

ReShape Medical Offers Non-Surgical Device for Weight Loss

ReShape Medical

ReShape Duo is First to Achieve Important Milestone in the U.S.

ReShape Medical Inc. has announced that its REDUCE Trial for the ReShape Duo® Intra-gastric Balloon, a non-surgical treatment for weight loss, has met its primary efficacy endpoints.

ReShape Medical, Inc. is the first medical device company to successfully meet its primary efficacy endpoints in a U.S., randomized, sham-controlled pivotal trial for weight loss. Study endpoints assessed weight loss and responder rates. The trial, which reached full enrollment in less than six months, involved eight U.S. sites and studied 326 patients. ReShape Medical, Inc. plans to submit a Premarket Approval application to the U.S. Food and Drug Administration (FDA) in the second quarter of 2014.

[Photos of the Day: Weight Loss Device Without Surgery](#) [1]

“Being the first device company to meet its primary efficacy endpoints in a randomized obesity trial is an important step forward on the path to FDA approval,” said President and CEO of ReShape Medical, Inc., Richard Thompson. We saw very significant interest in participation in this study, and are looking forward to bringing the first, non-surgical weight-loss device to the U.S. market, where ReShape Duo has the potential to help patients lose significantly more weight than diet and exercise programs alone.”

According to the Centers for Disease Control and Prevention, more than one-third of U.S. adults (35.7%) are obese, which is roughly 35 pounds over a healthy weight. Additionally, obesity is a major risk factor for serious medical conditions and contributes to 300,000 deaths each year. The ReShape procedure will fill a huge gap in the weight loss treatment continuum between diet, exercise, medications and risky and expensive surgical options.

The ReShape Duo dual-intra-gastric balloon is endoscopically placed down the esophagus and into the stomach, with a procedure that does not require any incisions, sutures or fixation to the body. The balloons are inflated with saline and take up much of the stomach’s volume, causing patients to eat smaller portions and to feel full sooner. The device does not change or alter the patient’s anatomy and is fully reversible. During the 24 week treatment period, patients work with dietitians, doctors and nurses to learn healthy diet and exercise habits to help them during and beyond the treatment period.

“Meeting the primary endpoints is an important accomplishment, as it convincingly

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demonstrates the superiority of the ReShape procedure over diet and exercise alone.” said Jaime Ponce, MD, Dalton, Georgia, Principal Investigator in the REDUCE trial. “The ReShape procedure offers a new alternative to help patients kick-start weight loss and learn new behaviors. We are excited about what this new treatment option may do for millions of people needing to lose excess weight.”

Thompson will present at the Canaccord Genuity Conference’s Medical Technology and Diagnostics Forum in New York on November 14, 2013.

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