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Soliton to Initiate Pivotal Cellulite Trial after Positive Proof-of-Concept Trial Results with 20-47% Improvement in Cellulite Severity Score

Proof of Concept Trial Reveal Significant Reduction in Cellulite with No Bruising, No Swelling and No Downtime after single 20-Minute non-invasive Procedure; Justifies proceeding with Pivotal Trial.

HOUSTON, May 29, 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 its decision to move forward with a pivotal trial in cellulite after positive data from its proof of concept clinical trial for the reduction of cellulite (the "POC Trial") confirmed.

The Pivotal cellulite study is being designed to take place at multiple clinical sites across the country with between 45 and 60 patients to be treated in the study. We hope to begin the study within the next three months.

Cellulite affects up to 90% of women and over a billion dollars per year is spent on treatment in the U.S. Now, results from this Trial suggest the potential for a totally new approach to treating cellulite. In a single 20-minute, non-invasive treatment, the Rapid Acoustic Pulse (RAP) device was applied to the surface of the patients' skin. The treatments required no anesthesia, caused no bruising, swelling or bleeding, and were evaluated as relatively painless by the trial participants, none of whom experienced any post-treatment discomfort or downtime. The data was originally presented at the SCALE (Symposium for Cosmetic Advances and Laser Education) conference in Nashville, Tennessee, by Dr. Elizabeth Tanzi on May 11, 2019.

The POC Trial involved a study of five patients with moderate to severe cellulite, each treated on their thighs, with a new higher-powered version of Soliton's RAP device. While the Company's RAP device intended to assist in tattoo removal was recently cleared by the FDA, this higher-powered version will require a new application for clearance for the cellulite indication. In the POC Trial, approximately 97% of treatments were rated 0 on a 0 to 10-point pain scale (with 0 being no pain). At the end of the 12-week POC Trial, in a blinded review by doctors of before and after photos, 100 percent correctly identified which photo was the "after." The three blinded reviewers, who are trained in the use of the cellulite severity scoring system, scored the before and after photos using the 5-point system. 100% of the patients showed clinical improvement. The range of improvement in cellulite severity

score was 20% to 47% and the average improvement for all patients was nearly a 30% improvement (1.24 reduction on the 0 to 5-point cellulite severity scale). As a point of reference, the only FDA approved method for long-term reduction of cellulite is an invasive treatment called Cellfina that produced an average improvement on the same scale of about 2 points. However, this is a procedure requiring topical anesthesia, penetration of the skin and involves potential bleeding, bruising and significant post-treatment discomfort and downtime. We believe Soliton RAP involves none of these potential negatives.

"The market for non-invasive cellulite treatments is about $1 billion in the U.S., so it is clear that many women who are affected by the condition are interested in finding ways to reduce or eliminate it," said Walter Klemp, co-founder and Executive Chairman of Soliton. "The very encouraging results of the POC Trial are driving our decision to launch the pivotal trial as quickly as possible and suggest we may be able to significantly improve the appearance of cellulite with a single completely non-invasive procedure. The procedure requires no recovery time and avoids the risks that go with even minimally invasive surgery."

How the Soliton Device Treats Cellulite

Although cellulite has many contributing factors, a primary cause of the deep dimples and ridges associated with cellulite is the presence of sclerotic septa connecting the dermis to the body's fascia through the layer of subcutaneous fat. Septa normally provide structure and uniformity to the skin, but over time they can lose uniformity and become stiff and less resilient with larger pockets of subcutaneous fat in-between. As the presence of subcutaneous fat increases, it can push up against the dermis causing it to bulge between these septa, leaving dimples and ridges where the septa refuse to yield.

Superficial therapies are largely ineffective at changing this condition and severing the offending septa is the most effective therapy. Currently, the only method cleared by the FDA for long-term reduction of cellulite is called Cellfina and involves the insertion of a blade or lance into the skin below the dermis. The blade is then moved from side to side in a sweeping motion to cut any septa in its path.

While this "invasive subcision" is immediately effective at removing or reducing deep dimples and ridges, it is also quite painful, requiring the subcutaneous injection of anesthesia. It can also cause bleeding and bruising and significant patient downtime due to ongoing soreness as the wounds from these skin penetrations and cutting actions heal. In addition, this method does very little to smooth or tighten the skin to remove the "orange peel" or "cottage cheese" appearance often associated with cellulite.

Soliton has created a new form of acoustic pulses, which was recently awarded "Best in Show" by the American Society for Laser Medicine and Surgery (ASLMS), that it has shown in animal models are capable of selective disruption of sclerotic septa without ever penetrating the skin. The procedure creates no bleeding or bruising and results in no post-treatment discomfort or downtime.

We believe the disrupted septa resulting from the acoustic pulses induces increased collagen production that thickens and tightens the skin over time. More normal and robust septa are rebuilt with the skin in a smoother position.

"We believe this could represent a new approach to reducing cellulite, which could represent

a significant change from the currently available invasive and non-invasive treatments, many of which only work with surface dimpling and can't help the big dimples in the skin that many want to eliminate," explained Dr. Chris Capelli, President, CEO, and co-founder of Soliton. "This new approach uses very fast, compressed acoustic pulses in the form of shockwaves and our data suggests that the acoustic pulses may be capable of achieving results previously only thought possible with invasive therapies."

The Trial was conducted by Dr. Michael Kaminer at SkinCare Physicians in Boston in collaboration with Dr. Elizabeth Tanzi of Capital Laser and Skin Care.

Dr. Kaminer stated: "Having led the clinical development of Cellfina, the only treatment with FDA clearance for producing long-term reduction of cellulite, I am particularly aware of the unmet need in the treatment of cellulite. Having a non-invasive alternative treatment could provide a real benefit for patients while also expanding the breadth of services offered by clinicians."

Drs. Kaminer and Tanzi are members of Soliton's Scientific Advisory Board.

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 planned commercial product is designed to use rapid pulses of designed acoustic shockwaves in conjunction with existing lasers to accelerate the removal of unwanted tattoos (RAP device). In addition, higher energy versions of acoustic pulse devices are in early stages of development for potential stand-alone treatment of cellulite and other indications. Both products are investigational and are not available for sale in the United States.

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 prove safe and effective for reducing cellulite in larger clinical trials and the timing of the commencement of 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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