FDA Approves New Eczema Drug Dupixent

The FDA has approved Dupixent (dupilumab) injection to treat adults with moderate to severe eczema (atopic dermatitis). Regeneron Pharmaceuticals, Inc.’s Dupixent is intended for patients whose eczema is not controlled adequately by topical therapies, or those for whom topical therapies are not advisable. Dupixent can be used with or without topical corticosteroids.

Dupixent is a human monoclonal antibody that is designed to specifically inhibit overactive signaling of two key proteins, IL-4 and IL-13, which are believed to be major drivers of the persistent underlying inflammation in AD. Dupixent comes in a pre-filled syringe and can be self-administered as a subcutaneous injection every other week after an initial loading dose. Dupixent can be used with or without topical corticosteroids. It should not be used in patients who are allergic to dupilumab or any of the ingredients in Dupixent.

The safety and efficacy of Dupixent were established in three placebo-controlled clinical trials with a total of 2,119 adult participants with moderate to severe atopic dermatitis not adequately controlled by topical medication(s). Overall, participants who received Dupixent achieved greater response, defined as clear or almost clear skin, and experienced a reduction in itch after 16 weeks of treatment.

Dupixent can cause side effects such as serious allergic reactions and eye problems, such as conjunctivitis and keratitis. If patients experience new or worsening eye symptoms such as redness, itching, pain, or visual changes, they should consult a health care provider. The most common side effects include injection site reactions; cold sores in the mouth or on the lips; and eye and eyelid inflammation, including redness, swelling, and itching. The safety and efficacy of Dupixent have not been established in the treatment of asthma. Patients who also have asthma should not adjust or stop their asthma treatment without talking to their physicians.

Regeneron and Sanofi Genzyme, the specialty care global business unit of Sanofi, will market Dupixent in the US. Regeneron and Sanofi recognize that Dupixent can only help those uncontrolled moderate to severe AD patients that were prescribed the medicine if they can both access the medicine and use it properly. Therefore, the companies have launched Dupixent MyWay, a comprehensive and specialized program that provides support and services to patients throughout every step of the treatment process. Visit dupixent.com for more information. The program is designed to help eligible patients who are uninsured, lack coverage, or need assistance with their out-of-pocket costs. It also offers personalized support from registered nurses and other specialists who are available 24/7.

Juvéderm Family Grows with Approval of Vollure XC

The FDA has approved Allergan plc’s Juvéderm Vollure XC for correction of moderate to severe facial wrinkles and folds, such as nasolabial folds, in adults older than 21. In the US pivotal clinical trial, a majority (59 percent) of patients saw improvement in moderate to severe nasolabial folds for up to 18 months. Patient satisfaction in the pivotal study was also high with 82 percent of patients reporting that they were very satisfied at 6 months and 68 percent at 18 months.

Like other products in the Juvéderm family, Vollure XC is formulated with Allergan’s proprietary Vycross technology, which blends different molecular weights of hyaluronic acid, contributing to the gel’s duration. The first Allergan product featuring Vycross technology, Juvéderm Voluma XC was FDA-approved to increase volume lost due to aging in the cheek area, followed by Juvéderm Volbella XC, which is FDA-approved for lip augmentation and correction of perioral rhytids. Now with Juvéderm Vollure XC, the Vycross technology yields a custom
After a transformational 2016, Aclaris Therapeutics kicked off 2017 with a new drug application for their lead candidate, A-101, an investigational treatment for seborrheic keratosis. If approved, Aclaris will look to launch the topical treatment in 2018.

Neal Walker, DO, MBA, President & CEO and Director of Aclaris Therapeutics, took time out from the sessions and sun at Maui Derm 2017 to give us some hints about what else is to come from this dermatologist-led biotechnology company.

1. ROBUST PIPELINE
“Aclaris’ pipeline includes A-101, a proprietary 40% hydrogen peroxide topical solution for the treatment of seborrheic keratosis (SK). In November 2016, we reported that two pivotal Phase 3 trials of A-101 met all primary and secondary endpoints of each trial, achieving clinically and statistically significant clearance of SK lesions. We plan to conduct an additional study in dermatosis papulosa nigra (DPN), a form of SK. We are also pursuing an additional dermatological indication for A-101 for the treatment of common warts. A-101 is in development for topical application in office. Exactly how much time this takes depends on how many lesions a patient has. If there are a dozen SKs, it would take about 10 minutes to apply. Patients then go home, and the lesion sloughs or crumbles off over time. In September 2015, we acquired a portfolio of oral and topical Janus Kinase (JAK) inhibitor compounds for the treatment of alopecia, vitiligo, and other dermatological conditions.”

