PIPELINE PREVIEWS

Pipeline Previews brings to you information on the newest drugs and medical products as they become available to the dermatologic community. This department may include additional information from the manufacturers, plus reports from physicians who wish to share their clinical experience with these new products. In addition, we will inform our readers about the latest drugs receiving Food and Drug Administration (FDA) approval.

Galderma Receives FDA Approval of Treatment for Rosacea

Galderma Laboratories, L.P. has announced that the FDA has approved Galderma's Soolantra® (ivermectin) Cream, 1% for the once-daily topical treatment of inflammatory lesions of rosacea.

The approval of Soolantra Cream was based on two pivotal phase 3, multicenter, randomized, doubleblind, 12-week, vehicle-controlled, parallel-group studies where Soolantra Cream met each of its coprimary efficacy endpoints. The onset of treatment effect was observed as early as week two with continuous improvement. In long-term extensions to the 12-week studies, Soolantra Cream was also safe and well-tolerated for an additional 40 weeks. Some study subjects experienced skin burning sensation and skin irritation while using Soolantra Cream.

Galderma also reports that in a separate head to head study with metronidazole 0.75% cream Soolantra Cream was shown to be more efficacious from as early as week three onwards.

FDA Approval of ONEXTON™ Gel for Acne Vulgaris

Valeant Pharmaceuticals International, Inc. has announced that it has received approval from the FDA for ONEXTON™ Gel (clindamycin phosphate and benzoyl peroxide), 1.2%/3.75%, for the once-daily treatment of comedonal (non-inflammatory) and inflammatory acne in patients 12 and older. ONEXTON™ Gel has a favorable cutaneous tolerability profile and contains no surfactants, alcohol or preservatives.

Valeant has touted the results of a pivotal trial with 498 patients with moderate to severe acne in which efficacy was assessed at week 12. ONEXTON™ Gel reduced non-inflammatory lesions by a mean of 52% vs. 28% vehicle, for mean absolute reductions of 19 vs. 10, respectively. ONEXTON™ Gel also reduced inflammatory lesions by a mean of 60% vs. 31% vehicle, for mean absolute reduction of 16 vs. 8, respectively. In addition, the proportion of patients experiencing treatment success in the ONEXTON™ group was twice that of vehicle (35% vs. 17%). Treatment success was defined as at least 2 grade improvement in the Evaluator Global Severity (EGS) score from baseline.

In the controlled clinical trial, according to Valeant, less than 1% of patients experienced a treatment related adverse event. The most common treatment-emergent and treatment-related adverse events were: burning sensation (0.4%), dermatitis contact (0.4%), pruritus (0.4%) and rash (0.4%). No ONEXTON™ patient had their treatment discontinued due to any adverse event.

CellCept Generic Released

Ascend Laboratories has launched its AB-rated generic version of Genentech's CellCept (mycophenolate mofetil) oral suspension, for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac, or hepatic transplants. CellCept® (mycophenolate mofetil). Generic CellCept oral suspension will be available as a dry powder that provides 200 mg of mycophenolate mofetil per milliliter after reconstitution.

Ascend advises that CellCept should be used concomitantly with cyclosporine and corticosteroids. CellCept carries a boxed warning regarding the risk of embryofetal toxicity, malignancies, and serious infections.

FDA Approves Generic Version of Valcyte® (valganciclovir)

The FDA has approved Dr. Reddy's and Endo's AB-rated generic versions of Roche's Valcyte (valganciclovir) 450 mg tablets. Valcyte is indicated for adult patients in the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome and prevention of CMV disease in kidney, heart, or kidney; pancreas transplant patients at high risk; pediatric patients in the prevention of CMV disease in kidney or heart transplant patients at high risk.

Roche's Valcyte is also available as an oral solution (50 mg/mL).

Hovione Files IND for Topical Minocycline

Hovione has announced that it has filed an Investigational New Drug (IND) Application with the FDA for minocycline gel, a novel formulation to administer topically using a new patented crystalline base form of minocycline, one of the most widely prescribed oral antibiotics for acne. Pending FDA's acceptance of the IND submission, Hovione plans to initiate human clinical Phase 1/2 studies in early 2015.

