Fact Sheet

kybella™
(deoxycholic acid) injection

WHAT IS SUBMENTAL FULLNESS?

- Submental fullness due to submental fat, sometimes referred to as "double chin," is a common, yet undertreated facial aesthetic condition. It can detract from an otherwise balanced and harmonious facial appearance[i] – leading to an older and heavier look.
- Submental fullness can impact a broad range of adults, and is not limited to people who are overweight. This condition can impact men or women of average weight and can be caused by aging, genetics and weight gain. It is often resistant to diet and exercise alone.[ii]
- According to a 2014 survey by the American Society for Dermatologic Surgery (ASDS), over 2/3 of consumers are bothered by submental fullness – nearly as many as those bothered by lines and wrinkles around the eyes.[iii]

WHAT IS KYBELLA™ (DEOXYCHOLIC ACID) INJECTION?

- KYBELLA™ (deoxycholic acid) injection, also known as ATX-101, is the first and only FDA-approved injectable drug that contours and improves the appearance of submental fullness due to submental fat.
- KYBELLA™ is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults. The safe and effective use of KYBELLA™ for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

HOW DOES KYBELLA™ WORK?

- KYBELLA™ is a non-human and non-animal formulation of deoxycholic acid, a naturally-occurring molecule in the body that aids in the breakdown and absorption of dietary fat.
- When injected into subcutaneous fat, KYBELLA™ causes the destruction of fat cells.[iv] Once destroyed, those cells cannot store or accumulate fat.[v] After the aesthetic response is achieved, retreatment with KYBELLA™ is not expected. Due to its cytolytic activity, KYBELLA™ should not be injected into or in close proximity to vulnerable anatomic structures.

HOW IS KYBELLA™ ADMINISTERED?

- KYBELLA™ is administered by injections into the fat under the chin.
- Each in-office treatment session is typically 15-20 minutes.
- Treatment with KYBELLA™ is customized by the physician to the patient's aesthetic goals for an improved chin profile.

WHAT ARE THE RESULTS OF KYBELLA™ CLINICAL TRIALS?

- In the pooled, pivotal Phase III studies, 68.2 percent of patients responded to KYBELLA™ based on a composite of validated physician and patient measurements.[vii]
- Many patients experienced visible results in two to four treatments. KYBELLA™ treatment resulted in high patient satisfaction.
  - In clinical studies, 28%, 43% and 55% of KYBELLA™-treated patients had a ≥1-grade composite improvement after 2, 3 and 4 treatments, respectively.
- 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.

IS KYBELLA™ SAFE?

- KYBELLA™ has been the focus of a global clinical development program involving over 20 clinical studies with more than 2,600 patients worldwide, of which over 1,600 have been treated with KYBELLA™.
- Production of KYBELLA™ is a highly controlled, quality-assured and validated, current Good Manufacturing Practices-compliant process to ensure patient safety. KYBELLA™ contains no human or animal-derived substances.

WHAT ARE THE SIDE EFFECTS WITH KYBELLA™?

- The safety profile of KYBELLA™ is well characterized. Side effects may include swelling, bruising, pain, numbness, redness or formation of small areas of firmness. Adverse events with KYBELLA™ infrequently resulted in discontinuation from study (1.6% of participants). Care must be taken when injecting KYBELLA™ to avoid the risk of marginal mandibular nerve injury and dysphagia.

Please see Important Safety Information on reverse side.

WHEN WILL KYBELLA™ BE AVAILABLE?

- 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.

ABOUT KYTHERA BIOPHARMACEUTICALS, INC.

- KYTHERA Biopharmaceuticals, Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of novel prescription products for the aesthetic medicine market. In addition to its lead product KYBELLA™, KYTHERA also licensed the worldwide rights to setipiprant, an early-stage potential treatment for hair loss. KYTHERA's longer-term strategy is to leverage its biotechnology and aesthetics experience to expand its product portfolio and pipeline. KYTHERA has submitted regulatory filings for ATX-101 in Canada, Switzerland and Australia. Find more information at www.kythera.com.

