FDA Approves Altreno Lotion for Acne from Ortho Dermatologics

The FDA approved the New Drug Application for Ortho Dermatologic's Altreno (tretinoin 0.05%) lotion, indicated for the topical treatment of acne vulgaris in patients aged 9 and up. Altreno is expected to be available during the fourth quarter of 2018.

"Today's FDA approval of Altreno builds upon our strong acne portfolio, providing physicians and patients a trusted retinoid in a lotion formulated to enhance the user’s experience with the inclusion of moisturizing attributes of hyaluronic acid, glycerin, and collagen," says Bill Humphries, president, Ortho Dermatologics, in a news release. “Altreno lotion spreads easily and is quickly absorbed into the skin allowing acne patients to easily incorporate this once-daily treatment into their skin care regimen.”

In clinical trials, Altreno lotion provided the proven efficacy of tretinoin in a generally well-tolerated formulation with skin dryness, pain, swelling, irritation and peeling reported in ≤4% of patients.

"Topical retinoids are a foundational treatment for all patients with acne, but they often cause skin irritation," says Joshua Zeichner, MD, director, Cosmetic and Clinical Research in Dermatology, The Mount Sinai Hospital, New York City. “With the efficacy expected from a retinoid, plus a proven tolerability profile, Altreno will be an ideal choice for many of my patients.”

Altreno was evaluated in two identical multicenter, randomized, double-blind, vehicle-controlled Phase 3 studies, totaling 1,640 patients to determine its safety and efficacy. The data demonstrated that Altreno lotion resulted in statistically significant reductions in both inflammatory and non-inflammatory lesions compared to vehicle. In the population of patients treated in these studies, patients treated with Altreno saw a mean absolute reduction of 13.1 and 13.9 in inflammatory lesions in trials 1 and 2, respectively, compared to 10.6 and 10.7 in patients treated with vehicle. In addition, those treated with Altreno saw a mean absolute reduction of and 17.8 and 21.9 in non-inflammatory lesions in trials 1 and 2, respectively, compared to 10.6 and 13.9 in patients treated with vehicle. Also at Week 12, 16.5 percent and 19.8 percent of patients in trials 1 and 2, respectively, achieved treatment success (at least a 2-grade improvement in global severity by Evaluator Global Severity Scores and ‘clear’ or ‘almost clear’) with tretinoin 0.05% lotion, compared to only 6.9 percent and 12.5 percent with vehicle.

The clinical trial data also showed patient satisfaction (as assessed by 1,396 patient satisfaction surveys completed at Week 12) was significantly greater with Altreno lotion by Week 12, with patient satisfaction of those treated with Altreno lotion increased by 53 percent compared to 43 percent with vehicle.

Psoriasis Myths, Stigmas Abound

Stigmatizing views and myths about psoriasis are pervasive among the general population and medical students in the US, according to multidisciplinary research from the Perelman School of Medicine at the University of Pennsylvania. The findings were published in Journal of the American Academy of Dermatology.

The study also found false perceptions about psoriasis continue to persist, including the belief that psoriasis is contagious and that it is not a serious illness.

“Although it’s widely recognized that the appearance of psoriasis can negatively impact patients’ social, professional, and intimate relationships, we wanted to quantify the perceptions patients with psoriasis face on a daily basis in order to understand how pervasive they are,” says the
study’s senior author Joel M. Gelfand, MD, MSCE, a professor of Dermatology and Epidemiology at Penn, in a news release. Rebecca L. Pearl, PhD, an assistant professor of Psychology in Psychiatry, was the lead author of the study.

Researchers used Amazon Mechanical Turk (MTurk), a web-based data collection service, to survey people about their perceptions of individuals with psoriasis. They also sent the survey directly to several hundred medical students. In all, 198 laypeople responded on MTurk and 187 medical students completed the emailed survey. All participants were shown images of people with psoriasis as well as close-up photos of psoriasis lesions.

Overall:
- 54 percent of laypeople who responded said they did not want to date someone with psoriasis
- 39 percent said they did not want to shake hands with someone suffering from the disease
- 32 percent said they did not want to have someone with psoriasis in their homes
- 57 percent said patients with psoriasis were insecure
- 53 percent said patients with psoriasis were sick
- 45 percent said patients with psoriasis were unattractive
- 27 percent said patients with psoriasis were contagious

Medical students demonstrated less stigmatizing views compared to the MTurk group. Among MTurk participants, those who knew someone with psoriasis or had heard of psoriasis demonstrated less stigmatizing attitudes.

