Therapeutics Focus: Psoriasis

MEDAC RECEIVES PATENT FOR INJECTABLE METHOTREXATE

Medac Pharma, Inc’s parent company medac GmbH has been issued a patent entitled “Concentrated Methotrexate Solutions,” directed to a method for the treatment of inflammatory autoimmune diseases by subcutaneously administering methotrexate (MTX) at a concentration of more than 30mg/ml. Medac Pharma and medac GmbH also filed a lawsuit in the United States District Court in New Jersey against Antares Pharma, Inc., LEO Pharma A/S, and LEO Pharma Inc. for their making, selling, and offering for sale methotrexate injection products for treating forms of rheumatoid arthritis, polyarticular idiopathic arthritis, and psoriasis.

GLOBAL PSORIASIS THERAPEUTICS MARKET OUTLOOK

Research and Markets (www.researchandmarkets.com/research/stdww/global_psoriasis) has announced the addition of the “Global Psoriasis Therapeutics Market” report to their offering.

The analysts forecast the Global Psoriasis Therapeutics market to grow at a CAGR of 4.06 percent during the 2012-2016 period. One of the key factors contributing to this market growth is the increasing uptake of biologics. The Global Psoriasis Therapeutics market has also been witnessing an increased focus on using combination therapies for treating psoriasis. However, the adverse side effects associated with psoriatic drugs could pose a challenge to the growth of this market.

The report, which was prepared based on an in-depth market analysis with inputs from industry experts, covers the market in the Americas, and the EMEA and APAC regions. It also covers the Global Psoriasis Therapeutics market landscape, its growth prospects in the coming years, and the key vendors in the market.

FDA APPROVES OTEZLA TO TREAT PSORIATIC ARTHRITIS

The FDA approved Otezla (Celgene, apremilast) to treat adults with active psoriatic arthritis (PsA).

“Relief of pain and inflammation and improving physical function are important treatment goals for patients with active psoriatic arthritis,” said Curtis Rosebraugh, M.D., MPH, director of the Office of Drug Evaluation II in the FDA’s Center for Drug Evaluation and Research. “Otezla provides a new treatment option for patients suffering from this disease.”

The safety and effectiveness of Otezla, an inhibitor of phosphodiesterase-4 (PDE-4), were evaluated in three clinical trials involving 1,493 patients with active PsA. Patients treated with Otezla showed improvement in signs and symptoms of PsA, including tender and swollen joints and physical function, compared to placebo.

Patients treated with Otezla should have their weight monitored regularly by a healthcare professional. If unexplained or clinically significant weight loss occurs, the weight loss should be evaluated and discontinuation of treatment should be considered. Treatment with Otezla was also associated with an increase in reports of depression compared to placebo.

The FDA is requiring a pregnancy exposure registry as a post-marketing requirement to assess the risks to pregnant women related to Otezla exposure.

In clinical trials, the most common side effects observed in patients treated with Otezla were diarrhea, nausea, and headache.

PHASE III RESULTS FOR SECUKINUMAB REPORTED

Results from the Phase III FEATURE and JUNCTURE studies show secukinumab (AIN457, Novartis), a selective interleukin-17A (IL-17A) inhibitor, met both co-primary endpoints at Week 12 based on Psoriasis Area and Severity Index (PASI) 75 and Investigator’s Global Assessment modified 2011 (IGA mod 2011) 0/1 response rates compared to placebo. Results from these studies, reported by the company, also demonstrated skin clearance at Week 12 based on PASI 90 response rates compared to placebo, usability and acceptability of the secukinumab pre-filled syringe (PFS) and autoinjector pen (AI), and an approximately 50 percent mean decrease in PASI scores from baseline by Week 3 (300mg) and Week 4 (150mg), according to the company.

