Celgene’s Otezla Approved for Moderate to Severe Plaque Psoriasis

The FDA has approved Celgene’s Otezla (apremilast), an oral, selective inhibitor of phosphodiesterase 4 (PDE4), for the treatment of patients with moderate to severe plaque psoriasis for whom phototherapy or systemic therapy is appropriate. Otezla is the first and only PDE4 inhibitor approved for the treatment of plaque psoriasis. The approval was based primarily on safety and efficacy results from the ESTEEM trials, in which Otezla treatment resulted in significant and clinically meaningful improvements in plaque psoriasis as measured by PASI scores at week 16. Moreover, sPGA scores of clear to almost clear were demonstrated in both studies. Side effects included diarrhea, nausea, upper respiratory tract infection, tension headache, and headache. Before starting Otezla, patients should inform their doctor if they have a history of depression or suicidal behavior and if these conditions or other mood changes develop or worsen while taking Otezla. Additionally, patients should have their weight checked regularly.

SKINPACT Program Launches with New Global Awards Initiative to Support the Dermatology Community

Galderma, in partnership with the International League of Dermatological Societies, has started a search for initiatives that will fulfill an important role in strengthening the global dermatology community.

Galderma launched a new global initiative under the SKINPACT Program that will provide support for two new projects in the field of community dermatology. The winning entries will be awarded funding to implement future projects to help shape advances in Community Leadership and Excellence in Education to improve communities and patient quality of life.

The SKINPACT Program recognizes those who see the true potential for advancement in their field and are willing to work passionately to make that vision a reality.

Galderma Initiates US Study of Novel Muscle Relaxant for Aesthetic Dermatology and Cosmetic Surgery

Galderma has initiated a Phase II clinical trial of a novel muscle relaxant in the US. The Phase II clinical trial is a multicenter, dose-ranging study designed to evaluate the safety and effectiveness of Galderma’s internally developed liquid form of botulinum toxin for the treatment of glabellar lines, and follows successful completion of a Phase I study earlier this year. Currently, all commercially available botulinum toxins come in powder form and have to be reconstituted with saline before use. The development of a liquid formulation has the potential to present healthcare professionals with a ready-to-use product that may result in a better patient experience and improved outcomes, according to Galderma.

“This trial initiation demonstrates Galderma’s commitment to innovation in the aesthetic market and is designed to strengthen and complement our current neurotoxin franchise,” said Humberto C. Antunes, President and CEO of Galderma. “Our current neurotoxin business, which includes Dysport and Azzalure, continues its strong performance in key markets around the world. The development of a liquid neurotoxin represents a significant advancement over existing commercial products and would allow us to further strengthen our position in the aesthetic category by better meeting physician and patient needs.”

Syneron Launches PicoWay Picosecond Device for Pigmented Lesion Treatment and Tattoo Removal

Syneron Medical Ltd. launched its new PicoWay picosecond device at the 23rd European Academy of Dermatology and Venereology (EADV) Congress, held in Amsterdam, The Netherlands, on October 8-12. PicoWay is a dual wavelength device, with 532nm and 1064nm wavelengths, which utilizes proprietary PicoWay technology to generate picosecond pulses for the treatment of pigmented lesions and tattoos, including recalcitrant tattoos. The staged launch of PicoWay begins in the international market during October 2014 and will continue in the United States in the first half of 2015, according to the company.

PicoWay incorporates high peak power and the short pulse durations to create the strongest photo-mechanical impact, which enables the most safe and effective fracturing of tattoo ink or pigmentation, Syneron says. The revolutionary PicoWay technology is integrated into a proven, reliable Candela platform.

PicoWay is CE marked and pending FDA clearance. Syneron anticipates that it will receive FDA clearance for PicoWay by the end of 2014.
Teledermatology App Teams Up with Dermatologists

A new teledermatology app is partnering with board- and state-certified dermatologists to assist patients with on-the-spot information regarding the detection and evaluation of skin disease in early stages. Having launched already in 13 states, Klara has partnered up with Dr. Mark Kaufmann, MD, Associate Professor at Mount Sinai Hospital in New York, and Dr. Chris Adigun, MD, Assistant Professor at NYU Langone Medical Center. According to the company, the app offers secure and private communication via smartphone between dermatologists and patients and is user-friendly for both parties. Using the Klara app, prospective patients photograph their skin problem, upload photos and answer a quick, yet thorough questionnaire developed by university clinics and leading dermatologists. The information is sent for review via a secure and HIPAA compliant channel to Klara’s participating dermatologists. Download of the Klara app is free, and consultations start at $39.

Ranbaxy Launches Absorica 25mg and 35mg Capsules

Ranbaxy Laboratories Inc., a wholly owned subsidiary of Ranbaxy Laboratories Limited, launched Absorica (isotretinoin) 25 mg and 35 mg capsules into the US healthcare market. The product, licensed by Ranbaxy from Cipher Pharmaceuticals, Inc., is indicated for the treatment of severe recalcitrant nodular acne in patients 12 years of age and older. Due to its high lipophilicity, oral absorption of isotretinoin is enhanced when given with a high-fat meal, however, Absorica, which is formulated using patented Lidose technology, can be given without regards to meals. The fasted AUC0-t of Absorica is approximately 83 percent greater than that of Accutane, while both products are bioequivalent under fed conditions. Absorica is therefore not interchangeable and not substitutable with generic products of Accutane, according to Ranbaxy.

Taclonex Granted New Indication for Scalp Plaque Psoriasis in Adolescents

LEO Pharma Inc., has received a new indication for Taclonex (calcipotriene and betamethasone dipropionate) Topical Suspension for a topical combination treatment of plaque psoriasis of the scalp in patients 12 to 17 years. The new indication represents the first indication for adolescent patients aged 12 years and older with scalp plaque psoriasis on the market. Taclonex Topical Suspension is a first-line, once-daily combination product indicated for treatment of both scalp and body plaque psoriasis in adults age 18 and above for up to eight weeks, and now for the treatment of plaque psoriasis of the scalp in pediatric patients 12 to 17 years for the same period.

GSK Presents Updated Results from Phase III BREAK-3 Study of Tafinlars

Results from the planned analysis of the Phase III BREAK-3 study in 250 patients with BRAF V600E mutant metastatic melanoma show benefit for the use of GSK’s Tafinlar (dabrafenib) over dacarbazine (DTIC). Forty-five percent of patients treated with dabrafenib only were alive at two years, compared to 32 percent of patients who began treatment with DTIC. Fifty-nine percent of patients on DTIC treatment whose disease progressed subsequently received dabrafenib treatment and are included in the DTIC control arm results.

BREAK-3 is a phase III, randomised, open-label study comparing the efficacy, safety, and tolerability of dabrafenib to DTIC in patients with advanced (Stage III) or metastatic (Stage IV) melanoma who harbour a BRAF V600E mutation.

Coronado Biosciences Forms Subsidiary to Acquire and License Dermatology Products for Commercialization

Coronado Biosciences, Inc. has formed a wholly owned subsidiary called Journey Medical Corporation (JMC) to acquire and license dermatology products. Under the leadership of CEO Claude Maroua, JMC will begin building a portfolio of dermatological assets focused on acne, steroid responsive dermatoses, pigmentation, and antifungals for promotion to dermatologists and pediatricians.

Coronado’s Chairman, President and CEO, Dr. Lindsay A. Rosenwald said, “Forming a specialized pharmaceutical company that focuses on dermatology will enable Coronado to diversify its business. Claude has a history of success in commercializing brands at top companies in this space, and we feel confident about his ability to bring this record of success to JMC.”