



## Foamix Announces Publication of Phase 3 FMX101 Acne Study in Journal of American Academy of Dermatology

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REHOVOT, Israel and BRIDGEWATER, N.J., June 04, 2019 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (NASDAQ: FOMX), a clinical-stage pharmaceutical company that specializes in developing and commercializing proprietary topical therapies for dermatological conditions, announced today the peer review publication of the Phase 3 study FX2017-22 ("Study 22") in the [Journal of the American Academy of Dermatology](#) (JAAD). Study 22 was conducted by Foamix to support the New Drug Application (NDA) submission of FMX101, which is currently under review by the FDA for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients nine years of age and older.

"We are pleased that the prestigious JAAD has chosen to highlight Study 22 in its current edition," said Dr. Iain Stuart, Chief Scientific Officer of Foamix. "The American Academy of Dermatology is the largest and most influential dermatology group in the United States and JAAD is the ideal platform to share the results from this successful Phase 3 study with the broader clinical dermatology community. As FMX101 is the first topical formulation of minocycline to reach regulatory agency review for the treatment of any disease, publication of this pivotal study in JAAD is befitting of its uniqueness and a testament to the innovation happening at Foamix."

### Highlights from the study:

- The study showed high statistically significant superiority of FMX101 compared with vehicle in both primary endpoints of absolute inflammatory lesion reduction and IGA treatment success at week 12.
- FMX101 also met all secondary endpoints, showing statistically significant improvement in absolute reductions in both inflammatory lesions (papules, pustules and nodules) and non-inflammatory lesions (open and closed comedones).
- There was a statistically significant reduction in inflammatory lesions versus vehicle as early as week 3 of treatment, and all subsequently assessed timepoints throughout the entire treatment course of the study.
- Statistically, participants were no more likely to experience treatment-emergent adverse events (TEAEs) from FMX101 than from vehicle treatment. The majority of TEAEs were mild to moderate.
- More than 95% of participants using FMX101 had no or mild skin tolerability scores at the treatment application site at week 12.

"These data show that FMX101 has potential as both a safe and effective option for patients," said Dr. T. Joseph Raouf of the Encino Research Center in Encino, CA., a clinical investigator on the study. "As a convenient, topical formulation of minocycline for acne, FMX101 has been designed to deliver the drug's bacteriostatic and anti-inflammatory effects while minimizing systemic absorption and the resulting safety concerns associated with oral minocycline. Given that acne is the most common skin condition in the United States, FMX101 has the potential to positively impact millions of people."

### 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 being developed for the treatment of moderate-to-severe acne, and FMX103, our novel minocycline foam being developed for the treatment of rosacea. We continue to pursue research & development of our proprietary, innovative topical technologies for the treatment of various skin conditions. We currently have development and license agreements relating to our technology with various pharmaceutical companies.

Foamix uses its website ([www.foamix.com](http://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 Foamix's website in addition to following its press releases, filings with the Securities and Exchange Commission, public conference calls, and webcasts.

### Forward-Looking Statements

This release includes forward-looking statements within the meaning of the 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 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, including specifically, its approval of FMX101; 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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