Foamix Announces Publication of Phase 3 Studies Evaluating FMX103 for the Treatment of Papulopustular Rosacea in Journal of the American Academy of Dermatology

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REHOVOT, Israel, and BRIDGEWATER, N.J., Feb. 06, 2020 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX) ("Foamix" or the "Company"), a specialty pharmaceutical company, announced today the publication of the Company's Phase 3 studies FX2016-11 and FX2016-12 (Studies 11 & 12) in the *Journal of the American Academy of Dermatology* (JAAD). Studies 11 and 12 were conducted by Foamix to support the New Drug Application (NDA) submission of FMX103 (minocycline, 1.5% foam), which is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of moderate to severe papulopustular rosacea in adults.

"The publication of these data represents another step forward in our efforts to bring an innovative, topical medication to market for moderate to severe papulopustular rosacea, which can be challenging to treat and represents an unmet need in dermatology with few new treatment developments in recent years," said Dr. Iain Stuart, Chief Scientific Officer of Foamix. "We are proud that JAAD has accepted studies FX2016-11 and FX2016-12 (Studies 11 & 12) for publication, ensuring that a broad range of dermatology healthcare professionals globally will have access to these important data."

Highlights from the Phase 3 Program:

- Both studies demonstrated high statistically significant superiority of FMX103 compared with vehicle in both primary endpoints of absolute inflammatory lesion reduction and Investigator's Global Assessment (IGA) treatment success at Week 12 where approximately half of subjects achieved treatment success as defined by the latter endpoint.
- There was a statistically significant reduction in inflammatory lesions versus vehicle as early as Week 4 of treatment, and all subsequently assessed timepoints throughout the entire treatment course of the study.
- Subjects were no more likely to experience treatment-emergent adverse events (TEAEs) from FMX103 than from vehicle treatment. The majority of TEAEs were mild to moderate.
- More than 95% of subjects using FMX103 had skin tolerability scores of none or mild at the treatment application site at Week 12.
- Specifically for erythema as part of skin tolerability assessments, 5.5% and 6.6% of subjects who received FMX103 in Studies 11 and 12 respectively, were assessed as being clear or almost clear at Baseline. At Week 12, 40.9% and 48.3% of subjects who received FMX103 respectively were assessed as clear or almost clear of erythema.

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 papulopustular rosacea are oral antibiotics (Drugs (2014) 74:1457-1465).

About Foamix Pharmaceuticals
Foamix is a specialty pharmaceutical company working to solve some of today's most difficult therapeutic challenges in dermatology and beyond.

With expertise in topical medicine innovation as a springboard, the Company is working to develop and commercialize solutions that were long thought impossible, including the world's first topical minocycline, AMZEEQ. Its proprietary Molecule Stabilizing Technology (MST™) is utilized in the Company's dermatology products and in other products currently in development: FMX103 for the potential treatment of moderate to severe papulopustular rosacea and FCD105 for the potential treatment of moderate to severe acne.

Foamix is a different type of specialty pharmaceutical company by design, driven to see the solutions, overcome barriers in all aspects of business, and reimagine what's possible for conditions with high unmet needs.

Foamix uses its website 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 Foamix's website in addition to following its press releases, filings with the Securities and Exchange Commission, public conference calls, and webcasts. For more information, visit www.foamix.com.

Forward-Looking Statements
This release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements in this press release which are not historical facts are forward-looking statements, including, but not limited to, statements regarding the future expectations, plans and prospects for Foamix; the Company's future development plans regarding FMX103, the potential approval of FMX103 by the FDA and the potential for FMX103 to address a significant unmet need. Forward-looking statements are based on Foamix's current knowledge and its 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, determination by the FDA that results from clinical trials are not sufficient to support registration or marketing approval of our product candidates; the

risk that our product candidates 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, rosacea 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. Foamix discusses many of these risks in greater detail in its periodic filings with the SEC, including under the heading “Risk Factors” in its most recent annual report and subsequent quarterly reports. Although Foamix believes 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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