July 1, 2020

Soliton Files 510(k) with FDA for RAP Device for the Reduction of Cellulite

- 510(k) Application for Premarket Clearance to include Recently Announced Pivotal Cellulite Trial Results

HOUSTON, July 1, 2020 /PRNewswire/ -- Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary aesthetic platform technology, today announced that it filed for 510(k) premarket clearance with the U.S. Food and Drug Administration ("FDA") of its second generation Rapid Acoustic Pulse ("RAP") device for the reduction in the appearance of cellulite on June 30, 2020.

The 510(k) filing is based on results from Soliton's pivotal cellulite clinical trial, which were recently presented in an oral presentation via the American Academy of Dermatology (AAD) 2020 VMX Virtual Conference on June 12, 2020. The RAP device demonstrated an average reduction of 32.5% in the Cellulite Severity Score and strong patient satisfaction demonstrated by 91.9% of subjects agreeing or strongly agreeing their cellulite appeared improved. There was a 1.16 mean change in the Cellulite Severity Score for all patients with a primary endpoint target of a 1.00 mean changes. The results were generated by a single, 20 to 30-minute, non-invasive treatment that required no anesthesia and caused no unexpected or serious adverse events. The treatment was well tolerated by the trial subjects, with an average pain score of 2.4 out of 10.

The RAP device was previously cleared by the FDA as an accessory to a 1064 nm Q-switched laser for tattoo removal of black ink on patients with skin tones on the Fitzpatrick scale between I and III.

"Our 510(k) submission for the reduction in cellulite appearance represents an exciting step forward in Soliton's U.S. commercialization plans for the RAP device," stated Christopher Capelli, MD, founder, President and CEO of Soliton. "Supported by our positive pivotal cellulite results generated with only one treatment session per patient, the RAP device has

the potential to offer patients a non-invasive treatment to reduce the appearance of cellulite. We hope to offer an innovative aesthetic technology to our customers capable of both tattoo removal and cellulite reduction."

About Soliton, Inc.

Soliton, Inc. is a medical device company with a novel and proprietary platform technology licensed from MD Anderson. The Company's first FDA cleared commercial product will use rapid pulses of acoustic shockwaves as an accessory to lasers for the removal of unwanted tattoos. The Company is based in Houston, Texas, and is actively engaged in bringing the Rapid Acoustic Pulse ("RAP") device to the market. The Company believes this "Soliton" method has the potential to lower tattoo removal costs for patients, while increasing profitability to practitioners, compared to current laser removal methods. Soliton has completed a clinical study using the RAP device to improve the appearance of cellulite and is investigating potential additional capabilities of the RAP technology. The device is currently cleared in the United States only for use in tattoo removal and is not yet cleared for use to address cellulite.

For more information about the Company, please visit:http://www.soliton.com

Forward-Looking Statements

This press release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which statements involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, whether the cellulite clinical trial data is sufficient to support Soliton's application to the FDA for consideration of clearance of its RAP technology for reduction in the appearance of cellulite, the potential for the 510(k) path to be appropriate with the FDA, the estimated timeline for the receipt of FDA clearance, the potential benefits of the RAP technology, and, if cleared by the FDA, expectations with respect to the potential acceptance and use of the RAP technology by doctors and patients. These statements relate to future events, future expectations, plans and prospects. Although Soliton believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, actual results or outcomes may prove to be materially different from the expectations expressed or implied by such forward-looking statements. Soliton has attempted to identify forward-looking statements by terminology including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," "may," "could," "might," "will," "would," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed in our filings with the Securities and Exchange Commission ("SEC"), including under the heading " Risk Factors" in the Form 10-K for year ended December 31, 2019 filed with the SEC and as updated in our Form 10-Q filings and in our other filings with the SEC. Any forward-looking statements contained in this release speak only as of its date. Soliton undertakes no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

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