“It’s possible that better education about the disease, as well as contact with individuals with psoriasis, may help to dispel myths and stereotypes and reduce negative perceptions,” Dr. Pearl says.

The researchers stressed the need for further research with a larger sample size before drawing any definitive conclusions. However, they said the findings do have implications for both public health and patient care.

“Future studies should evaluate the effects of education campaigns on people’s attitudes toward those with psoriasis, as well as efforts to incorporate patients with psoriasis into general medical education for physicians and other health care providers,” Dr. Gelfand says.

New from Thermi: Arvati Platform

Thermi, an Almirall company, is launching Arvati, a next-generation 510k FDA-cleared, true temperature-controlled radiofrequency platform that powers a range of Thermi procedures including ThermiTight, ThermiRase, ThermiSmooth Face, and ThermiVa.

Arvati delivers rapid, precise, and consistently controlled output of radiofrequency to tissue to induce positive tissue change by stimulating collagen production to enhance various skin areas. The platform is built upon increased power as well as optimized two-way real time temperature-controlled algorithms.

Arvati amplifies the science of heat with Epic Technology. With optimized radiofrequency delivery, Arvati provides consistent dosage of heat while keeping clinicians in complete control throughout the treatment. The technology also features an enhanced 50-watt capacity generator, which maximizes the power to efficiently treat all body areas while helping clinicians reach desired set temperatures 63 percent faster, thereby significantly reducing total treatment times. Arvati also includes software that offers real-time temperature monitoring with control algorithms that ensures a consistent temperature and radiofrequency dosage throughout the treatment with all the Arvati modalities. Initial experience shows temperature stays within one degree of the set temperature 99.7 percent of the treatment time.

As part of the Arvati launch, existing Thermi customers in the US will be offered the Arvati platform at a significant discount, and Arvati will become available in other markets around the world in the near-term.

FDA Accepts Ortho Derm’s Resubmission of NDA for Duobrii Lotion for Plaque Psoriasis

The FDA has accepted Ortho Dermatologics’ resubmitted New Drug Application (NDA) for Duobrii (halobetasol propionate and tazarotene; IDP-118) Lotion for the topical treatment of plaque psoriasis. The FDA accepted the application as a Class 2 resubmission, with a PDUFA action date of February 15, 2019.

“We are confident in our NDA resubmission for Duobrii and unwavering in our commitment to bring this new treatment option to patients,” says Bill Humphries, president.
Ortho Dermatologics, in a news release. “We have worked closely with the FDA to answer their questions regarding pharmacokinetic data, and we look forward to continued collaboration with the Agency through the remainder of the review process.”

If approved, Duobrii will be the first topical lotion that contains a unique combination of halobetasol propionate and tazarotene in one formulation for the treatment of plaque psoriasis in adult patients, allowing for a potentially expanded duration of use.

MC2 Therapeutics Reports Positive Topline Data for Investigational Topical for Psoriasis

MC2-01 Cream (calcipotriene and betamethasone dipropionate, w/w 0.005%/0.064%) from MC2 Therapeutics A/S achieved its primary and secondary endpoints, according to recently reported top-line data from the US Phase 3 study.

Results of the Phase 3 study (n=796) show that MC2-01 Cream is superior to Taclonex Topical Suspension at Week 8 based on treatment success, defined as a minimum two-point decrease in the Physician Global Assessment (PGA) score (40.1% versus 24.0%, p < 0.0001). Accordingly, the trial met its primary endpoint to demonstrate non-inferiority of MC2-01 Cream to Taclonex.

MC2-01 Cream achieved secondary endpoints, showing superiority to Taclonex based on percentage reduction in mPASI from baseline to Week 8 (64.8% versus 52.3%, p <0.0001) and superiority to Taclonex in Patient Treatment Convenience (p <0.0001). MC2-01 Cream provided a robust reduction in itch (60.2% at Week 4) measured by the frequency of a four-grade or greater improvement on an 11-point numeric rating scale of itch severity.

“The significant improvements in both treatment success and patient reported treatment convenience are particularly encouraging,” says Linda Stein Gold, MD, Director of Dermatology Clinical Research at Henry Ford Health System in Detroit, Michigan, and lead investigator in the study. “Enhanced patient satisfaction enabled by the MC2-01 Cream PAD formulation may increase treatment compliance among patients, and positively impact real-life treatment outcomes even further. As such PAD Technology holds the promise of redefining topicals.”

