Foamix Announces Positive Topline Results from Phase 3 Program Evaluating FMX103 Topical Minocycline Foam for Moderate-to-Severe Papulopustular Rosacea

November 7, 2018

FMX103 Demonstrated Highly Statistically Significant Improvement Compared with Vehicle in Both Co-Primary Efficacy Endpoints

Conference Call and Webcast Today at 8:30 a.m. ET

REHOVOT, Israel and BRIDGEWATER, N.J., Nov. 07, 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 from its Phase 3 program evaluating FMX103 1.5% minocycline foam, in the treatment of moderate-to-severe papulopustular rosacea. Studies FX2016-11 and FX2016-12 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 FMX103 was found to be favorable. Data from study FX2016-13 evaluating the long-term safety of FMX103 are expected to be reported in the first half of 2019.

Dr. Linda Stein Gold, a dermatologist at Henry Ford Health System, principal investigator in Study FX2016-12 and advisor to Foamix commented on the data, "These results are impressive, with treatment success being achieved in a high proportion (approximately 50%) of patients as well as clinically meaningful reductions in inflammatory lesions. Papulopustular rosacea is a serious medical condition that can cause considerable psychological distress to affected patients. Despite the prevalence of disease, there has been limited innovation from industry. If approved, based on the compelling data from these clinical trials, I believe FMX103 could become a valuable treatment approach for rosacea."

"We are very pleased with these top line Phase 3 results of FMX103, which demonstrate that FMX103 can provide a meaningful improvement in disease symptoms and confirm the positive results from previous clinical studies," said David Domzalski, CEO of Foamix. "FMX103 has the potential to address significant unmet medical needs in papulopustular rosacea. This product leverages our proprietary foam technology, and we believe if FMX103 is approved it would be the first topical minocycline product available for rosacea patients. We will continue to share further data from these studies as they become available over the remainder of 2018, and our goal is to file an NDA for FMX103 in the U.S. in 2019."

"This is the second positive Phase 3 outcome for a Foamix product in the past two months, as we also achieved success in our third, confirmatory Phase 3 trial of FMX101 4% minocycline foam for the treatment of moderate-to-severe acne," continued Mr. Domzalski. "The success of these Phase 3 trials provides further validation for our foam platform and represents the maturing of Foamix's clinical pipeline."

FX2016-11 and FX2016-12 Trial Design and Results

These identical, double-blind, randomized, vehicle-controlled Phase 3 studies enrolled a total of 1522 subjects, 18 years of age and older, with moderate-to-severe papulopustular rosacea at 100 sites in the United States (FX2016-11 enrollment: 751 subjects, FX2016-12 enrollment: 771 subjects). Patients were randomized 2:1 to receive either FMX103 minocycline foam (1.5%) or vehicle foam once daily for 12 weeks, respectively. 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 Papulopustular Rosacea Severity

In study FX2016-11, the mean inflammatory lesion count at baseline was 28.5 and 29.0 for the FMX103 and vehicle treatment groups, respectively. The proportion of subjects with an IGA score of 3 ("moderate") or 4 ("severe") was 89.7% and 10.3%, respectively, in the FMX103 treatment group and 86.7% and 13.3%, respectively, in the vehicle treatment group.

In study FX2016-12, the mean inflammatory lesion count at baseline was 30.0 and 30.2 for the FMX103 and vehicle treatment groups, respectively. The proportion of subjects with an IGA score of 3 ("moderate") or 4 ("severe") was 86.2% and 13.8%, respectively, in the FMX103 treatment group and 82.9% and 17.1%, respectively, in the vehicle treatment group.

Co-Primary Efficacy Assessments

The following table provides an overview of the efficacy results obtained for both co-primary endpoints for each study. In all cases, FMX103 demonstrated statistically significant improvement in subject disease severity when compared to vehicle foam.

FX2016-11 and FX2016-12 Co-Primary Endpoint Results

Study	**FX2016-11**			**FX2016-12**		
Co-primary Endpoint	**FMX103 N=495**	**Vehicle N=256**	**p-value**	**FMX103 N=514**	**Vehicle N=257**	**p-value**
Absolute Change from Baseline in Inflammatory Lesion count at Week 12*	-17.57	-15.65	0.0031	-18.54	-14.88	<0.0001
IGA treatment success at Week 12, defined as an IGA score of 0 or 1, and at least a 2-grade improvement (decrease) from	52.1%	43.0%	0.027	49.1%	39.0%	0.0077

baseline**

*ANCOVA, ITT, MI; **CMH test - stratified by analysis center, ITT, MI

Safety and Tolerability

The most commonly reported adverse event in both studies was upper respiratory tract infection (FX2016-11: 0.8% in the FMX103 treatment group and 2.0% in the vehicle treatment group. FX2016-12: 2.9% in the FMX103 treatment group and 3.1% in the vehicle treatment group). There were no treatment-related serious adverse events. A combined total of 9 subjects discontinued from FX2016-11 and FX2016-12 due to an adverse event (7 in the FMX103 treatment groups and 2 in the vehicle treatment groups). FMX103 appeared to be generally safe and well-tolerated.

Conference Call and Live Webcast (with slides) @ 8.30am Eastern Time

U.S. toll free	877-830-2597
International	785-424-1743
Passcode:	TOPLINE

Webcast: http://public.viavid.com/index.php?id=132210

Replays, Available through November 21st:

US toll free:	844-512-2921
International:	412-317-6671
Replay PIN:	13221

About Papulopustular 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 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 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, rosacea 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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