Cutanea Unveils Aktipak™ (erythromycin and benzoyl peroxide) Gel, 3%/5%, Convenient Acne Treatment for "On-the-Go" Patients

Combination therapy is Cutanea Life Sciences’ first entry in prescription dermatology market

WAYNE, PA, March 3, 2017 -- Cutanea Life Sciences, Inc. (CLS), a U.S. prescription dermatology company, announced that Aktipak™ (erythromycin and benzoyl peroxide) Gel, 3%/5%, a combination therapy indicated for the topical treatment of acne vulgaris, is its initial entry in the dermatology market, available through dermatologists' offices. Aktipak™ is contraindicated in individuals who have shown hypersensitivity to any of its components.¹

Aktipak™ is a portable, freshly mixed, patient-blended therapy that offers a flexible and convenient treatment option for active, "on-the-go" acne patients. The product comes in pocket-sized, single-dose, dual-chamber pouches (60 to a carton), each of which contain the antibiotic erythromycin and the antibacterial benzoyl peroxide in separate chambers. The patient opens the pouch and blends the gel contents immediately prior to use, enabling simple, convenient application with no mixing needed in the pharmacy. Aktipak™ has an 18-month shelf life from the date of manufacture, and no refrigeration is required. The 1.5" x 2.5" pouches tuck easily and discreetly into purses, gym bags and backpacks.

“At Cutanea Life Sciences, we are committed to focusing on underserved patient needs, and helping medical professionals optimize their practice time through our products and services,” said Robert J. Bitterman, President and CEO of CLS. “We are pleased that our initial market entry, Aktipak™, meets both objectives by providing a safe, effective and convenient treatment alternative for acne patients with active lifestyles.”

“As a professional school counselor who works with teenagers every day, I have seen first-hand what research has shown, that acne can have a profound psychosocial impact on teens including affecting their self-esteem, relationships and even academic achievement,”² said Anne LP
Flenner, Ed.S, 2016-17 President of the Florida Counseling Association and a member of the American Counseling Association. “As teens communicate constantly via Facebook, Twitter, Snapchat and Instagram, the visual, photo-driven nature of these platforms only serves to exacerbate feelings of embarrassment and anxiety over acne.”

A multicenter, randomized, double-blind parallel group study of the efficacy and tolerability of Aktipak™ versus vehicle was conducted in 217 acne patients age 13 years and older. At 8 weeks, treatment success, as defined by the Physician’s Global Acne Severity score, was demonstrated in 36 percent for the Aktipak™ group versus 12 percent for the vehicle group (p < 0.05). The most frequently reported adverse events in clinical trials of Aktipak™ include dry skin (7.6 percent), application site reaction (2.5 percent), blepharitis (1.7 percent), pruritus (1.7 percent) and photosensitivity (1.3 percent).

"Many of the young acne patients I see today lead very active lives, ranging from sports to travel and other activities," said Daniel Roling, M.D., Philadelphia area dermatologist. "The unique benefits of Aktipak™, including its portability, ease of use and long shelf life, should be a welcome fit for this population."

To learn more about Aktipak™, visit www.aktipak.com.

About Acne
According to the American Academy of Dermatology (AAD), acne is the most common skin condition in the U.S., affecting up to 50 million Americans annually, and 85 percent of people ages 12 to 24 will experience at least mild acne. It is a chronic, inflammatory skin disorder characterized by blackheads, whiteheads and pimples that occurs on the face, neck, shoulders, upper arms, chest and back. Acne has been shown to cause significant psychological problems, including poor self-image, depression and anxiety.

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.
CLS is pursuing therapies for the treatment of acne, rosacea, psoriasis, atopic dermatitis, and various forms of warts caused by human papillomavirus (HPV). It also has a novel soft tissue augmentation agent in early development. CLS intends to direct these products through the required regulatory pathway and, upon FDA clearance, commercialize them directly through a CLS sales force and commercial infrastructure that will focus primarily on dermatology medical practices.

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.

**About Aktipak™**

Contraindications: Aktipak™ is contraindicated in those individuals who have shown hypersensitivity to any of its components.

Precautions: For topical use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution because a possible cumulative irritancy effect may occur, especially
with the use of peeling, desquamating or abrasive agents. If severe irritation develops, discontinue use and institute appropriate therapy. The use of antibiotic agents may be associated with the overgrowth of non-susceptible organisms. If this occurs, discontinue use and take appropriate measures. Avoid contact with eyes and all mucous membranes.

Pregnancy: It is not known whether Aktipak™ can cause fetal harm when administered to a pregnant woman. Aktipak™ should be given to a pregnant woman only if clearly needed. It is not known whether the ingredients of Aktipak™ are excreted in human milk. Therefore, caution should be exercised when erythromycin is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of Aktipak™ in pediatric patients below 12 years of age have not been established.

Adverse Reactions: The most frequently reported adverse events reported in clinical trials include: dry skin, application site reaction, blepharitis, pruritus, and photosensitivity.

Please click here for the full Prescribing Information: http://bit.ly/2njB0Ie

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References

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1 Aktipak™ (erythromycin 3%-benzoyl peroxide 5%) Topical Gel [package insert]. Wayne, PA: Cutanea Life Sciences, Inc.; 2017.


5 Acne; American Academy of Dermatology. Retrieved February 23, 2017 from https://www.aad.org/media/stats/conditions