Foamix Announces Positive Results from Phase 3 Open-Label Safety Extension Evaluating FMX-101 Topical Minocycline Foam for Treatment up to 1 Year

January 4, 2018

Long Term Data on FMX-101 in Moderate-to-Severe Acne to be Presented at Winter Clinical Dermatology Conference (January 12th-17th)

REHOVOT, Israel and BRIDGEWATER, N.J., Jan. 04, 2018 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (NASDAQ:FOMX), (“Foamix”), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical foams to address unmet needs in dermatology, today announced positive safety data for its Phase 3 open-label safety extension study, evaluating FMX-101 in moderate-to-severe acne for a treatment period of up to 1 year.

The open-label safety extension enrolled a total of 657 patients, all of whom had completed 12 weeks of FMX-101 or vehicle treatment in the preceding double-blind phases of FX2014-04 or FX2014-05. Patients continued for up to an additional 40 weeks of open-label treatment with FMX-101.

291 patients completed a total of 52 weeks on FMX-101 therapy which is in excess of the subject sample size requirements specified in the regulatory guidance for this type of safety evaluation (ICH E1A, 1995). The key findings from the study are as follows:

- Non-dermal adverse events were comparable in type and frequency with those reported during the double-blinded portion of FX2014-04 and FX2014-05. The most frequently reported treatment-emergent adverse event was nasopharyngitis (common cold). In the open-label extension, 3 patients discontinued the study for non-dermal adverse events – abdominal pain (2 patients), back pain (1 subject). No serious drug-related adverse events were reported.

- Application site adverse events occurred in less than 2% of patients during the additional 40 weeks of open-label treatment with FMX-101. Four patients discontinued in the study for an application site adverse event – worsening of acne (2 patients), contact dermatitis (one subject), and localized facial edema (1 subject). In the assessment of facial dermal tolerability at Week 52, more than 95% of patients had “none” or “mild” signs and symptoms (erythema, dryness, hyperpigmentation, peeling, and itching), and no severe local tolerability scores were recorded.

- Subject satisfaction with FMX-101 treatment remained high when re-assessed at Week 52 which was consistent with scores obtained at Week 12 (end of double-blind phase).

“We are extremely encouraged that our comprehensive safety evaluation of FMX-101 has validated earlier data demonstrating that FMX-101 appears to be well tolerated, with an acceptable safety profile and very positive patient survey results in the treatment of moderate-to-severe acne vulgaris,” said David Domzalski, CEO of Foamix.

Data from this study will be presented in a poster forum at the Winter Clinical Dermatology Conference to be held January 12th – 17th at the Hyatt Regency in Maui, Hawaii. In addition, Foamix will also present the following posters from the FMX-101 development program at the conference:

- Pharmacokinetic Evaluation of Once-Daily Topical 4% Minocycline Foam in Adult and Pediatric Patients with Moderate-to-Severe Acne in Two Phase 1 Studies

- The Efficacy and Safety of FMX101, Minocycline Foam 4%, for the Treatment of Acne Vulgaris: A Pooled Analysis of Two Phase 3 Studies

About Acne

Acne is characterized by areas of scaly red skin, non-inflammatory blackheads and whiteheads, inflammatory lesions, papules and pustules and occasionally boils and scarring. It affects approximately 40 to 50 million people in the U.S. alone, of whom approximately 10 million suffer from moderate-to-severe acne. For most people, acne diminishes over time and tends to disappear or decrease, by age 25. However, some individuals continue to suffer from acne well into their 30s, 40s and later.

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, FMX102 for the treatment of impetigo, FMX103 for the treatment of rosacea 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.
Forward Looking Statements

This press release may include 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 that may be 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.

Contact:
Ilan Hadar
Foamix Pharmaceuticals Ltd.
+972-8-9316233
IR@foamixpharma.com

U.S. Investor Relations
Michael Rice
LifeSci Advisors, LLC
646-597-6979
mrice@lifesciadvisors.com

Source: Foamix, Ltd.