Bristol-Myers Squibb Receives Accelerated Approval of Opdivo (nivolumab) from FDA

Bristol-Myers Squibb Company has announced that the FDA approved Opdivo (nivolumab) injection, for intravenous use. Opdivo is a human programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following Yervoy (ipilimumab) and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this

indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

Opdivo demonstrated efficacy in a Phase 3, pivotal clinical trial with advanced melanoma in patients who had been previously treated and progressed with Yervoy and, if BRAF mutation positive, a BRAF inhibitor. The efficacy of Opdivo was evaluated based on a single-arm, non-comparative planned interim analysis of the first 120 patients who received Opdivo with a minimum of 6 months follow-up in the Phase 3 CheckMate -037 trial.

Opdivo achieved a 32% (95% CI: 23, 41) response rate (38/120) with a dosing strength and frequency of 3 mg/kg intravenously over 60 minutes every 2 weeks. 3% of patients (4/120) achieved a complete response, and 28% (34/120) achieved a partial response. Of 38 patients with responses, 33 patients (87%) had ongoing responses with durability of response ranging from 2.6+ to 10+ months, which included 13 patients with ongoing responses of 6 months or longer. Responses to Opdivo were demonstrated in both patients with and without BRAF mutation.

The safety profile of Opdivo has been demonstrated in the pivotal, Phase 3 CheckMate-037 trial. Serious adverse reactions occurred in 41% of patients receiving Opdivo. Grade 3 and 4 adverse reactions occurred in 42% of patients receiving Opdivo. The most frequent Grade 3 and 4 adverse drug reactions reported in 2% to <5% of patients receiving Opdivo were abdominal pain, hyponatremia, increased aspartate aminotransferase, and increased lipase. The most common adverse reaction (≥20%) reported with Opdivo was rash (21%).

CheckMate -037 was a randomized, Phase 3 trial evaluating Opdivo 3 mg/kg (n=268), administered every two weeks, or chemotherapy (n=102) (investigator's choice of either single-agent dacarbazine 1000 mg/m2 every 3 weeks or the combination of carboplatin AUC 6 every 3 weeks plus paclitaxel 175 mg/m2 every 3 weeks) in patients with advanced melanoma who had been previously treated and progressed with Yervoy and, if BRAF mutation positive, a BRAF inhibitor. No premedication is required with Opdivo.

The primary objective of this analysis of the CheckMate -037 trial was Objective Response Rate (ORR). CheckMate -037 included 90 participating trial sites in 14 countries, and included both institutional and community practice centers. The clinical study is ongoing to determine whether there is an overall survival benefit.

In the Opdivo treated patients (n=120), 76% of patients had M1C disease, 18% of patients had a history of brain metastases, and 56% of patients had elevated LDH levels. The median age of patients was 58. 22% of patients were BRAF V600 mutation positive.

Valeant Introduces AMBI Even & Clear CC+ Even Tone Environmental Shield

Valeant introduced the NEW AMBI® EVEN & CLEAR CC+ CREAM Even Tone Environmental Shield – the first color product in the AMBI® Skincare Line. Specially formulated to match the rich tones of women of color, this CC+ Cream contains argan oil, shea butter, and antioxidants to moisturize the skin.

AMBI® CC+ Cream provides broad-spectrum SPF 30 sunscreen protection from UV sun rays that can accelerate the formation of fine lines and wrinkles. This sunscreen is formulated not to leave the skin looking ashy or gray. "The addition of SPF 30 is significant," explains Dr. Dryer, "because many CC creams offer sunscreen with only SPF 20 and may leave a chalky residue on the skin. AMBI® CC+ Cream provides a higher level of sun protection with quality pigments, without sacrificing a luxurious feel and great coverage."

Available in Light/Medium and Medium/Dark, AMBI® CC+ Cream is designed to even skin tone instantly with soft focus technology, while helping to shield your skin from environmental elements that may cause uneven skin tone, dry out the skin, and accelerate fine lines and wrinkles. AMBI® EVEN & CLEAR CC+ Cream Even Tone Environmental Shield will be available at national mass, drug, and beauty supply retail stores in March 2015 with an SRP of $8.99.