Foamix Announces Dosing of First Patient in Phase 3 Rosacea Clinical Trials for FMX103 Minocycline Foam 1.5%

REHOVOT, Israel and BRIDGEWATER, New Jersey, June 12, 2017 /PRNewswire/ -- Foamix Pharmaceuticals Ltd. (NASDAQ: FOMX), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical foams to address unmet needs in dermatology, today announced that the first patient has been dosed in its Phase 3 program to evaluate the efficacy and safety of its topical Minocycline Foam 1.5%, FMX103.

"The initiation of this Phase 3 program marks an important milestone for Foamix's FMX103 and it moves us closer to our goal of providing an effective and convenient new treatment for the millions of patients suffering from moderate-to-severe rosacea," stated Dr. Dov Tamarkin, CEO of Foamix. "The design and clinical endpoints for this Phase 3 program are based on the results of our Phase 2 study, which was conducted in Germany with 233 rosacea patients, and our recent end-of-phase 2 meeting with the FDA. We expect topline data in mid-2018."

Study Design

The Phase 3 program consists of two multi-center studies. Each study will enroll approximately 750 patients with moderate-to-severe papulopustular rosacea into a 12-week double-blind, vehicle-controlled phase. This will be followed by a 9-month open-label safety extension phase with the active 1.5% minocycline foam. Both studies will be conducted at multiple sites throughout the United States. Patients will be randomized on a 2:1 basis (1.5% minocycline foam vs vehicle) and treated once daily for 12 weeks in the initial double-blind portions of the studies.

The primary efficacy endpoints are (1) the proportion of patients achieving success at week 12 based on an Investigator's Global Assessment (success is defined as a score of "clear" or "almost clear" and at least a 2-grade improvement from baseline), and (2) the mean change from baseline in inflammatory lesion counts in each treatment group at week 12. Safety evaluation will include reported adverse events, assessments of tolerability, clinical laboratory tests and vital signs.

Patients who complete the 12 weeks of treatment will have the option to continue in a long-term open-label safety extension to evaluate the safety of intermittent use of FMX103 for

up to an additional 9 months.

Foamix expects to report top-line results from the blinded phase of the clinical trials mid-2018.

About Rosacea

Papulopustular rosacea is a chronic skin disease causing inflammatory lesions (papules and pustules) on the nose, cheeks, chin and forehead. It can create psychosocial burdens, such as embarrassment, anxiety and low self-esteem that can adversely affect quality of life. Rosacea is most frequently seen in adults between 30 and 50 years of age. It affects more than 16 million people in the United States.

There is no known cure for rosacea. Mild papulopustular rosacea is treated by topical antimicrobials (metronidazole, clindamycin and ivermectin), azelaic acid or retinoids, while the mainstay for the treatment of moderate-to-severe rosacea are systemic antibiotics such as minocycline and doxycycline (Drugs (2014) 74:1457-1465).

About FMX103

FMX103 is Foamix's proprietary 1.5% minocycline foam formulation for moderate-to-severe papulopustular rosacea. In 2016, Foamix completed a dose-ranging Phase 2 clinical trial of FMX103 involving 233 patients with moderate-to-severe rosacea enrolled at 18 sites throughout Germany. This trial demonstrated both clinically and statistically significant efficacy for the 1.5% concentration of minocycline foam versus the vehicle control group. In the Phase 2 trial, patients on the 1.5% dose of minocycline foam had a 61.4% reduction in inflammatory papulopustular lesions at week 12 compared to a 29.7% reduction in the vehicle control group ($p<.001$, ANCOVA, multiple imputation method). Additionally, 25.3% of patients on FMX103, 1.5% achieved Investigator's Global Assessment ("IGA") success at week 12 (defined as a score of "clear" or "almost clear" (Grade 0 or 1), and improvement of at least 2 grades), versus 7.7% of patients on vehicle ($p=.001$, ITT Population; Cochran–Mantel–Haenszel test; multiple imputation method). No drug-related systemic side effects were observed. The FMX103 application is intended to be filed under the 505(b)(2) regulatory pathway.

About Foamix Pharmaceuticals

Foamix is a specialty pharmaceutical company focused on the development and commercialization of proprietary, innovative and differentiated topical drugs for dermatological therapy.

Our clinical stage product candidates include FMX101, our novel minocycline foam for the treatment of moderate-to-severe acne, FMX103 for the treatment of moderate-to-severe rosacea, FMX102 for the treatment of impetigo, and FDX104, our doxycycline foam for the management of acne-like rash induced by EGFRI anticancer drugs.

In addition, we have development and license agreements relating to our technology with various pharmaceutical companies including Bayer HealthCare and others.

For more information, please visit www.foamixpharma.com.

Forward Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the U.S. Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, such as statements regarding assumptions, expectations, forecasts, beliefs or intentions related to financial results, commercial results, timing and results of clinical trials and U.S. FDA and other regulatory agencies authorizations. Forward-looking statements are based on our current knowledge and our present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors including, but not limited to, unexpected delays, excess costs or unfavorable results of clinical trials, delays or denial in the U.S. FDA approval process, additional competition in the company's markets, denial of reimbursement by third party payors or inability to raise additional capital. We discuss many of these risks in greater detail under the heading "Risk Factors" in our most recent Annual Report on Form 20-F (File No. 17625089) filed on February 21, 2017 and elsewhere in that Annual Report. Any forward-looking statements made herein speak only as of the date of this release and Foamix undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

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