# Foamix Announces Dosing of First Patient in Third Phase 3 Acne Study for Minocycline Foam FMX101

**Company validates clinical development pathway via FDA Type B Meeting**

REHOVOT, Israel, and BRIDGEWATER, New Jersey, Aug. 3, 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 third Phase 3 study (Study FX2017-22) to evaluate the efficacy and safety of its topical Minocycline Foam 4%, FMX101 in patients with moderate-to-severe acne.

"During a recent Type B Meeting, the FDA confirmed that statistically significant findings from a third study would constitute replication of the Study FX2014-05 results, and would be sufficient to establish an efficacy claim. This confirmation supports our plans for conducting a third Phase 3 study," said David Domzalski, CEO of Foamix. "Initiating this study within four months of the release of the Study 04 and Study 05 results is a direct reflection of the focus and commitment of the entire Foamix team to bring new and innovative solutions to patients."

**Study Design (FX2017-22)**

FX2017-22 is a double-blind, vehicle-controlled, multi-center study that will enroll 1,500 patients with moderate-to-severe acne. This study will be conducted at approximately 80 sites throughout the United States. Patients will be randomized 1:1 to either 4% minocycline foam (FMX101) or vehicle, with once daily treatment for 12 weeks.

The primary 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 category 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.

As a result of the FDA discussion on the design of a third study, Foamix has decided to maintain the design agreed upon with FDA for Study FX2014-05.

Foamix will continue to run, in parallel, the long-term open-label safety extension to evaluate the safety of intermittent use of FMX101 under Study 04 and Study 05. The open-label safety extension is scheduled to complete by year-end 2017.

Foamix expects to report top-line results from Study FX2017-22 by mid-2018.

**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 acne market, 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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