SK Breakthrough: FDA Approves Eskata Topical Solution from Aclaris

The FDA has approved Eskata (hydrogen peroxide) topical solution, 40% (w/w) from Aclaris Therapeutics, Inc. for the treatment of seborrheic keratoses (SKs). SKs are non-cancerous skin growths that affect more than 83 million American adults. They may frequently appear in highly visible areas such as the face and neck, and can increase in size and number with age.

Eskata offers providers and patients a topical, non-invasive treatment option that can clear raised SKs with a low risk of scarring. Until now, there has not been an FDA-approved topical treatment for SKs, a condition that is more prevalent than acne, psoriasis, and rosacea combined.

In an interview with Practical Dermatology® magazine in November, Aclaris CEO Neal Walker, MD addressed market anticipation of the agent. “I think the thing that resonates with the doctors is that they already have these patients in the office. The problem was the headwind was always concern about creating a new issue for the patient. One of the worst things you can do is create a mark for a mark. If you’re removing something strictly for aesthetic reasons, you don’t want to do that,” Dr. Walker said. “SK shouldn’t be a throw away lesion—something you ignore. The patient’s coming in and asking you about it. They want an option. You’re the expert as the dermatologist. Treat it.”

NPF Launches New Resource for Youth with PsO, PsA

Our Spot, a new resource launched by The National Psoriasis Foundation (NPF), provides resources for kids and teens living with psoriasis and psoriatic arthritis. The program includes a website and welcome kit with age-appropriate information and resources to help support the needs of youth living with psoriatic disease—from toddlers to teens, and their parents and caregivers, too.

“Our Spot was developed specifically to address the unique needs of youth living with psoriatic disease,” said Jaime Lyn Moy, youth services committee chair, NPF. “Psoriatic disease can be overwhelming and isolating. We want to provide youth and their families a supportive environment where they can connect with others who know exactly what they are experiencing and learn ways to successfully manage their disease.”

Featuring stories from kids, teens, and parents about what it means to live with psoriatic disease, the Our Spot website also offers communication tips for both youth and parents in addressing different topics. Our Spot also offers educational materials. There is also an opportunity for parents to connect with other parents raising a child with psoriatic disease.

The Our Spot Welcome Kit offers age-appropriate materials for kids age 12 and under, and specific information for teens. Kits include materials about being diagnosed with psoriasis and psoriatic arthritis, a parents’ guide, recipes and snack tips, a symptom tracker journal, a one-year subscription to the NPF Psoriasis Advance magazine, and other items.

FDA Accepts NDA for Allergan, Paratek Acne Drug

The FDA accepted a New Drug Application (NDA) to review Seysara (sarecycline) for the treatment of moderate to severe acne vulgaris in patients nine years of age and older, Allergan plc and Paratek Pharmaceuticals, Inc. report.

Seysara is a once-daily, oral, narrow spectrum tetracycline-derived antibiotic with anti-inflammatory properties for the potential treatment of moderate to severe acne in the community setting.

Allergan completed the NDA submission in October 2017, and expects the Prescription Drug User Fee Act (PDUFA) action date to occur in the second half of 2018. Allergan has US rights to the development and commercialization of Seysara. Paratek retains all ex-US rights.
The application includes two identically designed, large, multicenter, randomized, double-blind, placebo-controlled, Phase 3 studies, which demonstrated that once-daily sarecycline 1.5 mg/kg significantly improved acne severity based on Investigator’s Global Assessment (IGA) success and significantly reduced inflammatory lesion count vs placebo at week 12 in patients with moderate to severe facial acne vulgaris. In March 2017, Allergan announced positive results of these Phase 3 studies, which met their primary efficacy endpoints.

**FDA Issues Final Rule for Certain Ingredients in OTC Healthcare Antiseptic Products**

The FDA has finalized a rule first proposed in 2015 that finds that triclosan and 23 other active ingredients are not generally recognized as safe and effective (GRASE) for use in over-the-counter (OTC) healthcare antiseptic products—including health care personnel hand washes and rubs, surgical hand scrubs and rubs, and patient antiseptic skin preparations—because no additional safety and effectiveness data were provided to the FDA to support monograph conditions for these 24 active ingredients.

As a result, products containing these active ingredients, intended for use in OTC healthcare antiseptics by healthcare professionals in a hospital setting or other healthcare situations outside the hospital, are not allowed to be marketed without undergoing pre-market review. Healthcare antiseptic drug products containing one or more of these non-GRASE active ingredients will be considered new drugs for which approved new drug applications (NDAs) are required for marketing. Manufacturers will have one year to comply with this final rule by reformulating or removing their products from the market. Based on the proposed rule, manufacturers have already started removing these ingredients from their products. Of the 24 active ingredients that the FDA is finding non-GRASE, triclosan is the only active ingredient currently being used in any marketed healthcare antiseptic products. So most currently marketed healthcare antiseptics

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**Take 5**

**WITH BOB RHTAGAN, PRESIDENT AND CHIEF EXECUTIVE OFFICER OF MERZ NORTH AMERICA**

*With model and original "Uptown Girl" Christie Brinkley as their first-ever celebrity spokesperson, Merz North America is coming out of the gates strong in 2018. Ms. Brinkley—who embodies beauty and aging gracefully—has helped put a face on two of the company’s aesthetic brands, Ultherapy and Xeomin, and the enthusiasm is now palpable. “Patients are now coming into their doctor’s offices and asking for these treatments by name and we expect this excitement and momentum to continue to grow,” says Bob Rhatigan, President and CEO of Merz North America.*

**AWARD-WINNING YEAR**

Last year was a year of significant evolution and accomplishments for Merz, and I am very optimistic about our future. It was an award-winning year for us. Merz North America has been recognized by Aesthetic Everything as the Top Aesthetics Company and the winner of four other 2017 Diamond Crystal Awards, including the recognition of Cellfina as the Top Minimally Invasive Procedure and Ultherapy as a Top Non-Surgical Procedure and I was proud to be named the top CEO. I chose Merz as the next step in my career because I knew culturally it would be a good fit. I’m glad to say that has proven to be true.

