

## 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.

### **KYTHERA Biopharmaceuticals Announces FDA Approval of KYBELLA™**

KYTHERA Biopharmaceuticals, Inc. (Nasdaq:KYTH) announced today that the U.S. Food and Drug Administration (FDA) has approved KYBELLA™, also known as ATX-101, “for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.” KYBELLA™ is the first and only approved non-surgical treatment for reduction of submental fullness, a common yet under-treated aesthetic condition.

KYBELLA™ is supported by a global clinical development program that includes over 20 clinical studies with more than 2,600 patients worldwide, of which over 1,600 have been treated with KYBELLA™. In the pivotal Phase III studies, 68.2 percent of patients responded to KYBELLA™ based on a composite of validated physician and patient measurements. <sup>ii</sup> Patients treated with KYBELLA™ reported an improvement in the amount of fat in the area under the chin. Patients also reported improvement in the emotional impact of submental fat when asked how happy, bothered, self-conscious, embarrassed, old and overweight they felt following treatment in relation to the amount of their submental fat.

The most common adverse reactions were associated with the injection site and included swelling, bruising, pain, numbness, erythema and formation of small areas of firmness around the treatment area. The percentage of adverse reactions reported as mild were 81 percent, moderate 17.4 percent, and severe 1.6 percent.

KYBELLA™ is administered by injections into the fat under the chin, tailored to the treatment goals of the patient and the physician. Each in-office treatment session is typically 15-20 minutes. Many patients experienced visible results in two to four treatments. Up to six treatments may be administered. Once the aesthetic response is achieved, retreatment is not expected.

KYTHERA has chosen to execute a training-led launch and developed a training program to educate physicians on the safe use of KYBELLA™, and its approved indication. Physician faculty education will begin in June 2015. KYBELLA™ physician training programs will initiate in late summer. Physicians will be able to purchase KYBELLA™ and treat their patients after they have been trained.

### **Topix Pharmaceuticals, Inc. Introduces Replenix® UltiMATTE™ Perfection SPF 50+, Tinted Physical Sunscreen**

Formulated with 16.2% micronized zinc oxide, to cover the broadest range of the UV protective spectrum, this SPF 50+ skin perfecting cream helps fight photo damage, which leads to premature skin aging.

Featuring innovative Universal Pigment Technology, this next generation BB cream combines Iron Oxide with an advanced light-diffusing pigment that blends with all skin tones. Ceramide 2 and Phospholipids support the skin matrix providing an all-day mattifying agent along with gentle hydrating benefits for even the most sensitive skin.

To round out this multi-tasking tinted sunscreen, Replenix® UltiMATTE™ Perfection SPF 50+ is infused with Green Tea Polyphenols, a signature of the Replenix® brand, to combat environmental damage and nourish the skin. A powerful blend of antioxidants including Resveratrol, Biotin, Co-Q10, Emblica, Centella Asiatica and Vitamin E help to calm and soothe the skin while absorbing free radicals and supporting a healthy skin structure. Ascorbic Acid (Vitamin C) adds brightening properties helping skin appear more radiant and toned, reducing the appearance of age spots and uneven skin tone.

### **AcneFree® Introduces NEW AcneFree® Drying Lotion**

AcneFree® has introduced NEW AcneFree® Drying Lotion, a fast acting treatment to help battle breakouts and occasional acne flare-ups. The hypoallergenic formula is created with an effective acne medication, salicylic acid, as well as a variety of other soothing and quick-drying ingredients. It has a unique two-phase solution that helps to reduce and treat breakouts. The clear solution contains 1% salicylic acid that unclogs pores, and the pink sediment contains soothing calamine to calm the treated area and cover the affected area overnight.

The formula also includes Niacinamide, which supports the skin’s natural ceramides and fatty acids that are essential for repairing and restoring the skin barrier – and may also reduce skin redness. In addition to Niacinamide, AcneFree® Drying Lotion also features quick-drying ingredients, such as sulfur and soothing ingredients, such as camphor that work together to gently calm the skin while salicylic acid treats the affected area.