2. UNMET NEEDS
“We tend to go where there is nothing approved or where significant treatment gaps exist. SK lesions are benign, but we see these commonly in practice and there are no FDA-approved medications. Currently available SK treatments including electrodesiccation and curettage, shave removal, lasers, and chemical peels may cause scarring or skin pigment changes. We don’t want to trade a mark for a mark.”

3. BETTING ON WINNERS
“Angela M. Christiano, PhD, the Richard and Mildred Rhodebeck Professor of Dermatology and professor of genetics and development at Columbia University in New York City, showed proof of concept in animals and humans that topical and oral JAK inhibitors can reawaken dormant hair follicles by blocking inflammatory signaling. This created a lot of excitement as these agents may be effective in treating male and female hair loss and scarring alopecia. Two JAK inhibitors are already approved by the FDA, XELJANZ (tofacitinib citrate) for rheumatoid arthritis and JAKAFI (ruxolitinib) for bone marrow cancer.”

4. THEY DO KNOW JAK
“We plan to begin an open-label study looking at JAK Inhibitors in vitiligo, and initiate a Phase 2 dose ranging trial with ATI-50001 for the oral treatment of alopecia totalis and alopecia universalis in the second half of 2017. We also plan to submit an Investigational New Drug Application for ATI-50002 for the topical treatment of patchy alopecia areata mid-2017, and start a Phase 2 dose ranging trial with ATI-50002 for the topical treatment of patchy alopecia areata in the second half of 2017.”

5. WARTS AND ALL
“During 2016, we reported positive data from a Phase 2 trial of A-101 45% Topical Solution for the treatment of common warts. WART-201 comprised 98 patients at six centers, and found that A-101 achieved statistically significant and clinically meaningful results on all primary and secondary endpoints. It was well tolerated and local skin reactions were primarily mild in severity and similar to placebo. We plan initiate two Phase 2 clinical trials of A-101 45% Topical Solution for the treatment of warts in mid-2017.”
engineered injectable gel product that was studied in the nasolabial folds. It delivers a long-lasting result—up to 18 months. Juvéderm Vollure XC is specifically tailored with a balance of gel firmness and low cohesivity, yielding a versatile formulation that adds subtle volume for the correction of moderate to severe facial wrinkles and folds.

The most common side effects seen in the clinical study were temporary injection site responses at the treatment site such as swelling, tenderness, bruising, firmness lumps/bumps, redness, pain, discoloration, and itching. Most of these side effects resolved within one week.

Positive Results Announced from SebuDerm Gel Study in Treatment of Seborrheic Dermatitis

The results of a clinical study evaluating the impact of Sonoma Pharmaceuticals, Inc.’s SebuDerm (topical hypochlorous acid) gel in the treatment of mild to moderate facial and scalp seborrheic dermatitis were presented at the 13th Annual Maui Dermatology Conference in Maui, HI.

In a 25-patient study, conducted by Zoe Draelos, MD, president of Dermatology Consulting Services in High Point, NC, two key metrics were utilized in assessing efficacy of SebuDerm; the first being the investigator’s global assessment (IGA) of efficacy improvement in appearance and symptoms from baseline; and secondly, the subject global assessment (SGA) of improvement in itching, burning, and stinging. No adverse effects were reported and overall treatment was well tolerated by the subjects.

The IGA of efficacy improvement from baseline was 33 percent at day 14 and 52 percent at day 28. The SGA of efficacy improvement from baseline was 62 percent through day 28.

Clarification

Several readers wrote in questioning a quote by Amy Wechsler, MD, that appeared in an article titled “Mind Your Business: Exploring the Mind/Skin Connection” in the Feb. 2017 issue of Practical Dermatology®. In the article, Dr. Wechsler stated that “when someone is going through a stressful period, molecules like cortisol are higher and cause inflammation.” Readers pointed out that cortisol is anti-inflammatory in nature. Dr. Wechsler stands by her original comment, and provided the following citation to back it up. Canalis E. Effect of Glucocorticoids on Type I Collagen Synthesis, Alkaline Phosphatase Activity, and Deoxyribonucleic Acid Content in Cultured Rat Calvariae. Endocrinology (1983) 112 (3):931-939.

The company received a FDA 510(k) clearance for SebuDerm Gel as a prescription product, intended to manage and relieve the burning, itching, erythema, scaling, and pain experienced with seborrhea and seborrheic dermatitis in December 2015. US commercialization is underway via Sonoma’s dermatology division IntraDerm Pharmaceuticals’ 30-plus-person direct sales team.

Phase 4 Studies of Restylane Refyne and Restylane Defyne Show Lasting Natural Benefit

Two Phase 4 clinical studies of Restylane Refyne and Restylane Defyne show that the natural-looking results last. Specifically, the Natural Expression study found that naturalness in facial expressions was at least maintained in 95 percent (60/63) of subjects (primary objective). Additionally, results from the Dynamic Strain study found that 83 percent (25/30) of subjects had enhanced attractiveness, looked younger and at least maintained naturalness, post Restylane Refyne and Restylane Defyne injections.