FEATURE results showed the efficacy of secukinumab 300mg and 150mg based on a statistically significant higher proportion of patients who achieved a PASI 75 response at Week 12 compared with placebo patients: 75.9 percent (300 mg) and 69.5 percent (150 mg) versus 0 percent.
for placebo (\(p < .0001\)). On the co-primary endpoint, the efficacy of secukinumab 300mg and 150mg was shown based on a statistically significant higher proportion of patients who achieved an IGA mod 2011 0/1 response at Week 12 compared with placebo: 69.0 percent (300mg) and 52.5 percent (150mg), versus 0 percent for placebo (\(p < .0001\)). Results from JUNCTURE also showed the efficacy of secukinumab 300mg and 150mg based on a statistically significant higher proportion of patients who achieved a PASI 75 response at Week 12 compared with placebo: 86.7 percent (300mg) and 71.7 percent (150mg), versus 3.3 percent for placebo (\(p < .0001\)). On the co-primary endpoint, the efficacy of secukinumab 300mg and 150mg was shown based on a statistically significant higher proportion of patients who achieved an IGA mod 2011 0/1 response at Week 12 compared with placebo: 73.3 percent (300mg) and 53.3 percent (150mg), versus 0 percent placebo (\(p < .0001\)).

More secukinumab patients in both studies experienced an improvement in PASI of greater than or equal to 90 percent (PASI 90) from baseline as compared to placebo. In FEATURE, 60.3 percent (300mg) and 45.8 percent (150mg) of secukinumab patients achieved a PASI 90 response at Week 12 compared to 0% of placebo patients (\(p < .0001\)). In JUNCTURE, 55 percent (300mg) and 40 percent (150mg) of secukinumab patients achieved a PASI 90 response at Week 12 compared to 0 percent of placebo patients (\(p < .0001\)).

In FEATURE (n=177), the most common adverse events (AEs) in any treatment group including placebo were diarrhea, nasopharyngitis, and headache. There were four serious adverse events in the study—three (5.1 percent) in the 300mg secukinumab arm and one (1.7 percent) in the placebo arm. Two patients (one in secukinumab 300mg arm, one in placebo arm) discontinued due to adverse event. In JUNCTURE (n=182), the most common AEs in any treatment group including placebo were nasopharyngitis, headache, pruritus and hypertension. There were a total of five serious adverse events in the study—one (1.7 percent) in the 300mg secukinumab arm, three (4.9 percent) in the 150mg secukinumab arm and one (1.6 percent) in the placebo arm. One patient in the placebo arm discontinued due to adverse event. There were no deaths reported during either study.

A secondary endpoint of both FEATURE and JUNCTURE measured patient satisfaction and usability with self-injection of secukinumab via PFS and AI, respectively. Satisfaction was assessed in both studies using a self-administered Self-Injection Assessment Questionnaire (SIAQ) which measures overall subject experience with subcutaneous self-injection before the first self-injection and after dosing on the domains of feelings about injections, self-confidence, satisfaction with self-injection, injection-site reactions, ease of use, and self-image. Overall, patient-reported acceptability of both the PFS and AI were high at baseline across both studies and remained high during the study.

**NPF AND NOVARTIS TWEETUP FOR PSORIASIS EDUCATION**

National Psoriasis Foundation (NPF) and Novartis sponsored a #PsOAAD Tweetup at the AAD Annual Meeting last month in an effort to highlight the experiences of patients living with psoriasis. Noe Baker, Public Relations Manager for the NPF, and psoriasis patient Sabrina Skiles moderated the event.

Speaking after the event, Ms. Baker noted that NPF supported the initiative because, “Bringing the patient experience to the forefront with healthcare providers is so important to us.” Social media provided an opportunity “to elevate the patient voice.”

When patients speak publicly about psoriasis and their experience, it helps remove some of the stigma of the disease, Ms. Skiles said. “The more people hear about it, especially from the patient perspective, they’re able to not be embarrassed by it,” she explained.

NPF surveys of psorias patients reveal that patients rely on social media as a way to connect with others without worrying about the perceptions of psoriasis. “Many patients tell us that before social media they felt very alone,” Ms. Baker says.

