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Foamix Pharmaceuticals Ltd. completed Phase 3 trials for FMX101

02 May 2017 | News

If approved, FMX101 will be the first FDA-approved topical minocycline treatment for moderate-to-severe acne.



Foamix Pharmaceuticals Ltd., a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical foams to address unmet needs in dermatology, 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.

If approved, 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.

Foamix is also developing FMX103, minocycline foam 1.5%, a topical foam formulation of minocycline for the treatment of moderate-to-severe papulopustular rosacea.