

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.

Valeant Pharmaceuticals Announces FDA Approval of Onexton™ Gel for the Treatment of Acne Vulgaris

Valeant Pharmaceuticals International, Inc. announced today that it has received approval from the Food and Drug Administration (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 is the first and only FDA-approved fixed combination 1.2% clindamycin phosphate and 3.75% benzoyl peroxide medication for the once-daily treatment of comedonal (non-inflammatory) and inflammatory acne. ONEXTON™ Gel has a favorable cutaneous tolerability profile and contains no surfactants, alcohol or preservatives. ONEXTON™ Gel has been studied extensively prior to its approval.

Apremilast Approval Expanded to Include Plaque Psoriasis

The oral phosphodiesterase-4 inhibitor apremilast is now indicated for the treatment of moderate to severe plaque psoriasis. On September 23, the manufacturer, Celgene, announced that the Food and Drug Administration had approved the expanded indication for apremilast, which was initially approved in March 2014 for treating psoriatic arthritis. The new indication is for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.

iCAD/Xoft System- New Axxent SPX Controller

iCAD debuted the new Axxent SPX Controller new controller arm for the Xoft® Axxent® Electronic Brachytherapy (eBx®) System® at this year's ASTRO meeting. The Axxent SPX Controller features a streamlined design to support enhanced mobility and flexibility for delivery of electronic brachytherapy treatment in a wider range of healthcare settings including smaller treatment rooms. The Axxent SPX Controller also features new software and an enhanced bar code scanning function that offers significant workflow benefits and improved technology support for HIPAA compliance. These features are also now available on the multi-platform Axxent MPX Controller, which remains commercially available as the company's platform product approved for use in all indications including breast IORT, breast APBI, skin, endometrial, and cervical cancer treatments.

Promius Pharma Launches Promiseb® Topical Cream – 60 Gram Option

Promius Pharma LLC has announced the launch of Promiseb® Topical Cream in a new 60 gram box. This well-regarded non-steroidal cream for the treatment of seborrheic dermatitis has demonstrated both anti-inflammatory and antifungal properties. The new 60 gram box provides an option for treatment of larger body surface areas, which may necessitate fewer refills.

Novartis Announces FDA Advisory Committee Unanimously Recommends Approval of AIN457 (secukinumab) for Patients With Moderate to Severe Plaque Psoriasis

Novartis announced the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) to the US Food and Drug Administration today voted unanimously to support the approval of AIN457 (secukinumab), a selective interleukin-17A (IL-17A) inhibitor, for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy (a drug that is absorbed into the bloodstream and distributed to all parts of the body) or phototherapy (light therapy). The DODAC based its recommendation on the safety and efficacy outcomes from 10 psoriasis Phase II/III clinical studies, which included nearly 4,000 patients with moderate-to-severe plaque psoriasis.