Foamix Announces Enrollment of First Patient in Phase 2 Acne Clinical Trial for FCD105 Minocycline 3% and Adapalene 0.3% Combination Foam

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REHOVOT, Israel and BRIDGEWATER, N.J., Sept. 19, 2019 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (NASDAQ:FOMX), today announced that the first patient has been enrolled in its Phase 2 clinical trial to evaluate the efficacy and safety of its topical combination foam, comprised of minocycline 3% and adapalene 0.3%, FCD105 for the treatment of moderate-to-severe acne vulgaris.

“FCD105 combines minocycline and adapalene, which are two leading agents for treating inflammatory and non-inflammatory comedonal acne lesions, respectively, in a convenient, foam-based product. We currently expect topline data from this study in mid-2020," said David Domzalski, CEO of Foamix. “The initiation of this Phase 2 clinical trial for FCD105 is an important milestone for Foamix, as this would be our first follow-on product behind our lead product candidates, FMX101 for moderate to severe acne vulgaris, and FMX103, for the treatment of moderate-to-severe papulopustular rosacea.”

Study Design

The Phase 2 clinical trial is expected to enroll approximately 400 patients, aged 12 years and older, with moderate-to-severe acne vulgaris. This prospective, randomized, double-blind, vehicle-controlled trial will be conducted at multiple sites throughout the United States. Patients will be randomized to one of four treatment arms: FCD105 foam, 0.3% adapalene foam, 3% minocycline foam or vehicle foam and will self-apply their assigned treatment once daily for 12 weeks. The study design follows current regulatory standards in evaluating the safety and efficacy of combination products of this type.

The primary endpoints are: 1) the proportion of patients achieving success at week 12 based on an Investigator’s Global Assessment (success is defined as a score of “clear” or “minimal” and at least a 2 category improvement from baseline), 2) the mean change from baseline in inflammatory lesion counts in each treatment group at week 12, and 3) the mean change from baseline in non-inflammatory lesion counts in each treatment group at week 12. Safety evaluation will include reported adverse events, skin tolerability assessments, physical examinations and vital signs.

About FCD105

FCD105 is Foamix’s proprietary 3% minocycline, 0.3% adapalene combination foam formulation intended for the treatment of moderate-to-severe acne vulgaris. FCD105 combines the bacteriostatic and anti-inflammatory properties of minocycline with the third-generation retinoid, adapalene, which acts in regulating the differentiation of follicular epithelial cells. Oral minocycline and topical adapalene products are approved for use in the treatment of acne vulgaris in the USA, with the latter available in combination and as monotherapy. Foamix’s FMX101 (minocycline 4% foam) New Drug Application (NDA) is undergoing review by FDA under the 505(b)(2) regulatory pathway with a PFUFA action date of 20 October 2019. Pending a successful development program, the FCD105 NDA is intended to be filed under the same regulatory pathway.

About Acne Vulgaris

Acne is a chronic, inflammatory skin condition that affects the skin’s oil glands and hair follicles. It is characterized by both inflammatory lesions (papules and pustules) and non-inflammatory lesions (open and closed comedones) affecting primarily the face and other areas of the body. Acne affects approximately 40 to 50 million people in the U.S. alone, of whom approximately 10 million have moderate-to-severe disease that significantly impacts self-esteem and quality of life. For most people, acne diminishes over time and tends to disappear or decrease, by age 25. However, some individuals, particularly women, can experience acne much later in life.

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 and FCD105 which are intended for the treatment of moderate-to-severe acne vulgaris and FMX103 which is intended for the treatment of moderate-to-severe papulopustular rosacea. We continue to pursue research and development of our proprietary, innovative topical technologies for the treatment of various skin conditions. We currently have development and license agreements relating to our technology with various pharmaceutical companies.

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 and Exchange Commission, public conference calls, and webcasts.

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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