, and/or extremities 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 disadvantages to public health. The limited tolerability of current treatment options greatly decreases the willingness of patients to be treated, compliant, and/or retreated. 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- and dermatology-focused pharmaceutical company, developing novel drugs to help people suffering from a range of 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, leading to well-tolerated and efficacious treatments. Vidac is developing VDA-1102 as a topical treatment for AK and other skin malignancies, and as a parenteral drug for treatment of solid tumors. For more information regarding Vidac Pharma, please visit www.vidacpharma.com.

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