June 15, 2020

Soliton Reports Positive Pivotal Cellulite Clinical Trial Results

- Average Reduction of 32.5% in Cellulite Severity Score from Single Treatment -

HOUSTON, June 15, 2020 /PRNewswire/ -- Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary platform technology, today announced that new positive data from the company's pivotal cellulite clinical trial was presented in an oral presentation via the American Academy of Dermatology (AAD) 2020 VMX Virtual Conference on June 12, 2020.

"We are pleased that our pivotal cellulite study demonstrated positive results and appreciate the opportunity to have our findings presented through this prestigious dermatology organization," stated Christopher Capelli, MD, founder, President and CEO of Soliton. "In addition to demonstrating an average 32.5% improvement in the Cellulite Severity Score in our subjects, patient satisfaction was strong with 91.9% of subjects agreeing or strongly agreeing that their cellulite appeared improved. Further, there were no unexpected or serious adverse events and the average pain scores were 2.4 on a 10-point scale."

For a more detailed overview of the results of this pivotal study, please view the brief presentation on the following website: https://secure.soliton.com/cellulite
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The pivotal cellulite clinical trial enrolled and treated 67 subjects at four clinical sites, of which 62 subjects were evaluated in the results analysis due to the exclusion of five patients for failing to meet inclusion criteria or incomplete follow-ups. Eighty-five percent (85%) of subjects responded to treatment with their improvement in the Cellulite Severity Scores ranging from 6.7% to 85.7%.

The majority of existing non-invasive cellulite treatment options on the market today recommend four to six treatments. The results seen in this study were generated by a single treatment session.

Dr. Elizabeth Tanzi, Director at Capital Laser & Skin Care, Chevy Chase, MD, member of Soliton's Scientific Advisory Board, and presenter of the trial results at AAD, commented "I am excited to bring the rapid acoustic pulse technology to my patients to improve the appearance of their cellulite, in particular given that it is a non-invasive procedure that requires no downtime. I think my patients will love it."

Cellulite affects between 80% and 90% of women and over a billion dollars per year is spent on treatment in the U.S. The Soliton clinical trial protocol provided for a single 20 to 30-minute, non-invasive treatment in which the Rapid Acoustic Pulse (RAP) device was applied to the surface of the subjects' skin. The treatment required no anesthesia, caused no unexpected or serious adverse events, and was evaluated as relatively painless by the trial subjects, with an average pain score of 2.4 out of 10.

Soliton is further reviewing and analyzing these results for inclusion in a marketing application to the U.S. Food and Drug Administration (FDA) and believes that these data are sufficient to support its 510(k) submission to the FDA for consideration of clearance of its RAP technology for reduction in the appearance of cellulite. We intend to file a 510(k) notification and believe there is a reasonable expectation that the FDA will allow us to utilize this clearance pathway in order to market the product. However, should the FDA deem our choice of predicate device to be inadequate, we would be required to convert our application to a De Novo request, which we estimate would extend the filing and review process by approximately six to nine months.

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 in preclinical testing, including the potential to assist existing fat reduction technology in the reduction of fat. 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 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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