UPDATE -- Foamix Receives FDA Approval of AMZEEQ™ Topical Minocycline Treatment for Millions of Moderate to Severe Acne Sufferers

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AMZEEQ is the First-ever FDA Approved Topical Form of Minocycline

AMZEEQ Offers Efficacy with Low Systemic Absorption

REHOVOT, Israel and BRIDGEWATER, N.J., Oct. 18, 2019 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (Nasdaq: FOMX) ("Foamix" or the "Company"), a specialty pharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has approved its novel AMZEEQ™ (minocycline) topical foam, 4%. AMZEEQ, formerly known as FMX101, is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older and is the first topical minocycline to be approved by the FDA for any condition.

"The FDA approval of AMZEEQ is a milestone moment in dermatology and the most significant advancement with minocycline in almost 50 years," said David Domzalski, Chief Executive Officer of Foamix. "We are proud that our proprietary technology platform has led to this new treatment option, which we believe can help address unmet treatment needs for moderate to severe acne patients. We are looking forward to bringing AMZEEQ to market in January 2020, and to our Company's first commercial launch."

Minocycline is a broad-spectrum antibiotic known for its efficacy in treating moderate to severe acne, but its use is limited in some patients due to systemic side effects when taken orally. Until now, minocycline has not been available as a topical treatment due to its instability in traditional topical formulations. In AMZEEQ, Foamix has leveraged its proprietary Molecule Stabilizing Technology (MST™) platform to effectively deliver minocycline in a foam-based vehicle.

"Our innovative MST™ technology allowed us to develop a topical formulation of minocycline in a convenient, once-daily treatment regimen that maintains the stability of the active ingredient while delivering it into the skin," said Iain Stuart, Ph.D, Chief Scientific Officer of Foamix. "The approval of AMZEEQ represents a significant step toward our goal of enhancing the standard of care for the millions of acne sufferers in the U.S. who deserve alternatives in treatment."

"The approval of AMZEEQ is exciting news that provides a much-needed option in the treatment of moderate to severe acne," said Linda Stein Gold, M.D., Director of Dermatology Clinical Research and Division Head of Dermatology at Henry Ford Health System in Detroit, Michigan. "Minocycline has been a trusted staple in acne treatment for decades, but has only been available in oral or systemic formulations. With the approval of AMZEEQ, I can now offer my patients a new, effective topical treatment option with a favorable tolerability profile."

The FDA approval of AMZEEQ is supported by data from three Phase 3 clinical trials in 2,418 patients of 9 years of age or older, making it one of the largest clinical programs for acne to date. In each 12-week, multicenter, randomized, double-blind, vehicle-controlled study, subjects with moderate to severe acne vulgaris were treated once-daily with AMZEEQ or vehicle. No other topical or systemic acne medication was permitted to be used by subjects during the study period. The studies each found statistically significant disease improvement with AMZEEQ versus vehicle for the co-primary endpoint of absolute reduction of inflammatory lesions, while studies 2 and 3 demonstrated a statistically significant improvement in IGA treatment success. IGA treatment success was defined as a score of 0 ("clear") or 1 ("almost clear") and at least a two-point decrease from baseline. AMZEEQ was well-tolerated and no treatment-related serious adverse events were reported. The most common adverse reaction was headache, which was reported in 3% of subjects treated with AMZEEQ versus 2% of subjects treated with vehicle.

AMZEEQ is expected to be available for prescribing in January 2020.

About AMZEEQ™

INDICATIONS AND USAGE

AMZEEQ™ (minocycline) topical foam, 4% is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older.

Limitations of Use: This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, AMZEEQ should be used only as indicated.

IMPORTANT SAFETY INFORMATION

Contraindications: Persons who have shown hypersensitivity to any of the tetracyclines or any other ingredient in AMZEEQ.

Warnings and Precautions

Flammability: The propellant in AMZEEQ is flammable. Instruct the patient to avoid fire, flame, and smoking during and immediately following application.