The findings were presented during the Galderma Symposium at the 15th Aesthetic & Anti-aging Medicine Annual World Congress (AMWC) taking place from April 6-8 in Monaco. Restylane Refyne and Restylane® Defyne were recently approved by the FDA for the treatment of nasolabial folds (NLF) or “laugh lines,” in patients over the age of 21.

No Antibiotics Needed For Mild Infected Eczema in Kids

Oral or topical antibiotics are not effective for treating milder clinically infected eczema in children, a new study in Annals of Family Medicine shows.

In the study of 113 children with clinical, non-severely infected eczema, participants received either oral and topical placebos (control), oral antibiotic (flucloloxacinil) and topical placebo, or topical antibiotic (fusidic acid) and oral placebo, for one week. All children also received standard eczema treatment with steroid creams and emollients.

There were no significant difference between the groups in the resolution of eczema symptoms at two weeks, four weeks, or three months. There was, however, a rapid resolution in response to mild to moderate strength topical corticosteroids and emollient treatment.

“Our research shows that even if there are signs of infection, children with milder eczema are unlikely to benefit from antibiotics, and their use can promote resistance and
allergy or skin sensitization,” said study author Nick Francis, MD, PhD, a Clinical Reader at Cardiff University in South Wales, UK, in a news release. “Providing or stepping up the potency of topical corticosteroids and emollients should be the main focus in the care of milder clinically infected eczema flares.”

**Investigational Acne Drug Performs Well in Phase 3 Trials**

Allergan and Paratek Pharmaceuticals, Inc.’s investigational acne drug performed well in two Phase 3 studies, the companies report. Sarecycline, 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, met its 12-week primary efficacy endpoints.

Allergan plans to file a New Drug Application (NDA) to the FDA in the second half of 2017.

The studies sought to evaluate the efficacy and safety of oral sarecycline 1.5mg/kg per day compared to placebo in treating inflammatory acne lesions in subjects with moderate to severe acne based on Investigators Global Assessment (IGA) scale score and inflammatory lesion counts. Patients were randomized (1:1) into two treatment groups to receive sarecycline tablets (60mg, 100mg, and 150mg, providing a dose of 1.5mg/kg/day) or placebo once a day for 12 weeks.

Sarecycline was statistically significantly superior to placebo with respect to primary efficacy endpoints. The most common adverse events reported in the sarecycline group were nausea, nasopharyngitis, and headache. The rate of discontinuation due to adverse events among sarecycline-treated patients in the two studies combined was 1.4 percent.

**Mosquito Virus Expert Discusses a Promising New Drug For Zika**

Thomas Voss, PhD, a world-renowned leader in infectious disease research, and his team, say there are two strategies for developing a defense program against Zika infection: prevention, achieved by developing an effective vaccine and vaccination program or the development of a drug that can kill viruses or inhibit their capability to reproduce. Voss estimates that a vaccine could be still three to five years away from being licensed and available to patients. Potentially, antiviral drugs to fight Zika could be developed in a shorter time.

Voss speculates that an antiviral drug shown to be safe in the laboratory could be rapidly scaled up and manufactured for clinical trials: “There is a unique window of opportunity right now to evaluate a potential drug in people as Zika is an active emerging virus,” states Voss.

The direction is to have a broad-spectrum antiviral that could treat Zika, Dengue, and Chikungunya viral infections because of their similar symptoms, making it difficult to discern them at an early stage. HSRx Biopharmaceutical, a biotech company based in Tucson, AZ, is developing that together with the Voss team. By utilizing a new technology platform that includes genomics, proteomics, and metabolomics sciences in tandem with proprietary mass spectrometer technology and databases, HSRx has identified a compound from a common berry that was isolated and tested extensively in cell culture and animals called HSRx 431. “HSRx 431 shows great efficacy and virtually no toxicity, and looks like it has a broad-spectrum of activity against Zika, Dengue, and Chikungunya viruses,” states Voss.

He believes that the HSRx compound is certainly ahead of the game for treating Zika virus. The hope is that it will prove to be safe and effective in humans, and made quickly available to the populations most at risk.

From the same family as Dengue virus, Zika causes similar symptoms (high fever, skin rashes, muscle and joint pain, and headache). The majority of cases are mild and last between two days to one week but in some cases, the virus can turn out to be very dangerous, even life threatening. According to the latest reports from the World Health Organization (WHO) there are now 70 countries with reported mosquito-borne Zika virus and the outbreak continues to spread. Zika is becoming a global problem and a solution is needed urgently.

