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.

Inocutis introduces NEW breakthrough TREATMENT FOR COLD SORES

Sitavig® 50mg (Acyclovir) Muco-Adhesive Buccal Tablet

If you have never experienced a cold sore, consider yourself lucky! Millions of people get more than one episode per year and for up to two weeks that the sore may last, virtually everyone is "watching your lips!" And, not in a good way.

Now, there is a breakthrough treatment for cold sores with the potential to abort, shorten the duration, increase the amount of time between episodes. South Carolina-based, Innocutis, is pleased to announce the introduction of Sitavig® (ACYCLOVIR), 50mg Buccal Tablet. Sitavig represents a treatment breakthrough in the herpes labialis (HSV-1 cold sore) category, because of its unique vehicle and delivery system.

Sitavig uses a proprietary delivery technology called Luriad® which consists of a tablet that sticks to the gum above the incisor tooth on the side of the lip that is infected with a cold sore. 8mm in diameter and 2.2 – 2.6 mm in thickness, this white-to-slightly-yellow tablet is tasteless and odorless. It dissolves to provide a sustained release of medicine. It is available by prescription only at local retail pharmacies.

Phase III Study Proves it Works!

A Phase III, randomized, double-blind, placebo controlled study[1], including 775 subjects demonstrated that a single low dose of Sitavig acyclovir buccal tablet improved all clinical parameters of labial herpes when applied shortly after symptoms occurred. Most notable, Sitavig decreased duration of episode, increased the percentages of blocked lesions and delayed by 105 days the recurrence of the next herpes episodes.[2] It is well known that the standard of care, systemic antiviral drugs, is typically prescribed at high doses in the treatment of labial herpes (HL). However, Sitavig's innovative drug delivery system that provides a high sustained-release local exposure of acyclovir in the oral mucosa, supporting its evaluation as single low dose in HL.

"We are very excited to bring Sitavig to the North American markets," said Charles Jenkins, Vice President of Marketing for Innocutis. "Up to ninety percent of Americans have been exposed to HSV-1 by the time they are 50, but there hasn't been a real breakthrough product to address this problem in many years. Sitavig is revolutionary because unlike systemic drugs and topical prescription creams, Sitavig requires application to the gum only once-per-episode."

If there is anything good to be said about cold sores it is that they often come with a warning; a tingling or burning sensation before anything is visible on the lips. This "warning" stage is called prodrome and when Sitavig was applied within one hour after prodrome. It provided clinical benefit to cold sore sufferers, reducing the occurrence of vesicular lesions, primary or non-primary, which is the most important burden of the disease. It also prevented and delayed the recurrence of the next herpes episode, making Sitavig an attractive alternative option to systemic antiviral treatment for individuals with recurrent cold sores when applied within one hour after the onset of prodromal symptoms.

The Promius Promise Physician Portal

To help physicians who would like to better be able to follow a patient's progress while taking Promius Pharma's generic isotretinoin, Zenatane™(isotretinoin capsules USP) AB rated to Accutane, the company has created a web-based provider portal. It was designed to allow any authorized prescriber using the Promius Promise, to obtain easy, instant access to secure patient data related to their prescriptions handled by the Promius Promise.

The HIPAA secured web portal includes a list of all patients who are enrolled in the Promius Promise program (when processed through Direct Success Pharmacy), patient demographics, dates of prescriptions received and prescription shipments, information on pending prescriptions, reports showing communication with the patients and HCP office to allow the patient to receive isotretinoin within the iPledge® Do Not Dispense window, and a messaging tool allowing HCP office to send questions and receive responses within the portal itself or on their smart phone devices as preferred.

Aqua Pharmaceuticals, LLC Announces FDA Approval of ACTICLATE™ Tablets

Aqua Pharmaceuticals, an Almirall company, announced ACTICLATE™, a tetracycline-class antibacterial indicated for the treatment of a number of infections, including adjunctive therapy in severe acne, is FDA-approved as 150 mg and 75 mg tablets.

ACTICLATE™ 150 mg tablets have two functional scores, providing several dosing options to physicians and patients. The ACTICLATE™ film-coated, round 75 mg tablets and oval-shaped, dual-scored 150 mg tablets are designed to be small and easy to swallow. Utilization of the latest manufacturing technology has allowed 150 mg of doxycycline to be formulated in a substantially reduced tablet size for ACTICLATE™.

ACTICLATE™ should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. Tablets are contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

Azelaic Acid 15% Foam a Possible Treatment for Papulopustular Rosacea

Bayer HealthCare announced positive results from a Phase III trial that evaluated a 15% foam formulation of its compound azelaic acid (AzA) for the topical treatment of inflammatory papules and pustules of rosacea. An AzA foam formulation is a potential treatment option to complement the currently available AzA gel formulation. Papulopustular rosacea is a skin disease causing inflammatory lesions (papules and pustules) as well as erythema (redness) on the nose, cheeks, chin and forehead.

After evaluating safety and tolerability, the overall frequency of adverse events (AEs) was 31% in the AzA 15% foam group and 25% in the vehicle group. The vast majority of AEs in both groups were mild to moderate. In the AzA 15% foam group, no severe drug-related and no serious drug-related AEs were reported. Overall, less than 2% of subjects discontinued treatment due to an AE, the frequency being slightly lower in the AzA 15% foam group. Detailed results of the trial will be presented at upcoming scientific meetings.

Exuviance Super Retinol Concentrate Unveiled

NeoStrata Company, Inc., the creator of the original Glycolic Acid peel, enthusiastically unveils the next major innovation in antiaging skincare– Exuviance Super Retinol Concentrate. The unique breakthrough formula goes beyond diminishing wrinkles, specifically created to defy gravity for superior, visible lifting and firming results.

The brand's patented NeoGlucosamine® is clinically proven to work synergistically with Retinol, super-charging and intensifying the ingredient's volumizing effects versus Retinol alone to lift and firm skin. A time-released microencapsulation delivers pure Retinol, maximizing potency and benefits, while minimizing irritation potential.

The high-performance ingredients in this formulation help build natural collagen and its surrounding support matrix to lift, firm and smooth wrinkles from the inside out while also increasing cellular renewal, refining texture and diminishing the appearance of age spots.