Adverse events seen in the trial were predictable pharmacological class effects typically associated with calcipotriene and topical corticosteroids. The safety profile of MC2-01 cream was similar to that known for Taclonex.

CLOSE UP

With Ashfaq A. Marghoob, MD

Practical Dermatology spoke with Ashfaq A. Marghoob, MD, Director of Memorial Sloan Kettering’s regional skin cancer clinic in Hauppauge, NY, about the reasons behind and results of his new study in JAMA Dermatology.

The study sought to make sure dermatoscopes with magnets are safe for patients with pacemakers, defibrillators, and other implanted devices in patients.

PD: Why is this topic important to study?
Ashfaq A. Marghoob, MD: Many dermatoscopes have magnets at the faceplate. With our aging population, many individuals will have pacemakers or defibrillators. These same individuals are at increased risk for developing skin cancer.

When evaluating a lesion in the vicinity of a cardiovascular implantable electronic device (CIED) with a dermatoscope that has magnets, it could theoretically shut the CIED down.

PD: Describe the research and your findings.

Dr. Marghoob: We measured the gauss strength of magnets in dermatoscopes and also evaluated their impact on CIEDs in an ex-vivo lab setting. The magnets were not strong enough to impact the CIED in the ex-vivo experiment. Also, with the dermatoscope faceplate in place, the gauss reading was below the CIED-required threshold.

PD: What’s the next step?

Dr. Marghoob: When evaluating a lesion in the vicinity of a CIED, use a scope without a magnet if available, and if you have a scope with a magnet then a) do not remove the faceplate, and b) use non-contact dermoscopy since the space between the scope and skin will diminish the magnet strength at the skin surface.
JW Pharmaceutical Signs Global Out-licensing Agreement for AD Drug Candidate with LEO Pharma

JW Pharmaceutical and LEO Pharma have signed a global licensing agreement for JW’s novel atopic dermatitis drug candidate, JW1601, under which, LEO Pharma will gain the exclusive rights to develop and commercialize JW1601 globally excluding Korea where JWP will maintain its exclusivity. JW will receive $17 million as upfront fee and stepwise development and sales milestone in sum of up to $385 million. Apart from the milestone payments, JWP will receive up to two-digit royalty based on the net sales.

JW1601 is an innovative new drug candidate developed by C&C Research Laboratories, a research and development company which is one of the affiliates of JWP. In May 2017, JWP acquired the global exclusive rights to develop and commercialize JW1601 and plans to submit IND for Phase 1 clinical trial within this year.

JW1601 has a dual mechanism of action that blocks the activation and migration of the immune cells that cause atopic dermatitis by selectively acting on the histamine H4 receptor and inhibiting the histamine signaling that causes itching. The drug is expected to show good efficacy because it has both anti-pruritic (anti-itch) and anti-inflammatory effect whereas the competing substances only show the efficacy in anti-inflammatory. It is also expected to demonstrate a good safety profile due to its high selectivity towards H4 receptor.

“We see a high unmet need for safe and effective oral treatments for people suffering from atopic dermatitis. It is therefore with great excitement that we partner with JW Pharmaceutical on their novel oral atopic dermatitis drug candidate, JW1601. At LEO Pharma, we continuously seek to expand our pipeline with new innovative solutions with the ultimate aim of bringing real life-changing medicines to the many patients we serve. This compound is a perfect fit with our existing biologics currently in Phase 3 (Tralokinumab) and phase I (LP0145) and our topical Delgocitinib currently in phase II,” said Kim Kjoeller, Executive Vice President, Global R&D, LEO Pharma.

FDA Committee Recommends Approval of Paratek’s Omadacycline

The Antimicrobials Drug Advisory Committee of the FDA voted in favor of the approval of intravenous (IV) and oral omadacycline for the treatment of acute bacterial skin and skin structure infections (ABSSSI) (17-1) and community-acquired bacterial pneumonia (CABP) (14-4). Paratek

Canfield Scientific Acquires Leading German Dermoscopy Company VISIONMED AG

The resulting business has decades of experience in aesthetic documentation, 3D imaging, clinical photography, and reflected light microscopy leading to more choices and services for customers.

