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Soliton Announces Site Selected for Clinical Trial to Treat Fibrotic Scars

Successful trials demonstrating Rapid Acoustic Pulse (RAP) technology to reduce keloid and hypertrophic scars may be indicative of a wider range of fibrosis-related indication

HOUSTON, Sept. 10, 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 selected Clear Dermatology & Aesthetic Center in Scottsdale, AZ as the site for its proof-of-concept ("POC") clinical trial for the use of its RAP technology for the treatment of keloid and hypertrophic scars. Dr. Brenda LaTowsky will serve as Principal Investigator.

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"We are proud to have Clear Dermatology & Aesthetic Center selected as the clinical site for what could be a ground-breaking new treatment for keloid and hypertrophic scars," added Dr. Brenda LaTowsky, Clinical Dermatologist and Principal Investigator of the study. "Unfortunately for many of our patients, the currently available treatment options are unacceptable, so a new non-invasive procedure could be quite important."

Keloid and hypertrophic scars (also called "fibrotic scars") represent wound healing gone awry. A typical example of a keloid scar would be a post-surgical scar that grows beyond its boundaries. Existing published research suggests that factors relating to the wound-healing environment (including tension at the boundary of the scar) can cause fibroblasts to become stuck in a hyper-productive loop, unable to stop the production of collagen that leads to the thickened, raised and dense structures often associated with these fibrotic scars.

The American Osteopathic College of Dermatology estimates that keloids affect around 10 percent of people, whereas hypertrophic scars are more common. Keloid scars are more prevalent among populations with darker skin pigmentation. Hypertrophic scars affect men and women from any racial group equally, although people between the ages of 10 and 30 years old are more likely to be affected.

Grand View Research estimates the global market for keloid and hypertrophic scars may reach $10.2 billion by 2025. There are few treatment options available for fibrotic scars, which in addition to being disfiguring, can also cause significant discomfort. Currently, the most common treatment is the direct injection of steroids into the scar, however this can require multiple injections and may not be a permanent solution.

"The initial study design calls for a blinded evaluation of treated scars before and 12 weeks after a single RAP treatment session," stated Dr. Chris Capelli, Soliton CEO and co-founder. "Our hope is to be able to demonstrate a clinically significant reduction in the volume and height of these scars that currently have limited treatment options. Our preclinical studies combined with published literature on the behavior of fibrotic tissue have suggested that our acoustic shockwaves may be capable of disrupting stiff, sclerotic structures created by unwanted fibrosis, of which keloids and hypertrophic scars are just one example. The disruption of stiff structures may help reset the targeted tissue to more normal fibroblast activity for lasting effects."

The Company's device for use as an accessory to 1064nm Q-switched lasers for tattoo removal was cleared on May 24, 2019, however technology for the treatment of cellulite and fibrotic scars is investigational and not available for sale in the United States. Soliton will file additional 510(k) applications for the use of RAP technology in these indications.

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 improve fibrotic conditions such as keloid or hypertrophic scars 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 the Soliton RAP device to demonstrate safety and efficacy in the reduction keloid and hypertrophic scars, the potential for efficacy in fibrotic scars to extend to other fibrotic disorders, and the ability for Soliton to receive FDA clearance for these additional indications. 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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