

Medimetriks Pharmaceuticals, Inc. Receives FDA Approval for Xepi (ozenoxacin) Cream 1%, a Novel Topical Antibiotic for Impetigo

FAIRFIELD, N.J., Dec. 14, 2017 /PRNewswire/ – Medimetriks Pharmaceuticals, Inc. announced today that the U.S. Food and Drug Administration (FDA) approved Xepi (ozenoxacin) Cream, 1%, a new chemical entity for the treatment of impetigo in patients two months of age and older when applied topically twice daily for 5 days. In the U.S., impetigo is estimated to account for approximately 10% of skin problems observed in pediatric clinics and is considered the most common bacterial skin infection.

“Impetigo is a highly contagious bacterial skin infection that affects millions of children and adults in the United States each year,” said Dr. Theodore Rosen, Professor of Dermatology at Baylor College of Medicine. “Given the positive efficacy data, concerns about increasing MRSA rates and emerging resistance to current treatments, Xepi™ has the potential to offer patients a safe and effective option that could fulfill an important unmet medical need.”

The approval of Xepi is based on a clinical development program that includes the results of two phase 3 multicenter, randomized, double-blind, vehicle-controlled trials that enrolled 877 subjects aged 2 months and older with impetigo. Xepi™ demonstrated superiority versus placebo on the pre-specified clinical and bacteriological endpoints when applied topically twice daily for 5 days. Bacterial success, defined as bacterial eradication or presumed eradication, was achieved

in 90.8% of patients using Xepi™ versus 69.8% for placebo (p

“We believe that Xepi has the potential to disrupt traditional impetigo treatment since patients may present with infections resistant to current topical therapies. The ability to cover both sensitive and resistant bacteria, such as MRSA, offers the potential to reduce treatment failures and enhance patient care,” stated Bradley Glassman, Chairman & Chief Executive Officer of Medimetriks. “The approval of Xepi is an important milestone for Medimetriks as the Company seeks to deliver innovation to Dermatology and address patient’s unmet skin care needs. We look forward to the launch of Xepi in the first quarter of 2018.”

Medimetriks licensed exclusive U.S. commercialization rights to Xepi™ from Ferrer, a leading, privately held Spanish pharmaceutical company, in March 2014.

About Impetigo

Impetigo, a highly contagious bacterial skin infection commonly treated by Dermatologists and Pediatricians, most often affects infants, young children and those involved in close contact sports or living in enclosed environments. Impetigo is estimated to account for approximately 10% of the skin problems observed in pediatric clinics in the United States and is considered the most common bacterial skin infection. Xepi is the first new topical treatment for impetigo in more than 10 years in a market that that generates more than 8 million prescriptions annually.

About Xepi

Xepi, a new chemical entity, belongs to a new generation of non-fluorinated quinolones. In two Phase 3 pivotal studies, Xepi showed positive efficacy and appeared to be safe and well tolerated in both adult and pediatric populations aged 2

months and older. In addition, Xepi™ has demonstrated excellent in vitro antibacterial activity against pathologically relevant bacteria and clinical isolates of organisms with emerging resistance to methicillin-resistant s. aureus (MRSA). Xepi represents a novel and potentially important therapy for the topical treatment of impetigo.

About Ferrer

Founded in 1959, Ferrer is a privately-held Spanish pharmaceutical company, with full vertical integration from R&D to distribution. It is present in more than 95 countries, with 24 international affiliates. Ferrer is active in the pharmaceutical, health, fine chemicals and food sectors, key areas for contributing to people's health and quality of life. In recent years, it has concentrated on diversifying across the whole healthcare spectrum, including prescription drugs, hospital products, vaccines, molecular diagnostics, OTC and self-care.

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About Medimetriks Pharmaceuticals, Inc.

Medimetriks Pharmaceuticals, Inc. is a leading independent branded Dermatology company with integrated development capabilities and robust commercial operations. The Company is dedicated to addressing unmet skin care needs through the development, licensing and commercialization of innovative prescription brands that advance patient care.

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Xepi (ozenoxacin) FDA Approval History