



**ReShape Lifesciences® Receives FDA PMA Supplement Approval for its Next-Generation Lap-Band® 2.0 FLEX**

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IRVINE, Calif., Dec. 12, 2023 (GLOBE NEWSWIRE) -- [ReShape Lifesciences](#)<sup>®</sup> (Nasdaq: RSLS), the premier physician-led weight loss and metabolic health solutions company, today announced that the U.S. Food and Drug Administration (FDA) has granted approval of a PMA supplement for the company's next generation, enhanced Lap-Band<sup>®</sup> 2.0 FLEX.

"PMA supplement approval for our next generation Lap-Band<sup>®</sup> 2.0 FLEX is a historic event for ReShape that is expected to be a key growth catalyst for the company's Lap-Band<sup>®</sup> franchise," stated Paul F. Hickey, President and Chief Executive Officer of ReShape Lifesciences. "The enhanced Lap-Band<sup>®</sup> 2.0 FLEX development effort was physician-led with the goal of improving the patient experience. Compared to our current Lap-Band, the Lap-Band<sup>®</sup> 2.0 has a new feature called FLEX Technology, which acts as a relief valve, allowing larger pieces of food to more easily pass through the narrowed passage (or stoma), created by the band. Specifically, the band momentarily relaxes before returning to its resting diameter, therefore, minimizing discomfort caused by passage of large food pieces through the stoma. The Lap-Band<sup>®</sup> system is the safest and most durable weight loss option for obese patients and is ideal for those who are averse to medically managed weight loss and who opt for the only available anatomy preserving surgery. We are preparing for our U.S. product launch of the Lap-Band 2.0 FLEX and look forward to providing updates on our progress."

"Based on my 20-year use of the Lap-Band<sup>®</sup>, over time, some patients have needed adjustments, particularly when related to urgent loosening to relieve food obstruction," stated Christine Ren-Fielding, M.D., Professor of Surgery at NYU Grossman School of Medicine, Director of the NYU Langone Weight Management Program and Chief of the Division of Bariatric Surgery. "Lap-Band 2.0<sup>®</sup> FLEX will potentially remedy this issue because of the ability for self-correction, utilizing an internal reservoir system. In addition, multi-modal therapy is becoming a mainstay in the bariatric surgery field. GLP-1 agonists can be used to complement and augment weight loss after surgery to help prevent weight regain."

#### **About ReShape Lifesciences<sup>®</sup>**

ReShape Lifesciences<sup>®</sup> is America's premier weight loss and metabolic health-solutions company, offering an integrated portfolio of proven products and services that manage and treat obesity and metabolic disease. The FDA-approved Lap-Band<sup>®</sup> System provides minimally invasive, long-term treatment of obesity and is an alternative to more invasive surgical stapling procedures such as the gastric bypass or sleeve gastrectomy. The investigational Diabetes Bloc-Stim Neuromodulation™ (DBSN™) system utilizes a proprietary vagus nerve block and stimulation technology platform for the treatment of Type 2 diabetes and metabolic disorders. The Obalon<sup>®</sup> balloon technology is a non-surgical, swallowable, gas-filled intra-gastric balloon that is designed to provide long-lasting weight loss. For more information, please visit [www.reshapelifesciences.com](http://www.reshapelifesciences.com).

#### **Forward-Looking Safe Harbor Statement**

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results could differ materially from those discussed due to known and unknown risks, uncertainties, and other factors. These forward-looking statements generally can be identified by the use of words such as "expect," "plan," "anticipate," "could," "may," "intend," "will," "continue," "future," other words of similar meaning and the use of future dates. Forward-looking statements in this press release include the statement that the PMA supplement approval is expected to be a key growth catalyst for the company's Lap-Band<sup>®</sup> franchise. These and additional risks and uncertainties are described more fully in the company's filings with the Securities and Exchange Commission, including those factors identified as "risk factors" in our most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q. We are providing this information as of the date of this press release and do not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise, except as required by law.

*Dr. Ren-Fielding receives consulting and other compensation from ReShape Lifesciences. Her views are her own and do not represent an endorsement by NYU Langone Health.*

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