FDA approves injection for melting away double-chin fat

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The Food and Drug Administration said Wednesday it approved an injection designed to melt away double-chin fat.

The agency approved a drug called Kybella for adults with moderate or severe fat below the chin, or submental fat. It's the first approved drug for Kythera Biopharmaceuticals.

The drug is a synthetic form of deoxycholic acid, a chemical the FDA said is naturally produced by the body and helps it absorb fats. It destroys fat cells by breaking down the cell membrane.

The agency says patients can get up to 50 injections in one sitting, but treatments should be at least one month apart and patients should get no more than six.

Kythera plans to start selling Kybella in the second half of 2015, and said in regulatory filings that it thinks the injection could top $500 million in annual sales.

The Westlake, California, company said deoxycholic acid is a safe ingredient found in several other approved drugs. It has also filed for marketing approval in Australia, Canada and Switzerland and wants to market the drug in other countries.

Citing market research and surveys by dermatologists, Kythera says U.S. consumers spend more than $1 billion a year on cosmetic facial

injections like the anti-wrinkle treatment Botox and dermal fillers, and that number is expected to keep growing. Many patients who undergo those treatments would also be willing to have a Kybella injection to eliminate fat under their chins, the company said in filings with the Securities and Exchange Commission.

Kybella isn't approved for injection into any other part of the body. The FDA said the most common side effects of the drug included swelling, bruising, pain, numbness, redness and hardness in the treatment area, while more serious side effects included trouble swallowing and nerve injury that can cause an uneven smile or muscle weakness.

Shares of Kythera Biopharmaceuticals Inc. fell $2.05, or 4.3 percent, to $45.59 Wednesday

An FDA advisory panel recommended approving Kybella on March 9. The company's stock has climbed 15 percent since March 4, a few days before the panel vote.