

ZELTIQ RECEIVES FDA CLEARANCE TO TREAT SUBMENTAL FAT WITH COOLSCULPTING PROCEDURE

The FDA granted an expanded clearance for ZELTIQ® Aesthetics, Inc.'s CoolSculpting procedure, paving the way for the introduction of the new, CoolMini™ applicator, which is designed to treat smaller pockets of fat, including the submental, or chin fat area. The CoolSculpting® procedure has demonstrated in more than 50 published clinical articles and 4,000 clinical trial patients to non-invasively and consistently reduce unwanted fat and the procedure has been successfully used in over two million treatments to date, according to the company.

The new CoolMini applicator is uniquely designed for small volume areas of fat. The applicator's size, shape and curvature is designed to comfortably fit these small, problem areas. Patients may see results as early as three weeks, with the most dramatic results generally observed one to three months following treatment.

The FDA clearance is based on data from a US pivotal clinical trial involving 60 male and female patients, ranging in age from 22 to 65 years. In the trial, patients received one to two treatments in the area under the chin, each six weeks apart resulting in an average of 20 percent fat reduction, which is in line with results achieved with other CoolSculpting applicators. Additionally, no significant adverse events were observed and patients experienced little to no discomfort or downtime.

Over 500 CoolMini treatments have been performed to date as a result of pilot clinical work, clinical trials, and the company's controlled European launch that commenced in June. The results, achieved in as little as one to two office visits, have been very encouraging with very high patient satisfaction and the same level of efficacy achieved with other CoolSculpting applicators.



Allergan Completes Acquisition of Kythera Maker Kythera

Allergan plc has successfully completed the acquisition of Kythera Biopharmaceuticals, Inc. Allergan acquired

Kythera in an all-cash transaction valued at approximately \$2.1 billion.

The acquisition of Kythera adds Kybella® (deoxycholic acid) injection, the first FDA approved non-surgical injection for improvement in the appearance of moderate to severe



submental fullness in adults. Kybella is administered by a trained physician who injects the product under a patient's chin to destroy fat cells, improving the appearance of the patient's chin area. Up to six treatments may be administered per patient no less than one month apart, and each in-office treatment session lasts approximately twenty minutes.

"The completion of the Kythera acquisition is an important moment for Allergan and our world-class aesthetics business, adding highly differentiated products and development programs that enhance our product offering to global customers and their patients," said Brent Saunders, CEO and President of Allergan. "Kybella is a game-changing product in facial aesthetics, and builds on our leadership in the facial aesthetics market."

Kythera recently announced the submission of a Marketing Authorization Application (MAA) in the European Union (EU), seeking approval for ATX-101 (deoxycholic acid) injection as a treatment for the reduction of submental fat when the presence of submental fat has a psychological impact for the patient. Additionally, Allergan will pursue the relevant clinical trial requirements and the regulatory pathways to license and commercialize this treatment in other countries.

The acquisition also adds Kythera's development product setipiprant (KYTH-105), a novel compound for the prevention of androgenetic alopecia (AGA), or male pattern hair loss, as well as additional early-stage development candidates. Kythera has submitted an Investigational New Drug Application (IND) to the FDA for setipiprant for the treatment of AGA. Allergan plans to conduct a human proof-of-concept study to evaluate the efficacy and safety of setipiprant in male subjects with AGA.

Revance Therapeutics Initiates Phase 3 Clinical Trial of Botulinum Toxin Type A Topical Gel for Crow's Feet

Revance Therapeutics, Inc. has commenced dosing patients in the Phase 3 pivotal study to evaluate the safety and efficacy of its RT001 investigational topical drug product candidate for the treatment of lateral canthal lines, or crow's feet. The Phase 3 trial will evaluate the safety and efficacy of a single, bilateral administration of RT001 topical gel compared to placebo in patients with moderate to severe crow's feet. The company plans to release interim results from this

Phase 3 study in the first half of 2016.

The Phase 3 trial is a randomized, double-blind, parallel-group, placebo-controlled study to evaluate the safety and efficacy of RT001, also referred to as RTT150 (Botulinum Toxin Type A) Topical Gel, for the treatment of moderate to severe lateral canthal lines. A total of up to 450 adult patients will be enrolled at multiple sites in the US and will be randomized 1:1 to a single treatment of either RT001 topical gel or placebo. The product will be applied to lateral canthal lines on both sides of the face using Revance's proprietary applicator.

The primary efficacy endpoints are composites based upon the Investigator's Global Assessment of Lateral Canthal Lines (IGA-LCL) assessment and the Patient Severity Assessment (PSA) between baseline and 28 days after treatment. One composite endpoint includes those patients with a 2-point or greater improvement as graded by the investigator's assessment and the patient's self-assessment. The other composite endpoint includes those patients who experience a 1-point or greater improvement in the investigator's and patient's assessments.

Patients will also be assessed at Day 28 for muscle paralysis (or paralytic effect) using electromyography (EMG). Additional information about the trial, including patient eligibility criteria, will be posted at www.clinicaltrials.gov.

FDA Approves Juvederm® Ultra XC for Use in Lips

Allergan has received FDA approval to market Juvederm® Ultra XC for injection into the lips and perioral area for lip augmentation in adults over the age of 21. It is the only dermal filler that has proven results lasting up to one year for lip augmentation.

In clinical trials of Juvederm® Ultra XC, the majority of subjects reported improvement in the softness, smoothness, and natural look and feel of their lips through one year. In clinical trials, 79 percent of subjects showed a meaningful improvement in lip fullness three months after treatment. Additionally, more than 78 percent of subjects reported an improvement in their overall satisfaction with the look and feel of their lips at one year after treatment. ■