AMZEEQ is a topical foam. While systemic absorption of AMZEEQ is low, and serious adverse reactions were not seen in clinical studies, the following adverse reactions associated with *oral* minocycline should be considered:

- ***Teratogenic effects, inhibition of bone growth & permanent tooth discoloration:*** Use during the second and third trimesters of pregnancy, infancy and childhood up to the age of 8 years may cause permanent discoloration of the teeth (yellow-gray-brown) and reversible inhibition of bone growth.
- ***Clostridium difficile associated diarrhea (CDAD):*** If CDAD occurs, discontinue AMZEEQ.
- ***Hepatotoxicity & metabolic effects:*** If renal impairment exists or if liver injury suspected, discontinue AMZEEQ.
- ***Central nervous system effects:*** Patients experiencing light-headedness, dizziness or vertigo should be cautioned about driving vehicles or operating heavy machinery.
- ***Intracranial hypertension:*** Clinical manifestations include headache, blurred vision, diplopia, and vision loss. Discontinue AMZEEQ immediately if symptoms occur.
- ***Autoimmune syndromes:*** Symptoms may be manifested by fever, rash, arthralgia, and malaise. Discontinue AMZEEQ immediately if symptoms occur.
- ***Photosensitivity:*** Patients should minimize or avoid exposure to natural or artificial sunlight while using AMZEEQ. Advise patients to discontinue treatment with AMZEEQ at the first evidence of sunburn.
- ***Hypersensitivity reactions:*** Discontinue AMZEEQ immediately if symptoms of anaphylaxis, serious skin reactions, erythema multiforme, and drug reaction with eosinophilia and systemic symptoms (DRESS) syndrome occur.
- ***Tissue hyperpigmentation:*** Discoloration of organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity (teeth, mucosa, alveolar bone), sclerae and heart valves.
- ***Superinfection:*** Overgrowth of non-susceptible organisms, including fungi. If superinfection occurs, discontinue AMZEEQ and institute appropriate therapy.

Adverse Reactions: The most common adverse reaction reported during clinical trials of AMZEEQ was headache.

To report SUSPECTED ADVERSE REACTIONS, contact Foamix Pharmaceuticals Inc. at **1-844-375-3673** or FDA at 1-800-FDA-1088 or visit **www.fda.gov/medwatch.**

Please see full Prescribing Information.

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 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, AMZEEQ. Its proprietary Molecule Stabilizing Technology (MST™) is utilized in the Company's dermatology products and in other products currently in development: FMX103 for the potential treatment of moderate to severe papulopustular rosacea and FCD105 for the potential treatment of moderate to severe acne.

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.

Foamix uses its website 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. 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. All statements in this press release which are not historical facts are forward-looking statements, including, but not limited to, statements regarding the future expectations, plans and prospects for Foamix; anticipated commercialization plans of AMZEEQ including the potential for AMZEEQ to treat moderate to severe acne vulgaris in adults and pediatric patients and projected date to be available for prescription; and expectations regarding the size of eligible patient population for AMZEEQ and the anticipated patient benefit. Forward-looking statements are based on Foamix's current knowledge and its 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, adverse events associated with AMZEEQ; the outcome of pricing, coverage and reimbursement negotiations with third party payors for AMZEEQ or any other products or product candidates that Foamix may commercialize in the future; whether, and to what extent, third party payors impose additional requirements before approving AMZEEQ prescription reimbursement; the eligible patient base and commercial potential of AMZEEQ or any of Foamix's other product or product candidates; additional competition in the acne and dermatology markets; inability to raise additional capital; Foamix's ability to recruit and retain key employees and its ability to stay in compliance with applicable laws, rules and regulations. Foamix discusses many of these risks in greater detail in its periodic filings with the SEC, including under the heading "Risk Factors" in its most recent annual report and subsequent quarterly reports. Although Foamix believes 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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