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**Skinfix OTC Products Now Available in US**

Several new OTC products for challenging skin conditions are now available from Skinfix, a brand whose products were available in Canada and England. According to the company, the line of all-natural, medicinal OTC balms is clinically proven to treat challenging skin conditions that affect all ages, effectively soothing diaper rash, dry, cracked skin, eczema, chafing from sports, and providing protection from wetness, irritation, and even pressure sores. The Skinfix collection debuts with four products, including a Diaper Repair Balm, a Gentle Eczema Balm (also formulated for use on babies and toddlers), a Body Repair Balm for eczema, dryness, and dermatitis, and Rapid Repair Balm, which treats rashes, chafing, and redness. Skinfixinc.com
TEOXANE LAUNCHES SKINCARE LINE  

Alphaeon and Teoxane recently launched a new specialized seven-product skincare line that offers all of the benefits of Teoxane’s patented Resilient Hyaluronic Acid® (RHA) technology. According to the company, RHA leads to long-lasting hydration and immediate tightening of the skin. Included in the line are the RHA Prime Solution for face and eyes, the RHA Serum (a fundamental revitalizing concentrate), RHA Advanced age defense cream for dry skin, RHA Advanced Combo age defense cream for normal to combination skin, RHA Skin Definer smoothing cream, RHA Deep Repair Balm, and RHA Post-Procedure.  Alphaeon.com

REVISION UNVEILS NEW EYE CREAM  

Revision Skincare’s new D.E.J. Eye Cream is an intensive anti-aging cream that specifically targets the dermal-epidermal junction and helps to tighten and brighten the skin around your eyes. Formulated with clinically-proven extracts, peptides, and anti-oxidants, the D.E.J. Eye Cream addresses the signs of aging by helping to hydrate, brighten, and firm the skin. It is ideal for all ages and skin types, even those with sensitive complexions. In a 12-week independent clinical study, 96 percent of patients experienced an improvement in the look of fine lines, firmness, and overall photodamage, and 90 percent experience improvement in upper eyelid appearance, according to the company.  Revisionskincare.com

NEW ANTI-AGING PRODUCTS FROM GMC MEDICAL NOW AVAILABLE  

GMC Medical has launched several new anti-aging products, including the A.G.E. Skin Defence Cream, which combines 10 antioxidants and 8 peptides to reduce fine lines and wrinkles and increase skin’s resiliency and elasticity. This cream is designed to protect the antioxidant barrier, which is the skin’s self defense system responsible for limiting the oxidation caused by internal and external sources. The company also recently launched the Serum Antioxidant 20, a vaccine-like serum that allows young skin to preserve its youth capital and mature skin to mitigate the aging process, as well as the Intense Moisture Serum, a treatment formulated to help replenish, protect and restore the skin’s moisture barrier for all sensitive skin types.  Gmcmedicalskincare.com

NEW AGENTS TO TREAT SCARS NOW AVAILABLE  

Several new products from Enaltus’ ScarAway brand are now available. These include the ScarAway® Silicone Daily Discs, which use advanced patented silicone technology that’s ideal for smaller scars resulting from biopsies, mole removal, and acne blemishes; ScarAway® Flex Long Sheets, which use new Flexisil™ technology to help shrink, flatten, and fade longer scars that may result from tummy tucks or other surgeries, as well as injuries and burns; and ScarAway® Scar Repair Gel, the only patented, transparent, self-drying 100% silicone gel designed to improve the appearance of scars and prevent abnormal and excessive scar formation. Featuring patented Kelo-cote® silicone technology, the product dries in minutes to form a flexible, breathable, waterproof sheet over the affected area.  Enaltus.com

Mederma PM intensive overnight scar cream  

Merz North America, the makers of Mederma, introduced Mederma PM Intensive Overnight Scar Cream, a new scar cream formulated to work at night, when skin naturally regenerates faster. Mederma PM is clinically shown to improve the overall appearance, size, color, and texture of scars, making them softer, smoother, and less noticeable, according to the company. The cream is also formulated with Tripeptol, a skin-nourishing complex with peptides, collagen, and antioxidants that complement the increased nighttime regeneration of the skin to promote healthy looking skin. Mederma PM should be applied once-nightly and can be used with moisturizers and anti-aging creams, but patients are cautioned to consult their healthcare professionals before using Mederma PM with topical prescription products. Mederma PM may be used on scars on the face and the body resulting from injury, cuts, surgery, burns, and acne. To help ensure effective and appropriate product use, Mederma offers text, email, and calendar reminders. Additionally, an iPhone app, the Mederma Progress Tracker, allows users to take photos of their scars every few days and create a time-lapse movie to see how Mederma helped improve the appearance of their scars over time. The app is available in the iTunes App store. Mederma PM is available in a 1-ounce tube and 1.7-ounce jar.  Mederma.com