Foamix Submits New Drug Application to U.S. FDA Seeking Approval of FMX101 in Treatment of Moderate-to-Severe Acne

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REHOVOT, Israel and BRIDGEWATER, N.J., Dec. 21, 2018 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical therapies to address unmet needs in dermatology, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for FMX101 for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients 9 years of age and older.

“Submission of this NDA is yet another important milestone for Foamix, and potentially brings us one step further to commercial launch of FMX101,” commented David Domzalski, Chief Executive Officer. “We are making this submission following successful efficacy and safety outcomes in our Phase 3 program for FMX101 and incorporating guidance received from the FDA in a Type B pre-NDA meeting held earlier in 2018. We look forward to working with the Agency in its review of our application.”

The NDA submission is supported by the previously communicated results from two Phase 3 trials, FX2014-05 and FX2017-22. In these trials, FMX101 met both co-primary endpoints, demonstrating statistically significant improvements in inflammatory lesion count and Investigator Global Assessment (IGA) treatment success. In these trials, the safety profile of FMX101 was generally favorable and consistent throughout the clinical development program. The NDA submission also incorporates information on chemistry manufacturing and controls, and data from non-clinical toxicology studies on FMX101.

“The comprehensive body of clinical data we have generated with FMX101 suggest that it may offer patients an efficacious treatment in a convenient and well tolerated topical foam formulation,” stated Iain A. Stuart, Ph.D., Senior Vice President, Research & Development, Foamix. “If approved, FMX101 has the potential to address a significant unmet need in the treatment of moderate-to-severe acne, which remains a difficult to treat condition.”

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 A/S 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 Foamix’s 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. 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 are 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 our 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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