ReShape Lifesciences Announces European Trial to Support CE-Mark of ReShape Vest

July 31, 2018

SAN CLEMENTE, Calif., July 31, 2018 /PRNewswire/ -- ReShape Lifesciences Inc. (NASDAQ:RSLS), a developer of minimally invasive medical devices to treat obesity and metabolic diseases, announced today the Company has commenced site initiation training for the first clinical trial site that will participate in the multi-center trial of the ReShape Vest™ to support CE Mark approval.

The trial, which will include study centers in Spain, Germany, Belgium, The Netherlands and the Czech Republic, seeks to enroll up to 95 subjects who will be followed for two years. Primary endpoints in this trial include percent Total Body Weight Loss and adverse event rates at 12 months. Enrollment is expected to begin in the third quarter of 2018.

"We have been very encouraged by the results to date with our ReShape Vest, our novel, less invasive treatment option for patients battling obesity," stated Dan Gladney, Chief Executive Officer and Chairman of the Board of ReShape Lifesciences. "We look forward to beginning our CE Mark study and are excited to be one step closer to having the ReShape Vest available as a treatment option for clinical use throughout the European Union."

It is expected that data from this study will be used for CE-Marking of the ReShape Vest. CE Marking is the European Union (EU) regulatory approval to commercialize a medical device. Receiving the CE Mark demonstrates that a product conforms to the European essential requirements for safety and performance.

About ReShape Lifesciences Inc.

ReShape Lifesciences™ is a medical device company focused on technologies to treat obesity and metabolic diseases. The FDA-approved ReShape Balloon™ System involves a non-surgical weight loss procedure that uses advanced balloon technology designed to take up room in the stomach to help people with a 30-40 kg/m^2 Body Mass Index (BMI) and at least one co-morbidity lose weight. ReShape vBloc™ Therapy, delivered by an FDA-approved pacemaker-like device called the ReShape vBloc System, is designed to help patients with a BMI of 40-45 kg/m^2, or a 35-39.9 kg/m^2 and at least one co-morbidity feel full and eat less by intermittently blocking hunger signals on the vagus nerve. The ReShape Vest™ System is an investigational, minimally invasive, laparoscopically implanted medical device that wraps around the stomach, emulating the gastric volume reduction effect of conventional weight-loss surgery, and is intended to enable rapid weight loss in obese and morbidly obese patients without permanently changing patient anatomy.

Forward-Looking Safe Harbor Statement:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements regarding our expectation that enrollment for the clinical trial will begin in the third quarter of 2018, that data from the study will be used for CE-Marking of the ReShape Vest, and that the clinical trial will bring us closer to having the ReShape Vest available as a treatment option for clinical use throughout the European Union. 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. These forward-looking statements are based on the current expectations of our management and involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others: risks and uncertainties related to our acquisitions of ReShape Medical, Inc. and BarioSurg, Inc.; risks related to the U.S. Food and Drug Administration's announcement to alert health care providers of unanticipated deaths involving the ReShape Balloon; our proposed ReShape Vest product may not be successfully developed and commercialized; our ability to continue as a going concern if we are unsuccessful in our pursuit of various funding options; our limited history of operations; our losses since inception and for the foreseeable future; our limited commercial sales experience; the competitive industry in which we operate; our ability to maintain compliance with the Nasdaq continued listing requirements; our dependence on third parties to initiate and perform our clinical trials; the need to obtain regulatory approval for our ReShape Vest and any modifications to our vBloc system or ReShape Balloon; physician adoption of our products; our ability to obtain third party coding, coverage or payment levels; ongoing regulatory compliance; our dependence on third party manufacturers and suppliers; the successful development of our sales and marketing capabilities; our ability to raise additional capital when needed; international commercialization and operation; our ability to attract and retain management and other personnel and to manage our growth effectively; potential product liability claims; the cost and management time of operating a public company; potential healthcare fraud and abuse claims; healthcare legislative reform; and our ability to obtain and maintain intellectual property protection for our technology and products. These and additional risks and uncertainties are described more fully in the Company's filings with the Securities and Exchange

Commission, particularly those factors identified as "risk factors" in our annual report on Form 10-K filed April 2, 2018. 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.

View original content with multimedia:http://www.prnewswire.com/news-releases/reshape-lifesciences-announces-european-trial-to-support-ce-mark-of-reshape-vest-300688924.html

SOURCE ReShape Lifesciences Inc.

Investor Contact: Scott Youngstrom, Chief Financial Officer, ReShape Lifesciences, Inc., 949-276-6042, syoungstrom@reshapelifesci.com; Debbie Kaster, Investor Relations, Gilmartin Group, 415-937-5403, debbie@gilmartinir.com