KYBELLA™ (deoxycholic acid) injection is indicated for improvement in the appearance of moderate to severe convexity or fullness associated with submental fat in adults.

The safe and effective use of KYBELLA for the treatment of subcutaneous fat outside the submental region has not been established and is not recommended.

Important Safety Information

KYBELLA should only be administered by a trained healthcare professional.

KYBELLA is contraindicated in the presence of infection at the injection sites.

Avoid injecting in proximity to vulnerable anatomic structures due to the increased risk of tissue damage.

Cases of marginal mandibular nerve injury, manifested as an asymmetric smile or facial muscle weakness, were reported during clinical trials. To avoid the potential for nerve injury, KYBELLA should not be injected into or in close proximity to the marginal mandibular branch of the facial nerve. All marginal mandibular nerve injuries reported from the trials resolved spontaneously (range 1-298 days, median 44 days).

Difficulty swallowing (dysphagia) occurred in the clinical trials in the setting of administration site reactions, e.g., pain, swelling, and induration of the submental area. Cases of dysphagia spontaneously resolved (range 1-81 days, median 3 days). Subjects with current or prior history of dysphagia were excluded from clinical trials. Avoid use of KYBELLA in these patients as current or prior history of dysphagia may exacerbate the condition.

In clinical trials, 72% of subjects treated with KYBELLA experienced injection site hematoma/bruising. KYBELLA should be used with caution in patients with bleeding abnormalities or who are currently being treated with antiplatelet or anticoagulant therapy as excessive bleeding or bruising in the treatment area may occur.

To avoid the potential of tissue damage, KYBELLA should not be injected into or in close proximity (1-1.5 cm) to salivary glands, lymph nodes and muscles.

The most commonly reported adverse reactions in the pivotal clinical trials were: injection site edema/swelling, hematoma/bruising, pain, numbness, erythema, and induration.

For full Prescribing Information, visit mykybella.com.

i. Swift A, Remington K. BeautiPHication: a global approach to facial beauty. CLIN PLAST SURG. 2011; 38:347-77.

ii. Huettner F et al, Facial Plast Surg. 2012;28:40-51; Schlessinger J et al. Skinmed. 2013;11(1):27-31

iii. American Society for Dermatologic Surgery 2014 Consumer Survey on Cosmetic Dermatologic Procedures (N=8,315); Exact survey language was, "How bothered are you by excess fat under the chin/neck?"

iv. Stryer L, ed. Biochemistry. 4th Edition. New York, NY: WH Freeman and Co.; 1995: 691-707

v. Package Insert 03/06, section 12.1 (ATX-101 is a cytolytic drug, which when injected into tissue physically disrupts the cell membrane causing lysis)

vi. Package Insert, section 13, Figure 4 (≥ 2-Grade and ≥ 1-Grade Composite Clinician and Patient Response)
• 28%, 43% and 55% of KYBELLA-treated patients had a ≥1-grade composite improvement after 2, 3 and 4 treatments, respectively.

vii. Dayan SH, Jones DH, Carruthers J, et al. A Pooled Analysis of the Safety and Efficacy Results of the Multicenter, Double-Blind, Randomized, Placebo-Controlled Phase 3 REFINE-1 and REFINE-2 Trials of ATX-101, a Submental Contouring Injectable Drug for the Reduction of Submental Fat. Plastic and Reconstructive Surgery. 2014;134(4S-1):123.
• 82% of ATX-101 patients achieved ^{3}1-grade improvement from baseline as assessed by clinicians at 12 weeks after the last treatment.

viii. Package Insert, section 13, Figure 4 (≥ 2-Grade and ≥ 1-Grade Composite Clinician and Patient Response)
• 28%, 43% and 55% of KYBELLA-treated patients had a ≥1-grade composite improvement after 2, 3 and 4 treatments, respectively.

KYTHERA®
biopharmaceuticals