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Soliton Announces First Follow-up Visit Conducted in the Pivotal Cellulite Clinical Trial

HOUSTON, Nov. 12, 2019 /PRNewswire/ -- Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary platform technology licensed from The University of Texas on behalf of the MD Anderson Cancer Center ("MD Anderson"), today announced that it has begun the first follow-up visits for patients in its pivotal cellulite trial.

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Dr. Chris Capelli, President, CEO and co-founder of Soliton, commented, "The start of the follow-up visits is a significant milestone. We are hopeful that the results from our pivotal trial will be as strong as those seen in our proof-of-concept study in cellulite. This would support the filing of our 510(k) application with the FDA for the treatment of cellulite, which we expect to occur in the first half of 2020. With the planned limited launch of our device in 2020 for the indication of tattoo removal, regulatory clearance for this new indication would put us on track to expand nationally and internationally with two indications in 2021."

Cellulite affects up to 90% of women and over a billion dollars per year is spent on treatment in the U.S. Results from our initial proof of concept clinical trial suggest the potential for a new approach to treating cellulite. In the proof of concept trial, the Soliton Rapid Acoustic Pulse ("RAP") device was applied to the surface of the patient's skin for a single 20-minute, non-invasive treatment. The treatments in the pivotal study required no anesthesia, caused no bruising, swelling or infection, and were evaluated by the trial participants as an average of 2.4 on a pain scale of 0-10. None of the patients experienced any post-treatment downtime.

Based on biopsies from our own animal studies, Soliton's RAP device appears to be capable of selective disruption of the fibrotic septa that contribute to the appearance of cellulite. The new discovery, referred to as "acoustic subcision," helps explain the recent proof-of-concept trial results showing an improvement in the appearance of cellulite following use of the Company's RAP device.

[To read a detailed description of acoustic subcision, read page 10 of our shareholder letter here: <https://www.soliton.com/shareholder-letter-2019>]

Together with the device's demonstrated ability to stimulate new collagen production in animal models, this represents what the Company believes is a potentially important new

way to treat cellulite and improve the appearance of the skin. The Soliton device used in this trial has not been reviewed or cleared by the FDA for marketing and, accordingly, none of the information in this press release is intended to promote the sale or use of the device. The device is investigational and is not available for sale in the United States.

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 is investigating potential additional capabilities of the RAP technology in clinical and preclinical testing, including the potential to improve the appearance of cellulite by creating mechanical stress at the cellular level and inducing significant collagen growth and the potential to treat keloid and hypertrophic scars by targeting the stiffened environment in the intracellular matrix.

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

Forward-Looking Statements

Some of the statements in this release are 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 involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the ability of Soliton to complete the pivotal cellulite trial, the ability of Soliton's acoustic shockwave device to prove safe or effective in reducing cellulite in the pivotal clinical trial, the ability of Soliton to file the 510(k) application with the FDA for the treatment of cellulite in the first half of 2020 and to receive FDA clearance for the cellulite indication, and the ability of Soliton to expand nationally and internationally with two indications in 2021. 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, expectations may prove to have been materially different from the results 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," "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 under in our SEC filings, including under the heading "Item 1A. Risk Factors" in the Form 10-K for year ended December 31, 2018 we filed with the SEC and updated from time to time in our Form 10-Q filings and in our other public 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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