Foamix Pharmaceuticals Announces Plans for Additional Phase 3 Trial for FMX101 in Moderate to Severe Acne

Pooled Analyses of Phase 3 Data Show Additional Statistically Significant Effects on Primary and Secondary Efficacy Endpoints

Commencement of 3rd Phase 3 Trial Planned mid 2017; Submittal of NDA Planned in H2-2018

Conference Call and Live Webcast with Slides at 8:30am ET Tomorrow, May 2nd

REHOVOT, Israel and BRIDGEWATER, NJ, May 1, 2017 /PRNewswire/ -- Foamix Pharmaceuticals Ltd. (NASDAQ: FOMX), ("Foamix"), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical foams to address unmet needs in dermatology, today announced results from additional analysis of the recently completed Phase 3 pivotal trials for its lead candidate FMX101 in moderate to severe acne.

Foamix has reviewed its regulatory strategy for FMX101. Based on the knowledge gained from the results of the first two pivotal trials (Trials 04 and 05), the company intends to conduct a third U.S. Phase 3 Trial, beginning mid-year, in patients with moderate to severe acne. If the results will be positive, this trial is expected to form the basis for a New Drug Application (NDA) which the company plans to submit in the second half of 2018.

"The totality of the clinical efficacy results for FMX101, including the further analysis we conducted of the Phase 3 data, are positive. Inconsistent results were noted in only one of the efficacy endpoints and the product appears to be safe and well tolerated," said Dov Tamarkin, Ph.D., CEO of Foamix. "Based on our analysis of the efficacy results from Trials 04 and 05, we plan to conduct a third trial to validate the results, with the same co-primary endpoints and enrollment criteria but with a substantially increased sample size. We intend to begin enrolling patients in this third trial mid-year. If approved, we believe FMX101 will be the first FDA-approved topical minocycline treatment for moderate-to-severe acne, a skin disorder that affects millions of people with potentially significant psychological and social implications."

Additional Phase 3 Analysis -- Pooled Data Statistically Significant for Both Co-Primary Efficacy Endpoints

Foamix previously announced topline data from two double-blind, randomized, placebo-

controlled Phase 3 trials (Trials 04 and 05) that had investigated FMX101in a total of 961 patients with moderate-to-severe acne. Patients had been treated with either FMX101 (minocycline foam 4%) or vehicle foam once daily over 12 weeks. The results of the co-primary endpoints (absolute change in the number of inflammatory lesions and the proportion of patients achieving investigator global assessment (IGA) success at week 12) for trials 04 and 05 were presented separately.

The new analysis, presented below, reflects the pooled data results for the co-primary endpoints from the two trials. Also presented are data from secondary efficacy endpoint analyses -- reduction of non-inflammatory lesion count at week 12, and percent changes in inflammatory lesion count at week 3, 6, 9 and 12.

As previously announced, FMX101 was generally safe and well tolerated with no drug-related serious adverse events identified.

Co-primary endpoint - Absolute change from baseline in inflammatory lesion count at week 12:

- Trial 04: reduction of 14.16 lesions (or -14.16) for FMX101 and reduction of 11.17 lesions (or -11.17) for the vehicle ($p<0.01$)
- Trial 05: -13.46 for FMX101 and -10.72 for vehicle ($p<0.01$)
- ***Pooled Analysis: Absolute change in inflammatory lesion count was -13.79 for the FMX101, 4% treatment group and -10.94 for vehicle (p=0.0001)***

Co-primary endpoint - Proportion of patients with Investigator's Global Assessment (IGA) success at week 12:

- Trial 04: IGA treatment success for FMX101, 4% treatment group was 8.09% versus 4.77% in vehicle ($p=0.2178$)
- Trial 05: IGA treatment success for FMX101, 4% treatment group was 14.67% versus 7.89% in vehicle ($p<0.05$)
- ***Pooled Analysis: IGA treatment success was 11.51% for FMX101, 4% treatment group and 6.34% for vehicle (p<0.05)***

Additional Phase 3 Analyses – Results Statistically Significant for Secondary Efficacy Endpoints

Secondary efficacy endpoint - Percent change from baseline in inflammatory lesion count at weeks 3, 6, 9 and 12:

- Trial 04: reduction of 29% for FMX101 vs. reduction of 19% for vehicle, or -29% vs. -19%, at week 3 ($p<.001$); -37% vs. -26% at week 6 ($p<.001$); -42% vs. -28% at week

9 (p<.0001); and -44% vs. -34% at week 12 (p<0.01)
- Trial 05: reduction of 34% for FMX101 vs. reduction of 21% for vehicle, or -34% vs. -21%, at week 3 (p<.0001); -39% vs. -27% at week 6 (p<.0001); -43% vs. -31% at week 9 (p<.001); and: -43% vs. -34% at week 12 (p<0.01)

Secondary efficacy endpoint – Absolute change from baseline in non-inflammatory lesion count at week 12

- Trial 04: reduction of 16.45 lesions (or -16.45) for the FMX101, 4% treatment group and reduction of 10.30 lesions (or -10.30) for the vehicle (p<0.01)
- Trial 05: -13.20 for the FMX101, 4% treatment group and -7.00 for the vehicle (p<0.05)
- ***Pooled Analysis: Absolute change in non-inflammatory lesion count was -14.76 for the FMX101, 4% treatment group and -8.64 for vehicle (p<0.01)***

FMX101 Third Pivotal Trial (Trial 22) to Commence by Mid-Year

In order to achieve the necessary statistical power, compared with the prior Phase 3 trials, the target patient enrollment number has been increased to 1,500. Patients will be randomized 1:1 to receive either FMX101 (minocycline foam 4%) or vehicle foam once daily over 12 weeks. The co-primary efficacy endpoints will be identical to the prior Phase 3 trials: 1) mean change from baseline in the inflammatory lesion count, and 2) proportion of patients with IGA scores of "Clear" or "Almost Clear", with improvement of at least two grades from baseline. The inclusion criteria will be consistent with the prior Phase 3 trials. The trial is planned to be conducted at approximately 80 clinical sites in the U.S.

Changes to Planned Phase 3 Trial Design for FMX103 in Papulopustular Rosacea

Foamix is also developing FMX103, minocycline foam 1.5%, a topical foam formulation of minocycline for the treatment of moderate-to-severe papulopustular rosacea. Based on the outcome of the Phase 3 studies for FMX101 and the increase in the number of patient to be enrolled to the third Phase 3 trial in acne, the company has also increased the sample size for the two planned Phase 3 studies for FMX103 in papulopustular rosacea. The sample size is being increased from 600 patients per trial to 750 patients per trial, for a total of 1500 patients across the two trials. As previously communicated, the company intends to commence the Phase 3 studies for FMX103 mid-year 2017.

Conference Call Information:

May 2, 2017 @ 8.30am EDT

Investors: 877-548-7911

International: 719-325-4769

Israel Investors: 1 80 925 8243

Conference ID: 8394096

Webcast: http://public.viavid.com/index.php?id=124227

Replays, Available through May 16 EDT

Toll-Free: 844-512-2921

International: 412-317-6671

Replay PIN: 8394096

About Foamix Pharmaceuticals Ltd.

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 EGFRI 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.

Forward Looking Statements

This press release includes 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 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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