Zika virus is transmitted via mosquitoes of the Aedes genus, from mother to fetus during pregnancy, through blood transfusions, or sexually. Scientific data links Zika infections during pregnancy to congenital birth defects, including microcephaly. Other severe fetal defects include eye defects, hearing loss, and impaired growth. Countries with Zika outbreaks have seen an increase in Guillain-Barre syndrome cases in adults.

**Serloptitant May Stop the Itch of Prurigo Nodularis**

Menlo Therapeutics Inc.’s Serloptitant performed well in a Phase 2 trial (TCP-102) evaluating it as a treatment of pruritus associated with prurigo nodularis, successfully meeting its primary efficacy endpoint and key secondary endpoints. There are no currently approved treatments for prurigo nodularis.

The 127-subject multi-center, randomized, placebo-
controlled, trial evaluated treatment with once-daily, orally administered serlopitant 5mg tablets compared with placebo for 8 weeks. The trial was conducted at 15 clinical study sites in Germany. All subjects had severe pruritus as determined by a visual analog scale (VAS) pruritus score ≥7 on a 0-10 scale at screening. Serlopitant is a small-molecule, highly potent and selective neurokinin receptor 1 (NK1) antagonist. Substance P and its receptor, NK1, have been implicated by a number of preclinical and clinical studies to be important in the origin of pruritus.

At 8 weeks, the serlopitant-treated group reported a 48 percent reduction in average pruritus severity as compared with a 26 percent reduction in the placebo-treated group. A statistically significant greater reduction of pruritus in the serlopitant 5mg group compared with control was observed at every evaluation timepoint (weeks 2, 4, and 8) on the primary measure of pruritus in the study. Multiple additional measures of itch in this study confirmed the findings of reduced pruritus in serlopitant-treated subjects vs. the placebo group.

Serlopitant was well tolerated in this trial and had an overall safety profile comparable with placebo. Observed adverse events were generally mild to moderate.

New Treatment May Reduce Blistering in EBS

In a possible breakthrough in the treatment of epidermolysis bullosa simplex (EBS), dicarein 1% ointment reduced blistering in patients with this rare genetic connective tissue disorder. The new findings were presented in a late-breaker session at the American Academy of Dermatology Annual Meeting in Orlando.

There are currently no approved treatment options for EBS. The investigational dicarein 1% ointment (CCP-020), under development by Castle Creek Pharmaceuticals, blocks an inflammatory signaling pathway.

The multicenter, randomized, double-blind, placebo-controlled Phase 2 trial included 17 patients with EBS who were treated for four weeks followed by three-month follow-up and subsequent cross-over in year two. Results showed a 60 percent reduction in blistering among patients treated with dicarein 1% vs. 15 percent reduction in the placebo group at four weeks. At three months, 67 percent of patients in the placebo group returned to baseline blistering levels vs. 12.5 percent of the dicarein group. Topical dicarein 1% was well tolerated with no treatment-related adverse events reported.

Dr. George J. Hruza Elected AAD President-Elect

George J. Hruza, MD, MBA, FAAD, has been elected president-elect of the American Academy of Dermatology. Dr. Hruza also will hold this position for the American Academy of Dermatology Association. He will be installed as president-elect in February 2018 and hold the office of president for one year beginning in March 2019.

Pershing Square Capital Management, L.P. Announces Sale of Its Investment in Valeant

Pershing Square Capital Management, L.P. has sold its investment in Valeant Pharmaceuticals International, Inc. Pershing Square CEO Bill Ackman and Vice Chairman Steve Fraidin will remain on the Valeant board until the upcoming annual meeting but will not stand for re-election.

ADAM Names Lori Skraba 2017 Practice Manager of the Year

The Association of Dermatology Administrators and Managers (ADAM) named Lori Skraba of DuBois Dermatology and Cosmetics in DuBois, PA, the recipient of the annual Practice Manager of the Year award. The ADAM Practice Manager of the Year award, made possible in collaboration with CareCredit, recognizes a top professional from the organization who best demonstrates outstanding leadership qualities, management skills, and consistently goes above and beyond their responsibilities within the practice.

Merz Names Bob Rhatigan New President, CEO

Allergan vet Bob Rhatigan is the new President and Chief Executive Officer (CEO) of Merz North America, and Patrick Urban will serve as Chief Commercial Officer, effective immediately.

Apax Partners To Acquire Syneron for Close to $400 million

An affiliate of funds advised by Apax Partners will acquire all of the outstanding shares of Syneron Candela for $11.00 per share in cash in a transaction valued at approximately $397 million.

Novan Forms Advisory Council Focused on Nitric Oxide Technologies in Dermatology

Novan, Inc. has formed an Advisory Council comprised of key opinion leaders with broad expertise in dermatology. These leading physicians will provide medical advice and drug-development insight to the company’s senior leadership team and board of directors.

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