



Foamix Announces Additional Positive Topline Results from Third Phase 3 Trial (Study FX2017-22) Evaluating FMX101 Topical Minocycline Foam for Moderate-to-Severe Acne

October 1, 2018

- **Statistically significant improvement demonstrated in reduction of non-inflammatory lesions**
- **Dermal tolerability scores consistent with previous Phase 3 studies**
- **Re-analysis including patients from discontinued investigator site consistent with primary ITT analysis for both co-primary endpoints, reflecting highly statistically significant results**

REHOVOT, Israel and BRIDGEWATER, N.J., Oct. 01, 2018 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (NASDAQ: FOMX), ("Foamix"), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical therapies to address unmet needs in dermatology, today announced additional topline results from its third Phase 3 clinical trial (FX2017-22) of FMX101 for the treatment of moderate-to-severe acne. As the company previously communicated, the study met both co-primary endpoints of (1) absolute change from baseline in inflammatory lesion count at Week 12, and (2) Investigator Global Assessment ("IGA") treatment success at Week 12, defined as an IGA score of 0 or 1, and at least a 2-grade improvement (decrease) from baseline. Results from both co-primary endpoints demonstrated highly statistically significant results for FMX101 vs vehicle, with p-values <0.0001. The safety profile of FMX101 was consistent with that determined from the two prior Phase 3 studies (FX2014-04 and FX2014-05). Additional study results and analysis are as follows:

Key Secondary Efficacy Assessments

1. Significant reduction in the number of non-inflammatory lesions

The mean reduction in non-inflammatory lesion count at Week 12 relative to Baseline was -18.83 for the FMX101 treatment group and -15.67 for the vehicle treatment group (p=0.0080, ANCOVA, ITT, MI).

2. Percent change in inflammatory lesion count at Week 3, 6, 9 and 12

At Week 12, the percent change in inflammatory lesion count was -56% for the FMX101 treatment group and -43% for the vehicle treatment group (p<0.0001). A statistically significant difference in percent reduction in inflammatory lesion count between treatment groups was also observed at week 3, 6, and 9 [all assessed timepoints] (p<0.0001).

During the study, quality issues were identified at one clinical site requiring discontinuation of the site from the study and removal of corresponding subject data from the intent-to-treat population (19 enrolled subjects). Supplemental re-analysis of both co-primary endpoints including data from these subjects demonstrated comparable results to the primary analyses with equally high statistical significance between the treatment groups (p<0.0001 for both analyses).

Safety and Tolerability – Dermal Tolerability

Dermal tolerability was assessed by scoring the severity of itching, skin peeling, erythema, hyperpigmentation and dryness on a scale of 0 to 3 with 0 = none, 1 = mild, 2 = moderate and 3 = severe. These assessments were made at study weeks 3, 6, 9 and 12.

At Week 12, greater than 95% of scores were 0 (none) or 1 (mild). These tolerability scores were comparable with the equivalent assessments made in the Company's earlier phase 3 studies (FX2014-04 and FX2014-05).

"The data from this confirmatory Phase 3 study are impressive, and the reductions in inflammatory lesions and proportion of patients achieving clinical success appear consistent with prior studies of FMX101, including Study 05," stated Edward Lain, MD MBA, Chief Medical Officer, Sanova Dermatology and Principal Investigator in Study FX2017-22. "The treatment benefits of oral antibiotics, including minocycline, have been well documented in moderate-to-severe acne but their use is limited by systemic side effects, which can be serious. The strong body of clinical data on FMX101, including the results from this most recent Phase 3 trial, suggest that it may offer patients an efficacious treatment in a convenient and safe topical foam formulation. I believe that, if approved, it has the potential to address a significant unmet need in this difficult to treat condition."

David Domzalski, CEO of Foamix, will present these study results along with an overall corporate update at the Cantor Fitzgerald Global Healthcare Conference tomorrow, October 2nd at 12:15pm Eastern Time. Updated presentation materials are available on the company's website under "[Investors – Events and Presentations](#)" at www.foamix.com.

Cantor Fitzgerald Global Healthcare Conference 2018

Date: Tuesday, October 2
Time: 12:15pm Eastern Time
Location: InterContinental New York Barclay Hotel
Webcast: <http://wsw.com/webcast/cantor7/fomx/>

About Acne

Acne is a chronic, inflammatory skin condition that affects the skin's oil glands and hair follicles. It is characterized by both inflammatory lesions (papules and pustules) and non-inflammatory lesions (open and closed comedones) affecting primarily the face and other areas of the body. Acne

affects approximately 40 to 50 million people in the U.S. alone, of whom approximately 10 million have moderate-to-severe disease that significantly impacts self-esteem and quality of life. For most people, acne diminishes over time and tends to disappear or decrease, by age 25. However, some individuals, particularly women, can experience acne much later in life.

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 leading clinical stage product candidates are FMX101, our novel minocycline foam for the treatment of moderate-to-severe acne and FMX103, our novel minocycline foam for the treatment of rosacea. We continue to pursue research & development of our proprietary, innovative foam technologies for the treatment of various skin conditions. We currently have development and license agreements relating to our technology with various pharmaceutical companies including LEO Pharma, as assignee to our license with Bayer, and others.

Foamix uses its website (www.Foamix.com) as a channel to distribute information about Foamix and its product candidates from time to time. Foamix may use its website to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor the Foamix website in addition to following its press releases, filings with the Securities & Exchange Commission ("SEC"), public conference calls, and webcasts.

Forward Looking Statements

This 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 created by those sections. 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 in clinical trials or announcement of results, excess costs or unfavorable results of clinical trials, delays or denial in the U.S. FDA approval process, additional competition in the acne and dermatology markets, denial of reimbursement by third party payors or inability to raise additional capital, our ability to recruit and retain key employees and our ability to stay in compliance with applicable laws, rules and regulations. We discuss many of these risks in greater detail in our annual and other periodic filings with the SEC, including under the heading "Risk Factors" in our most recent annual report. Although we believe these forward-looking statements are reasonable, they speak only as of the date of this announcement and Foamix undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law. Given these risks and uncertainties, you should not rely upon forward-looking statements as predictions of future events.

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Source: Foamix, Ltd.