

## **Foamix Reports Topline Results from Phase 3 Trials for FMX101 in Patients with Acne**

**Conference Call and Webcast Today at 8:30 a.m. EDT**

**REHOVOT, Israel, and BRIDGEWATER, New Jersey, March 27, 2017**

[/PRNewswire/](#) -- Foamix Pharmaceuticals Ltd. (NASDAQ: FOMX), today announced the topline results of its two Phase 3 clinical trials investigating FMX101, Trial 04 and Trial 05, in patients with moderate-to-severe acne.

In the intent-to-treat analysis, FMX101 demonstrated statistical significance compared to vehicle on both co-primary endpoints in Trial 05, but did not demonstrate statistical significance on one of the two co-primary endpoints in Trial 04, specifically IGA success.

Key top-line data:

- Co-primary endpoint - Absolute changes from baseline in the number of inflammatory lesions
  - Trial 04: -14.16 for FMX101 and -11.17 for the vehicle (p=0.0071); percent reductions were 43.93% for FMX101 and 34.03% for the vehicle (p<0.01)
  - Trial 05: -13.46 for FMX101 and -10.72 for vehicle (p=0.0058); percent reductions were 42.94% for FMX101 and 33.94% for vehicle in Trial 05 (p<0.01)
- Co-primary endpoint - Proportions of patients with Investigator's Global Assessment (IGA) success
  - Trial 04: 8.09% for FMX101 and 4.77% for the vehicle (p=0.2178)
  - Trial 05: 14.67% for FMX101 and 7.89% for the vehicle (p=0.0423)
- FMX101 was generally safe and well-tolerated.

"Whereas Trial 05 showed significance in both primary endpoints, Trial 04 did not meet significance for the IGA score endpoint," said Dov Tamarkin, Ph.D., CEO of Foamix. "Our team has not yet received the full data set and we intend to provide an update on the program as soon as we complete our analysis. As we have previously announced, the safety extensions for trials 04 and 05 are fully enrolled and continue as planned."

The two double-blind, randomized, placebo-controlled Phase 3 trials (Trials No. 04 and 05) included a total of 961 subjects with moderate-to-severe acne. Subjects were randomized to receive either FMX101 (minocycline foam 4%) or vehicle foam once daily over 12 weeks.

The two co-primary endpoints were the absolute change in the number of inflammatory lesions (papules and pustules); and the proportion of patients achieving success at week 12, as defined by an IGA score of "clear" or "almost clear" and at least a two-grade improvement from baseline at week 12.

As stated in our recent earnings call, as of Dec. 31, 2016, Foamix had cash and investments of \$131 million. We expect our cash and investments to fund our operations into mid-2019 including the continued development of our pipeline.

## **Conference Call Information**

***March 27th, 2017 @ 8.30am EDT***

Investors: 1-888-599-8686

International: 1-913-312-1486

Israel Investors: 1 80 924 6064

Conference ID: 9541840

Webcast: <http://public.viavid.com/index.php?id=123589>

Replays, Available through April 9th:

Toll-Free: 1-877-870-5176

International: 1-858-384-5517

Replay PIN: 9541840

## **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 clinical stage product candidates include FMX101, our novel minocycline foam for the treatment of moderate-to-severe acne, FMX103 for the treatment of moderate-to-severe rosacea, FMX102 for the treatment of impetigo, and FDX104, our doxycycline foam for the management of acne-like rash induced by EGFR anticancer drugs.

In addition, we have development and license agreements relating to our technology with various pharmaceutical companies including Bayer HealthCare and others.

For more information, please visit [www.foamixpharma.com](http://www.foamixpharma.com).

### **Forward Looking Statements**

This press release may include forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the U.S. Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. 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, excess costs or unfavorable results of clinical trials, delays or denial in the U.S. FDA approval process, additional competition in the acne market, denial of reimbursement by third party payors or inability to raise additional capital. We discuss many of these risks in greater detail under the heading "Risk Factors" in our most recent Annual Report on Form 20-F (File No. 17625089) filed on February 21, 2017 and elsewhere in that Annual Report. Any forward-looking statements that may be made herein speak only as of the date of this release and Foamix undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

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