Foamix to Present Data on its Topical Product Candidates for Acne, Rosacea at 39th Annual Fall Clinical Dermatology Conference

October 10, 2019

REHOVOT, Israel and BRIDGEWATER, N.J., Oct. 10, 2019 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX) ("Foamix" or the "Company"), a clinical stage specialty pharmaceutical company, today announced it will present results from nine clinical trials in five posters relating to its investigational topical product candidates FMX101 for the treatment of moderate-to-severe acne and FMX103 for the treatment of moderate-to-severe papulopustular rosacea in adults, at the 39th Annual Fall Clinical Dermatology Conference® October 17-20 in Las Vegas, Nevada.

Poster highlights include:

- Long-term safety and efficacy data from the open-label extension of two Phase III studies (Study 04 and Study 05) of FMX101 in patients with moderate-to-severe acne for a total treatment period of up to 52 weeks.
- Data from three 12-week Phase III studies (FX2014-04, FX2014-05, and FX2017-22) that showed the safety and tolerability of FMX101 in pediatric patients (ages 9 - 17) with moderate-to-severe acne.
- An ex-vivo permeation and penetration assessment in human skin, in which FMX101 and FMX103 delivered similar concentrations of minocycline to the epidermis and sebaceous appendage.

These three posters will also be published in an upcoming edition of SKIN, The Journal of Cutaneous Medicine®, the official journal of the National Society for Cutaneous Medicine.

Foamix will present results of a comparative trial of FMX101 versus five commercially available acne treatments in miscibility with sebum.

Additionally, Foamix will present study endpoints achieved with FMX103 in patients with moderate-to-severe papulopustular rosacea in two Phase III 12-week pivotal clinical studies (FX2016-11 and FX2016-12).

All posters will be presented Friday, October 18, 7:00 am to 4:30 pm and Saturday, October 19, 7:00 am to 1:00 pm Pacific Time in the Conference Exhibit Hall at Wynn Las Vegas.

"We're extremely pleased to have the opportunity to present these results at Fall Clinical, a prestigious meeting where dermatology thought leaders discuss the latest advancements in the field, and to update the dermatology community on the progress of FMX101 and FMX103," said David Domzalski, Chief Executive Officer, Foamix.

Poster Presentation Details

Title: An Open-Label Extension of Two Phase 3 Studies Evaluating Long-Term Efficacy of FMX101 4% Minocycline Foam for the Treatment of Acne Vulgaris
Authors: Linda Stein Gold, MD; Sunil Dhawan, MD; Jonathan Weiss, MD; Zoe Diana Draelos, MD; Herman Ellman, MD; Iain Stuart, PhD

Title: Clinical Safety and Pharmacokinetics of FMX101 4% Minocycline Foam in Pediatric Patients for the Treatment of Moderate-to-Severe Acne Vulgaris
Authors: Lawrence F. Eichenfield, MD, Linda Stein Gold, MD, Nanette Silverberg, MD, Tooraj Joseph Raoof, MD, Deirdre Hooper, MD, Angela Moore, MD, Martin N. Zaiac, MD, Tory Sullivan, MD, Leon Kircik, MD, Edward L. Lain, MD, MBA, Sunil Dhawan, MD, Terry M. Jones, MD, Jonathan Weiss, MD, Zoe D. Draelos, MD, Herman Ellman, MD, Tina deVries, PhD, Jasmina Jankicevic, MD, Iain Stuart, PhD

Title: Ex Vivo Human Skin Assessment of Minocycline Permeation and Penetration into Epidermis, Dermis, and Sebaceous Appendages
Authors: Russell Elliott, PhD, Gary Lawrence, Vassilis Stakias, PharmD, Iain Stuart, PhD

Title: The Impact of FMX101 4% Minocycline Foam on the Physical Properties of Human Sebum: A Comparison with 5 Different Commercial Acne Treatments
Authors: Yohan Hazot; Lenny Margulis, PhD; Shay Burban; Russell Elliott, PhD; Iain Stuart, PhD

Title: Efficacy and Safety of FMX103 (1.5% Minocycline Foam) in the Treatment of Moderate-to-Severe Papulopustular Rosacea: Results From Two Phase 3 Randomized, Multicenter, Double-Blind, Vehicle-Controlled Studies
Authors: Linda Stein Gold, MD, James Q. Del Rosso, DO, Neal D. Bhatia, MD, Deirdre Hooper, MD, Walter Nahm, MD, PhD, Iain Stuart, PhD

Foamix previously announced that the U.S. Food & Drug Administration (FDA) has set an action date of October 20, 2019 under the Prescription Drug User Fee Act for FMX101 for the treatment of inflammatory lesions of non-nodular moderate-to-severe acne vulgaris in adults and pediatric patients nine years of age and older. A New Drug Application for FMX103 for the treatment of moderate-to-severe papulopustular rosacea in adults has also been submitted and is awaiting acceptance by the FDA. The safety and efficacy of FMX101 and FMX103 have not been established and there is no guarantee that they will receive health authority approval or become commercially available.

About Acne
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 truncal 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 may impact 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 Papulopustular Rosacea
Papulopustular rosacea is a chronic skin disease causing inflammatory lesions (papules and pustules) on the nose, cheeks, chin and forehead. It can create psychosocial burdens, such as embarrassment, anxiety and low self-esteem that can adversely affect quality of life. Rosacea is most frequently seen in adults between 30 and 50 years of age. It affects more than 16 million people in the United States.

There is no known cure for rosacea. Mild papulopustular rosacea is currently treated by topical antimicrobials (metronidazole, clindamycin and ivermectin), azelaic acid or retinoids, while the mainstays for the treatment of moderate-to-severe rosacea are systemic antibiotics.

About Foamix Pharmaceuticals
Foamix is a specialty pharmaceutical company working to solve some of today's most difficult therapeutic challenges in dermatology and beyond.

With expertise in topical medicine innovation as a springboard, the Company is working to develop and commercialize solutions that were long thought impossible, including the world's first topical minocycline foam. Its proprietary Molecule Stabilizing Technology (MST™) is utilized in the Company's dermatology products in late stage development: FMX101 for the potential treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older, and FMX103 for the potential treatment of moderate-to-severe papulopustular rosacea in adults.

Foamix is a different type of specialty pharmaceutical company by design, driven to see the solutions, overcome barriers in all aspects of business, and reimagine what's possible for conditions with high unmet needs.

For more information, visit www.foamix.com.

Forward-Looking Statements
This release includes forward-looking statements within the meaning of the 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 upcoming Company presentations. 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. Although we believe these forward-looking statements are reasonable, they speak only as of the date of this announcement and Foamix undertakes no obligation to update publicly such forward-looking statements 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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