Foamix Announces Positive Results from Phase 3 Open-Label Safety Study Evaluating FMX103 Topical Minocycline Foam for Treatment up to 1 Year

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Long Term Data on FMX103 Demonstrated a Generally Favorable Safety Profile; 81.6% of Patients Achieved Clear or Almost Clear Skin at 52 Weeks

REHOVOT, Israel and BRIDGEWATER, N.J., Feb. 27, 2019 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (NASDAQ:FOMX) ("Foamix" or the "Company"), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical therapies to address unmet needs in dermatology, today announced positive safety and efficacy data for its Phase 3 open-label safety study (FX2016-13), evaluating FMX103 in moderate-to-severe papulopustular rosacea for a treatment period of up to 1 year.

The open-label safety study enrolled a total of 505 patients, all of whom had completed 12 weeks of FMX103 or vehicle treatment in the preceding double-blind studies (FX2016-11 or FX2016-12). Patients continued on open-label treatment with FMX103 for up to an additional 40 weeks.

Four hundred and sixty-five (465) patients received FMX103 therapy for at least 26 weeks and 272 patients received FMX103 therapy for a total of 52 weeks, which is in excess of the subject sample size requirements specified in the regulatory guidance for this type of safety evaluation (ICH E1A, 1995). A total of 410 patients completed participation in the study. The key safety findings from the study are as follows:

- Non-cutaneous adverse events were comparable in type and frequency with those reported during the double-blinded portion of studies FX2016-11 and FX2016-12. The most frequently reported treatment-emergent adverse event was upper respiratory tract infection i.e. common cold (3.8%). Four (4) patients discontinued the study due to a non-application site adverse event – mydriasis, anemia/leukocytosis, appendicitis and enchondromatosis. No serious drug-related adverse events were reported.

- Cutaneous adverse events occurred in 1% or less of patients during the additional 40 weeks of open-label treatment with FMX103 with the most frequently reported treatment emergent adverse event being contact dermatitis (1.0%). Two (2) patients discontinued in the study for an application site adverse event – worsening of rosacea and contact dermatitis. In the assessment of facial dermal tolerability at Week 52, more than 95% of patients had either no signs or symptoms, or signs/symptoms that were classified "mild" (burning/stinging, flushing/blushing, dryness, itching, peeling and hyperpigmentation). The severity of key clinical manifestations of rosacea - erythema and telangiectasia - had both significantly improved when compared to Baseline of the preceding double-blind studies.

- Patient satisfaction with FMX103 treatment remained high when re-assessed at Week 52 which was consistent with scores obtained at Week 12 (end of double-blind studies).

Open label efficacy was also assessed as a secondary objective throughout the additional 40-week FMX103 treatment course. The key efficacy findings from the study were:

- Mean absolute reduction of inflammatory lesion count, compared to Baseline of the preceding double-blinded study (FX2016-11 or FX2016-12), was -23.0 for subjects treated with FMX103 for 52 weeks and –22.5 for subjects treated for 40 weeks. Corresponding mean inflammatory lesion counts at Baseline of the preceding double-blind studies for these groups were 28.8 and 28.7, respectively (all observed cases).

- The proportion of subjects achieving Investigator Global Assessment (IGA) treatment success at Week 52, defined as at least a 2-step improvement resulting in a 0 (clear) or 1 (almost clear) score compared to Baseline of the preceding double-blinded study (FX2016-11 or FX2016-12), was 81.6% for subjects treated with FMX103 for 52 weeks and 76.0% for subjects treated for 40 weeks (all observed cases).

"We are encouraged that our comprehensive safety evaluation has validated prior data from studies FX2016-11 and FX2016-12 demonstrating that FMX103 appears to be well tolerated with an acceptable overall safety profile and high patient satisfaction in the treatment of moderate-to-severe papulopustular rosacea," said David Domzalski, CEO of Foamix. "These data represent the final clinical study dataset necessary for inclusion in the NDA submission for FMX103. The Foamix team is diligently working through submission preparations across the CMC, preclinical and clinical disciplines for what we plan to be our second NDA submission to the US FDA."

"These impressive safety results underscore our belief that FMX103 has the potential to address significant unmet needs in the management of this difficult to treat condition. We are also pleased to see evidence of continued improvements in both inflammatory lesion reduction and in IGA treatment success scores beyond what was reported for the co-primary endpoints at Week 12," said Dr Iain Stuart, Chief Scientific Officer of Foamix. "Current therapies generally provide little relief from symptoms and, as a consequence, patients continue to seek alternatives. We look forward to continuing to communicate data on FMX103, as well as on our acne candidate, FMX101, over the course of 2019."

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 (JAAD (2015) 72:749-758). 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, public conference calls, and webcasts.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the future development plans of FMX101 and FMX103 and the Company's commercial activities. All statements other than statements of historical facts are forward-looking statements. Any forward-looking statements are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but not limited to, determination by the FDA that results from clinical trials are not sufficient to support registration or marketing approval of FMX101; the risk that FMX101 product candidate will not be successfully developed, approved or commercialized; unexpected delays in clinical trials or announcement of results; our ability to effectively and timely conduct clinical trials in light of excess costs or unfavorable results of clinical trials; delays or denial in the U.S. regulatory approval process and the risks that the current or planned clinical trials will be insufficient to support future regulatory submissions or to support marketing approval in the United States of our product candidates; additional competition in the acne and dermatology markets; risks associated with denial of reimbursement by third party payors; our ability to raise additional capital; and our ability to recruit and retain key employees. For a discussion of other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in our most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in our subsequent filings with the Securities and Exchange Commission. Although we believe these forward-looking statements are reasonable, they speak only as of the date of this release and we undertake no obligation to update this information 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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