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Soliton Completes Site Enrollment and Conducts Initial Site Training to Start Pivotal Cellulite Trial

HOUSTON, Aug. 6, 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 the company has completed their site initiation visit for the first site to be included in its upcoming expanded pivotal Cellulite Trial. Site initiation visits are for initial clinical staff training and protocol reviews with the staff in advance of patient treatments. The company also announced that patient enrollment for the trial has been initiated at the initial trial site.

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The initial training, site visit and enrollment were completed at Chicago Cosmetic Surgery and Dermatology with treatment supervised by Omer Ibrahim, MD FAAD and Carolyn I. Jacob, MD FAAD, both Board Certified Dermatologists. Site initiation visits at the three additional trial sites will be conducted over the next six weeks. Patient enrollment will occur concurrently.

Dr. Chris Capelli, President, CEO and co-founder of Soliton, commented, "The completion of these important steps in the clinical trial process moves Soliton closer to the treatment of enrolled patients in this pivotal cellulite trial. We look forward to completing site visits and enrollment at the other trial sites and initiating patient treatments at each site in the very near future."

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 patients' skin for a single 20-minute, non-invasive treatment. The treatments required no anesthesia, caused no bruising, swelling or infection, and were evaluated by the trial participants as a "0" on a pain scale of 0-10 in 97% of the treatments. None of the patients experienced any post-treatment downtime. 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 preclinical testing, including the potential to assist existing fat reduction technology in the reduction of fat as well as improving the appearance of cellulite by creating mechanical stress at the cellular level and inducing significant collagen growth.

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's acoustic shockwave device to reduce cellulite in a larger clinical trial or to receive FDA clearance for the cellulite indication, and the ability of Soliton to successfully conclude the pivotal clinical trial. 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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