



KYTHERA Biopharmaceuticals Announces US Availability of KYBELLA™ – First FDA-Approved Injectable Treatment for “Double Chin” – Through KYBELLA™ Trained Physicians

Westlake Village, Calif., June 19, 2015 -- KYTHERA Biopharmaceuticals, Inc. (NASDAQ: KYTH) today announced the U.S. availability of KYBELLA™ (deoxycholic acid) injection, the first and only FDA-approved non-surgical treatment for reduction of submental fullness, a common yet under-treated aesthetic condition also known as “double chin.” KYBELLA™ was approved in April by the U.S. Food and Drug Administration (FDA), and can now be purchased by physicians who have been trained on the safe use of KYBELLA™ and its approved indication.

Training began earlier this month for KYBELLA™ physician trainers, with broader KYBELLA™ physician training programs to begin in late summer. Only physicians who have participated in a training program will be able to purchase KYBELLA™ and treat patients. KYBELLA™ will be available to trained physicians in a pack of four, 2 mL, single-patient use vials at a cost of \$1,200 per pack or \$300 per vial.

“Many people complain that a double chin makes them feel older and heavier than they actually are,” said Frederick C. Beddingfield, III, M.D., Ph.D., Chief Medical Officer, KYTHERA. “With KYBELLA™, for the first time, people have access to a non-surgical solution to address this long-standing but common aesthetic complaint. KYBELLA™ causes the destruction of fat cells, so once the aesthetic response is achieved, retreatment is not expected.”

KYBELLA™ is administered by injections into the fat under the chin, tailored to the treatment goals of the patient and their physician. In clinical trials, many patients experienced visible results in two to four treatments,ⁱ though up to six treatments may be administered. The average dose was 2-3 vials per treatment session (which equates to 4-6 mL). KYBELLA™ treatment resulted in high patient satisfaction during clinical trials. In fact, 79 percent of KYBELLA™-treated patients reported satisfaction with their appearance in association with their face and chin. Patients also reported improvement in the visual and 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.

Health care practitioners and consumers can visit www.MyKYBELLA.com for further product and prescribing information, and to find physicians who have been trained on the use of KYBELLA™.



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™.ⁱⁱ

The most common adverse reactions were associated with the injection site and included swelling, bruising, pain, numbness, erythema and formation of areas of hardness in the treatment area. The percentage of adverse reactions reported as mild were 81 percent, moderate 17.4 percent, and severe 1.6 percent. In clinical trials, the incidence and severity of most side effects decreased with subsequent KYBELLA™ treatments. KYBELLA™ can cause serious side effects, including trouble swallowing (2% of clinical trial patients) and nerve injury in the jaw that can cause an uneven smile or facial muscle weakness (4% of clinical trial patients). Adverse reactions resulted in study discontinuation in 1.6 percent of subjects.

About Submental Fullness

Submental fullness is a common yet undertreated condition that can detract from an otherwise balanced and harmonious facial appearanceⁱⁱⁱ – leading to an older and heavier look.^{iv} Submental fullness can affect adults – both women and men – of all ages, weight and gender. Influenced by multiple factors including aging and genetics, submental fullness is often resistant to diet and exercise. According to a survey by the American Society for Dermatologic Surgery (ASDS), nearly as many consumers are bothered by submental fullness (68%) as by lines and wrinkles around the eyes (71%).^v

About KYBELLA™

KYBELLA™ is the first and only approved injectable drug for contouring moderate to severe submental fullness, a condition that is commonly referred to as a double chin. 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.^{vi} When injected into subcutaneous fat, KYBELLA™ causes the destruction of fat cells. Once destroyed, those cells cannot store or accumulate fat.^{vii}

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.

About KYTHERA®



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 (KYTH-105), 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.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding KYTHERA, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 including the ability of KYBELLA™ to be a first-in-class submental contouring injectable drug, anticipated commercial availability of KYBELLA™ in June 2015, the ability of KYBELLA™ to be a less-invasive, non-surgical option for the treatment of submental fullness, the average dose of 2-3 vials (4-6 mL) per treatment session, and expectations regarding our longer-term strategy. Such forward-looking statements involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the commercialization process, our substantial dependence on KYBELLA™, and other matters that could affect the commercial availability of KYBELLA™. KYTHERA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of the Company in general, see KYTHERA's reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended March 31, 2015 and its Report on Form 10-K for the year ended December 31, 2014.

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¹ Package Insert, section 13, Figure 4 (≥ 2-Grade and ≥ 1-Grade Composite Clinician and Patient Response).

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- 28%, 43% and 55% of KYBELLA-treated patients had a ≥ 1 -grade composite improvement after 2, 3 and 4 treatments, respectively.
 - 59% of KYBELLA-treated patients received all six treatments.

ⁱⁱ Kythera Data On file; Phase I-III clinical studies globally.

ⁱⁱⁱ Swift A, Remington K. BeautiPHication: a global approach to facial beauty. *Clin Plast Surg.* 2011; 38:347-77.

^{iv} Dayan S. Neck rejuvenation. In: Hirsch, *Aesthetic Rejuvenation: A Regional Approach.* 1st ed. New York, NY: McGraw Hill Professional Publishing; 2008: 123-147.

^v 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?"

^{vi} Stryer L, ed. *Biochemistry.* 4th Edition. New York, NY: WH Freeman and Co.; 1995: 691-707.

^{vii} 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).