**CHRISTIE BRINKLEY, ENOUGH SAID**

One of the exciting new ways that we are impacting the market is through our partnership with Christie Brinkley. Merz has never had a celebrity spokesperson before. Christie Brinkley had used both Xeomin and Ultherapy prior to our work with her, and loved her results. Christie is the perfect partner to help Merz educate consumers about Xeomin and Ultherapy because she shares our vision that adults of all ages should feel confident in how they present themselves to the world. She is excited to educate women about these treatment options.

**CUSTOMER APPRECIATION**

We work every day to be the most admired, trusted, and innovative aesthetics and neurotoxin company, and to build a culture that is centered around the customer. In all locations in North America (Raleigh, Mesa, Franksville, and Toronto), we have prominent signage on the walls with the

(Continued on page 16)
will not be impacted by this final rule.

In response to requests from industry, the FDA has deferred final rulemaking for one year, subject to renewal, on six specific ingredients that are the most commonly used in currently marketed OTC healthcare antiseptic products—alcohol (ethanol), isopropyl alcohol, povidone-iodine, benzalkonium chloride, benzethonium chloride, and chloroxylenol (PCMX)—to provide manufacturers with more time to complete the scientific studies necessary to fill the data gaps identified so that the agency can make a safety and efficacy determination about these ingredients. The final rule does not affect healthcare antiseptics that are currently marketed under new drug applications and abbreviated new drug applications.

Biofrontera Files Investigational NDA for Phase 3 Trial of Ameluz for BCC

Biofrontera AG has filed an investigational new drug (IND) application with the FDA for its proposed Phase 3 study protocol to evaluate Ameluz photodynamic therapy (PDT) for the treatment of superficial basal cell carcinoma.

Ameluz is currently approved and available in the EU for the photodynamic therapy of superficial and nodular BCC. It is also approved in both the US and EU for lesion-directed and field-directed PDT of actinic keratosis, a skin cancer precursor.

Aclaris Initiates Pilot Clinical Trial of ATI-50002 Topical for Vitiligo

Aclaris Therapeutics, Inc., initiated a Phase 2 open-label clinical trial of ATI-50002, a topical Janus Kinase (JAK) 1/3 inhibitor (ATI-50002 Topical) and investigational drug, for the treatment of non-segmental vitiligo of the face.

This trial will evaluate the safety, tolerability and preliminary efficacy of ATI-50002 Topical applied twice daily in 24 adult subjects with non-segmental vitiligo of the face. This 24-week trial will be conducted at three investigational centers within the US.

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Study: Increased Risk of Uterine Fibroids Seen in African-American Women with CCCA

African-American women with central centrifugal cicatricial alopecia (CCCA) have an increased chance of developing uterine fibroids, a new study suggests.

The study, which appears in the December 27 issue of JAMA Dermatology, analyzed patient data from the Johns Hopkins electronic medical record system (Epic) of 487,104 black women ages 18 and older, and the prevalence of those with fibroids was compared in patients with and without CCCA.

Overall, the researchers found that 13.9 percent of women with CCCA also had a history of uterine fibroids compared to only 3.3 percent of black women without the condition. In absolute numbers, out of the 486,000 women who were reviewed, 16,212 had fibroids.

Within that population, 447 had CCCA, of which 62 had fibroids. The findings translate to a fivefold increased risk of uterine fibroids in women with CCCA, compared to age, sex and race matched controls.

Exactly how the two conditions are linked is unknown, however the excess scar tissue that forms as a result of CCCA may also explain the higher risk for uterine fibroids, which are characterized by fibrous growths in the lining of the womb.

Women with this type of scarring alopecia should be screened not only for fibroids, but also for other disorders associated with excess fibrous tissue, says study author Crystal Aguh, MD, Assistant Professor of Dermatology at the Johns Hopkins University School of Medicine in Baltimore.

People of African descent, she notes, are more prone to develop other disorders of abnormal scarring, termed fibro proliferative disorders, such as keloids, scleroderma, and some types of lupus and clogged arteries.

The other authors on this paper were Ginette A. Okoye, M.D. of Johns Hopkins and Yemisi Dina of Meharry Medical College.

BY THE NUMBERS

71 Percent of teens who’ve had acne who feel that acne has a negative effect on their body image and attractiveness, according to results of a survey commissioned by Cutanea Life Sciences, Inc. and conducted by Harris Poll among 1,010 teenagers, ages 15-19. The poll results further revealed that 72 percent of teens who use social media and have had acne agree most people their age are self-conscious about their acne on social media, and 68 percent of teens believe that most of their peers edit or alter their photos on social media if they have acne to hide it. Moreover, 58 percent of teens who’ve had acne have offered to take a photo to get out of being in the picture.