Lupin Launches Generic Clobetasol Cream in the US

Lupin’s Clobetasol Propionate Cream USP 0.05% is the generic equivalent of Fougera Pharmaceuticals Inc.’s Temovate Cream, 0.05%. It is a super-high potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

Escalier Biosciences’ Doses First PsO Patient with ESR-114; Announces Clinical Advisory Board

The study is designed to evaluate the safety, tolerability, dose-response and pharmacokinetics of two concentrations of ESR-114 topical gel compared with its vehicle (placebo). More than 110 subjects with mild to moderate psoriasis will be randomized into this double-blind, placebo-controlled trial across 10 centers in the US and Canada.

Pulse Biosciences: First Patient Treated in BCC Study

The first patient has been treated in a clinical study to evaluate Nano-Pulse Stimulation (NPS) from Pulse Biosciences, Inc. for the treatment of Basal Cell Carcinoma (BCC). NPS is a non-thermal therapy that utilizes ultra-short, nanosecond pulsed electric fields that directly affect and disrupt intracellular structures and have been shown to induce immunogenic cell death in pre-clinical cancer models.

FDA Approves Poteligeo for Cutaneous T-Cell Lymphomas

The FDA approved Poteligeo (mogamulizumab-kpkc) injection for intravenous use for the treatment of adult patients with two types of cutaneous T-cell lymphoma (CTCL)—relapsed or refractory mycosis fungoides (MF) or Sézary syndrome (SS) after at least one prior systemic therapy. This approval provides a new treatment option for patients with MF and is the first FDA approval of a drug specifically for SS.

Castle Creek Pharmaceuticals Gets FDA Fast Track Designation for Diacerein 1% Ointment for EBS

Under the Fast Track designation, Castle Creek Pharmaceuticals, LLC. has the opportunity for priority review and more frequent interactions with the FDA throughout the CCP-020 development program. The FDA previously granted Orphan Drug Designation and Rare Pediatric Disease eligibility to CCP-020 for the treatment of epidermolysis bullosa (EB).
Pharmaceuticals, Inc.’s omadacycline is a modernized tetracycline being developed as a once-daily IV and oral, broad spectrum antibiotic for the treatment of serious community-acquired infections.

As part of its recommendation, the Advisory Committee considered data from the omadacycline global development program, which included three completed Phase 3 studies evaluating the safety and efficacy of the once-daily IV and oral formulations of omadacycline for the treatment of ABSSSI and CABP. In all three studies, omadacycline met all primary and secondary efficacy outcomes designated by the FDA and was generally safe and well-tolerated. A total of nearly 2,000 adult patients received omadacycline administered once-daily as part of the clinical trials. The Advisory Committee was asked to vote on whether the data provided substantial evidence of the safety and effectiveness of omadacycline in both ABSSSI and CABP.

The Prescription Drug User Fee Act (PDUFA) date for both new drug applications is in early October 2018.

(Continued on page 25)
Wake Forest Researchers: #2 in Probiotic Advancement

Scientists at Wake Forest School of Medicine say they have developed a probiotic “cocktail” derived from gut bacteria strains found in infant feces that may help increase the body’s ability to produce short-chain fatty acids (SCFAs).

“Short-chain fatty acids are a key component of good gut health,” says lead investigator Hariom Yadav, PhD, assistant professor of molecular medicine at Wake Forest School of Medicine. “People with diabetes, obesity, autoimmune disorders and cancers frequently have fewer short-chain fatty acids. Increasing them may be helpful in maintaining or even restoring a normal gut environment, and hopefully, improving health.”

Over the past decade, research has shown that specific probiotic strains can effectively prevent or treat certain diseases in both animal models and humans. These reports have led to an extensive demand for probiotic supplements over the last decade, thereby prompting a massive increase in the development of new probiotic products for the consumer market.

The School of Medicine team designed this study to examine the effects of probiotic strains derived from healthy human fecal samples and to determine how they worked.

Researchers collected fecal samples from the diapers of 34 healthy infants. After following a robust protocol of isolation, characterization and safety validation of infant gut-origin Lactobacillus and Enterococcus strains with probiotic attributes, the researchers selected the 10 best out of the 321 analyzed.

To test the ability of these human-origin probiotics to change the gut microbiome—bacteria that live inside the digestive track—and their capacity to produce SCFAs, mice were given a single dose, as well as five consecutive doses of this 10-strain probiotic cocktail. Then the researchers injected the same probiotic mixture in the same doses into a human feces medium.

The scientists found that the single- and five-dose feeding of these selected probiotics modulated the gut microbiome and enhanced the production of SCFAs in mouse gut and human feces.

The authors say the study was limited in that it didn’t test the probiotic mixture in any disease models. The study appears in the August 23 online edition of Scientific Reports, a Nature publication.