Foamix Announces FDA Acceptance of New Drug Application for FMX101 Minocycline Foam for the Treatment of Moderate-to-Severe Acne

March 7, 2019

PDUFA Target Action Date of October 20th, 2019

REHOVOT, Israel, and BRIDGEWATER, N.J., March 07, 2019 (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 the U.S. Food & Drug Administration (FDA) has accepted for review the New Drug Application (NDA) for FMX101. Foamix is seeking approval of FMX101 for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in patients nine years of age and older. The FDA has set October 20th, 2019 as the Prescription Drug User Fee Act (PDUFA) action date.

"The acceptance of this NDA is an important step toward potentially making FMX101 available to patients and we look forward to working with the FDA during this review process," said David Domzalski, Chief Executive Officer. "The application incorporates what we believe to be a very strong clinical data package. 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."

The NDA 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. No treatment-related serious adverse events have been identified in the FMX101 clinical development program, whereas the most common adverse event was upper respiratory tract infection. The NDA submission also incorporates information on chemistry manufacturing and controls, and data from non-clinical toxicology studies on FMX101.

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 and FMX103, the PDUFA date of FMX101, the potential approval of FMX101 by the FDA, the potential for FMX101 to address a significant unmet need 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 are 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 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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