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.

FDA Approves Cynosure 532 nm Laser for Tattoo Removal

The FDA has approved the Cynosure 532 nm laser delivery system that works with the company's PicoSure picosecond aesthetic laser to create a dual-wavelength laser system for removing tattoos of all colors. Cynosure reports that this new wavelength laser improves removal of red, orange, and yellow tattoo ink in fewer treatments than previous lasers.

KYTHERA ATX-101 (deoxycholic acid) Injection and Submental Fullness

KYTHERA Biopharmaceuticals, Inc. has announced that the FDA Dermatologic and Ophthalmic Drugs Advisory Committee has voted unanimously to support the approval of ATX-101 (deoxycholic acid) injection for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults, also known as a double chin. If approved, ATX-101 would be a first-in-class submental contouring injectable drug.

The committee's recommendation, although not binding, will be considered by the FDA as it continues its review of ATX-101. If approved by the FDA, KYTHERA anticipates launching ATX-101 in the second half of 2015.

ATX-101 is a patented formulation of a pure, non-animal derived version of deoxycholic acid, a naturally occurring molecule in the body that aids in the breakdown of dietary fat. ATX-101 has been the subject of 19 clinical studies involving more than 2,600 patients covering a span of ages (19-65) and BMI (18-40). A New Drug Application (NDA) was submitted to the U.S. Food and Drug Administration (FDA) in May 2014 and has a Prescription Drug User Fee Act (PDUFA) action date of May 13, 2015. Additionally, KYTHERA has submitted regulatory filings in Canada, Switzerland and Australia. If approved, ATX-101 would be a less-invasive, non-surgical option for the treatment of submental fullness.

Generic Version of Temovate® (clobetasol cream 0.05%)

Actavis has announced that it has launched a generic version of Fougera's Temovate® (clobetasol cream 0.05%) in the U.S. Temovate® is a high-potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

FDA Approves Radiesse® (+) With Integral 0.3% Lidocaine

Merz North America has announced that Radiesse® (+) with integral 0.3% Lidocaine ("Radiesse® Plus") has received FDA approval and is now available to US physicians. Radiesse® (+) provides the immediate lift of wrinkles and folds, stimulation of natural collagen production, and the lasting results that patients and physicians expect from Radiesse®, as well as providing patients significant reduction in pain due to the addition of lidocaine.

Radiesse® (+) injectable implant is an opaque, dermal filler that contains a small quantity of local anesthetic (lidocaine). Radiesse® (+) temporarily adds volume to help smooth moderate to severe facial wrinkles and folds, such as nasolabial folds. Radiesse® (+) is composed of calcium hydroxylapatite (CaHA) microspheres suspended in a water-based gel carrier.

Radiesse® (+) is a robust filler providing high elasticity (G') and viscosity1. In a clinical study, 101 patients received Radiesse® on one side of the face and Radiesse® (+) on the other side of the face. Patients rated their pain on a scale of 0 to 10. On the scale, 0 was no pain and 10 was very severe pain. Immediately after injection, patients rated their pain about 6.7 on a scale of 0 to 10 for the side of the face injected with Radiesse® compared to about 2.3 on the same scale for the side of the face treated with Radiesse® (+). Sixty (60) minutes after treatment, patients rated their pain about 1.1 on a scale of 0 to 10 for the side of the face injected with Radiesse® compared to about 0.3 on the same scale for the side of the face treated with Radiesse® (+).

Promius Pharma Launches Zenatane 30mg Dose

Promius Pharma, LLC has announced that ZENATANE™ (Isotretinoin Capsules USP) are now available in a 30mg dose. Zenatane, AB rated equivalent to Accutane 30mg, has been introduced in response to dermatologists who have continued to request this strength of the drug.

Zenatane 30mg will also be supported by The Promius Promise, a pharmacy service designed specifically to support Zenatane prescribers and patients. The Promius Promise program is designed to assist with patient education about treatment requirements and deliver Zenatane within 24 hours to US locations, at a reduced expense, for eligible patients. Promius explains that, pursuant to the Promius Promise, eligible patients will have a money saving rebate automatically applied, and will receive free shipping anywhere in the US. The Promius Promise will also assist with insurance questions and challenges if necessary.

iCAD to Present Positive Four-year Data on Xoft® Axxent® Electronic Brachytherapy (eBx®) System® for Non-melanoma Skin Cancer (NMSC)

iCAD, Inc. is presenting new positive data from its longest-running non melanoma skin cancer (NMSC) clinical trial to-date at this year's American Academy of Dermatology meeting. Results indicate that patients treated with the Xoft System for NMSC experienced good to excellent cosmesis with few reoccurrences to date.

The Xoft System is an isotope-free radiation treatment cleared by the U.S. Food and Drug Administration and CE marked in the EU for use anywhere in the body, including for the treatment of early-stage breast cancer, gynecological cancers and non-melanoma skin cancer. It utilizes a proprietary miniaturized x-ray as the radiation source that delivers precise treatment directly to cancerous areas while sparing healthy tissue and organs. The Xoft System requires only minimal shielding and therefore does not require room redesign or construction investment. Minimal shielding also allows medical personnel to remain in the room with the patient during treatment. The mobility of the Xoft System makes it easy to treat patients at multiple locations and to easily store the system when not in use. Xoft is a wholly owned subsidiary of iCAD, Inc.