



Newly Approved Treatment for Impetigo to be Commercialized by Cutanea Life Sciences, Inc.

Exclusive US rights acquired by CLS

March 5, 2018 (WAYNE, PA) – Cutanea Life Sciences, Inc. has acquired the exclusive US commercialization rights for Xepi™ (ozenoxacin) Cream, 1% from Medimetriks Pharmaceuticals, Inc. Xepi™ is licensed from Spanish drug maker FERRER INTERNACIONAL, S.A., who developed the patented topical impetigo treatment that was recently approved for use in the U.S. by the Food and Drug Administration.

Xepi™ represents the first non-fluorinated topical quinolone indicated for the treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age or older. Xepi™ is applied topically twice daily for 5 days.

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 generates more than 8 million prescriptions annually.

Xepi™ has bactericidal activity against *Staphylococcus aureus* and *Streptococcus pyogenes*, and can be used to treat pediatric patients as young as two months old as well as adults.

Lawrence F. Eichenfield, M.D., a world-renowned Professor of Dermatology and Pediatrics at Rady Children's Hospital in San Diego and the University of California San Diego said, "The introduction of Xepi™, as a new drug to combat impetigo, will be a welcomed addition given concerns about increasing bacterial resistance rates."

Xepi™ has been shown to be active against most isolates of *S. aureus* (including methicillin-resistant isolates) and *S. pyogenes*, both *in vitro* and in clinical infections and represents a novel therapy for the topical treatment of impetigo. Furthermore, in clinical trials, Xepi™ was found to be negligibly absorbed, safe, and well tolerated in pediatric and adult patients aged 2 months and older.

Cutanea will immediately begin commercialization planning for the U.S. launch.

Indication & Important Safety Information

INDICATION

Xepi™ is indicated for the topical treatment of impetigo due to *Staphylococcus aureus* or *Streptococcus pyogenes* in adult and pediatric patients 2 months of age and older.

The safety profile of Xepi™ in pediatric patients 2 months and older was similar to that of adults. The safety and effectiveness of Xepi™ in pediatric patients younger than 2 months of age have not been established.

WARNINGS AND PRECAUTIONS

Potential for Microbial Overgrowth: Prolonged use of Xepi™ may result in overgrowth of non-susceptible bacteria and fungi. If such infections occur, discontinue use and institute alternative therapy.

ADVERSE REACTIONS

Adverse reactions (rosacea and seborrheic dermatitis) were reported in 1 adult patient treated with Xepi™.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

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. Visit www.ferrer.com.

About Cutanea Life Sciences

Cutanea Life Sciences, Inc., headquartered in Wayne, PA, is a specialty pharmaceutical company whose mission is to develop innovative technologies, optimizing intellectual property and therapeutic applications culminating in market leading products to treat diseases and disorders of the skin and related tissue. CLS seeks to improve human health and appearance, and create value for patients and medical professionals by satisfying underserved medical needs. CLS is a wholly-owned subsidiary of the Osaka-based Maruho Co., Ltd., a leading dermatology company in Japan that celebrated its 100th anniversary in 2015.

Cutanea is pursuing therapies for the treatment of acne, rosacea, psoriasis, atopic dermatitis, and various forms of warts caused by human papillomavirus (HPV). Cutanea is currently directing these programs through the various stages of drug development as required for investigational drugs. Upon FDA clearance, these programs will be commercialized directly through the Cutanea marketing and sales organization.

For more information, visit www.cutanea.com and follow CLS on [Facebook](#), [Twitter](#), [LinkedIn](#) and [Instagram](#).

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as “predicts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from CLS’s current expectations. CLS’s expectations and, therefore, any forward-looking statements in this press release could be affected by risks and uncertainties relating to a number of factors, including the following: the success, cost and timing of CLS’s product development activities, studies and clinical trials; the success of competing products that are or become available; CLS’s ability to commercialize its product candidates; the size and growth potential of the markets for CLS’s product candidates, and CLS’s ability to service those markets; CLS’s ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; the rate and degree of market acceptance of CLS’s product candidates; and CLS’s expectations regarding its ability to obtain and adequately maintain sufficient intellectual property protection for its product candidates. Any forward-looking statements that CLS makes in this press release speak only as of the date of this press release. CLS assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Media Contacts

Karen Dombek, MCS Healthcare Public Relations
(908) 234-9900
karend@mcspr.com

Robert Partridge, Cutanea Life Sciences
(484) 568-4298
rpartridge@cutanea.com

Andy Hachadorian, Cutanea Life Sciences
(484) 568-4323
ahachadorian@cutanea.com