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

September 11, 2018

FMX101 Demonstrated Highly Statistically Significant Improvement Compared with Vehicle in Both Co-Primary Efficacy Endpoints

Conference Call and Webcast Tomorrow at 8:00 a.m. EDT

REHOVOT, Israel and BRIDGEWATER, N.J., Sept. 11, 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 the topline results of its third Phase 3 clinical trial (FX2017-22) of FMX101 for the treatment of moderate-to-severe acne. 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. The safety profile of FMX101 was found to be consistent with that determined from the two prior Phase 3 studies (FX2014-04 and FX2014-05). Foamix plans to continue to share data from this study as they become available over the remainder of 2018.

"We are extremely pleased with the topline results of this confirmatory Phase 3 trial. These study results should support a finding that FMX101 appears to be safe and effective in the treatment of moderate-to-severe acne," said David Domzalski, CEO of Foamix. "This is the most significant milestone to date for Foamix and brings us closer to helping patients who struggle with the physical and psycho-social effects of acne. If approved, we believe FMX101 would be the first topical minocycline product available for patients in the United States."

Mr. Domzalski further stated, "On behalf of Foamix, I wish to thank all patients, caregivers/guardians, investigators and support staff who participated in the advancement of this clinical program. With the conclusion of this third study, we are now in position to finalize our efforts to submit the company's first NDA."

"The data from this confirmatory Phase 3 study are impressive, and the reductions in inflammatory lesions and the proportions of subjects achieving treatment success highlight significant improvements in disease severity for those that received FMX101 in the study," stated Iain A. Stuart, Ph.D., Senior Vice President, Research & Development, Foamix. "The strong body of clinical data we have generated with 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. If approved, it has the potential to address a significant unmet need in this difficult to treat condition."

FX2017-22 Trial Design and Results
The double-blind, randomized, vehicle-controlled Phase 3 trial enrolled 1507 patients with moderate-to-severe acne at 89 sites in the United States. Patients were randomized to receive either FMX101 minocycline foam (4%) or vehicle foam once daily for 12 weeks. The co-primary efficacy endpoints were: (1) the absolute change from baseline in the number of inflammatory lesions, and (2) Investigator Global Assessment (IGA) treatment success, where success is defined as an IGA score of 0 or 1, and at least a 2-grade improvement (decrease) from baseline. Safety and tolerability were also evaluated.

Baseline Acne Severity
The mean inflammatory lesion count at baseline was 30.7 and 30.8 for the FMX101 and vehicle treatment groups, respectively. The proportion of subjects with an IGA score of 3 ("moderate") or 4 ("severe") was 84.0% and 16.0%, respectively, in the FMX101 treatment group and 83.5% and 16.5%, respectively, in the vehicle treatment group.

Co-Primary Efficacy Assessments

1. **Significant reduction in the number of inflammatory lesions**

The mean reduction in inflammatory lesion count at Week 12 relative to baseline was -16.93 for the FMX101 treatment group and -13.40 for the vehicle treatment group ($p<0.0001$, ANCOVA, ITT, MI).

2. ***Significant improvement in Investigator's Global Assessment (IGA) treatment success***

The proportion of subjects that achieved IGA treatment success at Week 12 was 30.80% for the FMX101 treatment group and 19.63% for the vehicle treatment group ($p<0.0001$, CMH test - stratified by analysis center, ITT, MI).

Safety and Tolerability
The most commonly reported adverse event in the study was (viral) upper respiratory tract infection (6.4% in both FMX101 and vehicle treatment groups). There were no treatment-related serious adverse events. A total of 5 subjects discontinued the study due to an adverse event (3 in the FMX101 treatment group and 2 in the vehicle treatment group). FMX101 appeared to be generally safe and well-tolerated.

Conference Call & Webcast (with slides)
Wednesday, September 12th @ 8:00am Eastern Time

Toll Free:	800-239-9838
International:	323-794-2551
Conference ID:	8358883

Webcast: http://public.viavid.com/index.php?id=131341

Replays, Available through September 26th

Toll Free: 844-512-2921
International: 412-317-6671
Replay PIN: 8358883

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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