

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.

Lilly's Taltz® (ixekizumab) Receives U.S. FDA Approval for the Treatment of Moderate-to-Severe Plaque Psoriasis

Eli Lilly and Company announced that the FDA has approved Taltz® (ixekizumab) injection 80 mg/mL for the treatment of moderate-to-severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. Taltz should not be used in patients with a previous hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients. Taltz is designed to specifically target IL-17A, a protein that plays a role in driving underlying inflammation in psoriasis.

The FDA approval of Taltz was based on findings from the largest Phase 3 trial program approved to date—more than 3,800 patients with moderate-to-severe plaque psoriasis from 21 countries. This number includes patients who began the trial on Taltz or placebo, or active comparator (U.S.-approved etanercept). This clinical program included three double-blind, multicenter, Phase 3 studies—UNCOVER-1, UNCOVER-2 and UNCOVER-3—which demonstrated the safety and efficacy of Taltz in patients with moderate-to-severe plaque psoriasis. All three studies evaluated the safety and efficacy of Taltz (80 mg every two weeks, following a 160-mg starting dose) compared to placebo after 12 weeks. UNCOVER-2 and UNCOVER-3 included an additional comparator arm in which patients received U.S.-approved etanercept (50 mg twice a week) for 12 weeks. UNCOVER-1 and UNCOVER-2 also evaluated response rates with Taltz during the maintenance period through 60 weeks.

Taltz will be available in the U.S. beginning in the second quarter of 2016.

The Canadian Form of Kybella Is Now Available

Allergan plc announced BELKYRA™ (deoxycholic acid injection) is the first and only Health Canada approved non-surgical injectable treatment specifically designed to improve the appearance of moderate to severe amounts of fat under the chin – commonly known as "double chin" in adults. BELKYRA™ is deoxycholic acid, a naturally-occurring molecule in the body that aids in the breakdown and absorption of dietary fat. When injected into fat under the chin, BELKYRA™ can cause the destruction of fat cells. Once destroyed, those cells cannot store or accumulate fat any longer.

In clinical studies on adults with moderate to severe fullness under the chin, 79 per cent of people treated with BELKYRA™ reported improved satisfaction with the appearance of the area beneath their chin 12 weeks after their last treatment. After being treated with BELKYRA™, patients also reported improvement in self-perception, including feeling happier and younger, based on their chin profile, as well as feeling less embarrassed, less self-conscious, less overweight, and less bothered by submental fullness.

Suneva Medical Introduces Regenica® Rejuvenating Dual Serum

Suneva Medical, Inc., a privately-held aesthetics company, announced the launch of Regenica® Rejuvenating Dual Serum, the latest addition to the Regenica® skin care line. Backed by science and clinical data, the new serum represents a revolutionary breakthrough in skin care and was specifically developed to improve the appearance of skin tone, texture and brightness, as well as reduce the appearance of fine lines, wrinkles and pores. The powerful, dual chamber serum is created using the most advanced growth factor technology that combines a 95 percent concentration of MRCx™—a unique, proprietary blend of growth factors, cytokines and proteins—and anti-aging ingredients including advanced copper peptides, amino acids, antioxidants and plant-based extracts.