



Cutanea Life Sciences, Inc. Launches Xepi™ (ozenoxacin) Cream, 1%, A Novel Topical Prescription Impetigo Treatment Approved by the U.S. FDA

A non-fluorinated topical quinolone indicated to treat impetigo, a very common bacterial skin infection

WAYNE, PA, November 8, 2018 – Cutanea Life Sciences, Inc. (Cutanea) today announced the U.S. launch of Xepi™ (ozenoxacin) Cream, 1% for the treatment of impetigo in adult and pediatric patients 2 months of age or older.¹ The availability by prescription of Xepi™ marks the first novel topical prescription treatment for impetigo in the last 10 years.² Xepi™ was approved by the U.S. Food and Drug Administration on December 11, 2017.³

Xepi™ is a non-fluorinated topical quinolone indicated for the treatment of impetigo due to *Staphylococcus aureus* and/or *Streptococcus pyogenes*. Xepi™ is applied topically twice daily for five days.¹

“Impetigo is the leading bacterial skin infection seen by childhood health care providers. Crowding, heat and skin trauma are among the factors that lead to increased frequency,” said Lawrence A. Schachner, M.D., Director of the Division of Pediatric Dermatology at the University of Miami Miller School of Medicine. “It had been a decade since a new topical antibiotic has been approved for this disorder. Therefore, Xepi™ is a very welcome and timely new addition to the armamentarium against certain strains of bacteria that may be resistant.”

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.⁴ Impetigo is estimated to account for approximately 10% of the skin problems observed in pediatric clinics in the U.S. and is considered one of the most common bacterial skin infections.^{5,6}

“We are pleased to be commercializing Xepi™ in the U.S. market, and making this unique advance in impetigo therapy available to health care professionals and parents to manage a troublesome skin disorder that afflicts several million young children each year,” said Robert J. Bitterman, Sr., CEO and President of Cutanea Life Sciences, Inc. “Xepi™ is consistent with our mission at Cutanea to provide topical, innovative therapies that address underserved patient needs in dermatology.”

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. In clinical trials, Xepi™ was found to be negligibly absorbed, safe and well tolerated in pediatric and adult patients aged 2 months and older.¹

About Impetigo

Impetigo is a highly contagious bacterial skin infection commonly treated by dermatologists and pediatricians that most often affects infants, young children and those involved in close contact sports or living in enclosed environments. Two types of bacteria, *Staphylococcus aureus* and/or *Streptococcus pyogenes*, cause most cases of impetigo by getting into the body through a minor cut, scrape or insect bite.⁴ Impetigo is estimated to account for approximately 10% of the skin problems observed in pediatric clinics in the U.S. and is considered one of the most common bacterial skin infections.^{5,6} There are more than 3 million cases of impetigo in the U.S. every year.⁷

Xepi™ IMPORTANT SAFETY INFORMATION

INDICATIONS AND USAGE

Xepi™ (ozenoxacin) Cream, 1% is a topical prescription medicine approved for the treatment of impetigo, a common skin infection caused by bacteria (*Staphylococcus aureus* or *Streptococcus pyogenes*) and is approved for adults and children two months of age and older. The safety and effectiveness of Xepi™ have not been established in patients younger than 2 months of age. Use Xepi™ for the entire time, as directed by your Health Care Provider.

IMPORTANT SAFETY INFORMATION

Do not use Xepi™ if the affected area of impetigo is bigger than the size of the child's two (2) hands.

Xepi™ is for external use only. Do not swallow Xepi™ or use in the eyes, on the mouth or lips, inside the nose, or inside the female genital area. Wash your hands after application if hands are not the area for treatment.

WARNINGS AND PRECAUTIONS:

The prolonged use of Xepi™ may result in hard-to-treat bacteria. Notify your healthcare practitioner if there is no improvement in symptoms within 3 days after starting use of Xepi™.

MOST COMMON SIDE EFFECTS

Rosacea (a skin condition that may include redness, flushing and acne-like lesions) and seborrheic dermatitis (a skin condition that causes scaly patches and red skin) were reported in 1 adult patient treated with Xepi™.

For full Prescribing Information for Xepi™ please click [here](#) or call 1-844-780-8152.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

About Cutanea Life Sciences, Inc.

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. Cutanea 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 approval, 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](#).

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.

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.

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References

¹ Xepi™ (ozenoxacin) Cream, 1% [package insert], Wayne, PA: Cutanea Life Sciences, 2018
<http://www.cutanea.com/sites/default/files/inline-files/xepi-insert-final.pdf>

² Data on File. Cutanea Life Sciences, 2018

³ Drug Trial Snapshot; U.S. Food and Drug Administration. Retrieved April 24, 2018 from
<https://www.fda.gov/Drugs/InformationOnDrugs/ucm590778.htm>

⁴ Impetigo; American Academy of Dermatology. Retrieved April 24, 2018 from
<https://www.aad.org/public/diseases/contagious-skin-diseases/impetigo#overview>

⁵ Bacterial Diseases. In: Bologna J, Jorizzo JL, Schaffer JV, ed. Dermatology. 3rd ed. Elsevier Saunders; 2012:1187-1189.

⁶ Akiyode O. Impetigo in children and adolescents. US Pharm. 2013;38(6):68-71

⁷ How to Treat Impetigo and Control This Common Skin Infection; U.S. Food and Drug Administration. Retrieved April 24, 2018 from
<https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048837.htm>