January 26, 2021

Soliton Announces Collaboration with US Navy to Conduct Proof-of-Concept Study for Fibrotic Scars

The company expects to initiate the externally funded study in the first half of 2021

HOUSTON, Jan. 26, 2021 /PRNewswire/ -- Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary platform technology, today announced it has entered into a collaboration with the US Navy to conduct a multi-treatment proof-of-concept clinical study to evaluate the safety, and efficacy of multiple treatments with Soliton's Rapid Acoustic Pulse (RAP) device for the improvement in the appearance of fibrotic scars. The study will be a US-based, single-center, prospective trial, examining a maximum of 25 patients.

"We are extremely pleased to collaborate with the US Navy and investigate the safety and efficacy of our RAP device in improving the appearance of fibrotic scars," commented Brad Hauser, Soliton CEO and President. "The results from our previous proof-of-concept Keloid and Hypertrophic Scar trial were extremely encouraging, as the RAP device demonstrated reductions in both the volume of the scars and the height of the scars after a single 6-minute treatment. We look forward to building on the tremendous promise our RAP Device has demonstrated in this adjacent indication and exploring its ability to improve the standard of care in this large market, which size is expected to reach an estimated value of $10.0 billion by 2025."

Dr. Curtis L. Hardy, Dermatology Resident at the Naval Medical Center San Diego, will serve as the principal investigator for the trial. The trial will investigate efficacy, measured by improvement in fibrotic scar appearance using Global Aesthetic Improvement Scale (GAIS) as determined by the Investigator at the 12-week follow up visit, as a primary endpoint. Additionally, the trial will examine safety, measured by unexpected adverse events or

serious adverse events attributable to the RAP device immediately post-treatments and at the 12-week follow-up visit as a second primary endpoint. The trial will be conducted in a single US-based center and examine a maximum of 25 patients. The US Navy will be responsible for the recruitment and treatment of the subjects, with Soliton providing equipment and contributing to the design of the clinical protocol.

Soliton previously announced positive results from its single-site proof-of-concept IRB-approved human clinical study to evaluate the safety, and efficacy of the RAP device for the temporary improvement in the appearance of fibrotic scars. A single 6-minute RAP session was used to treat 11 fibrotic scars in 10 participants. 3D scar assessment of the pre- and post-treatment photographs of 11 treated scars demonstrated an average reduction in volume of 29.6% ($p<0.01$) and an average reduction in height of 14.6% ($p<0.005$). While the 12-week data demonstrated an improvement in volume reduction over 6 weeks, this was without any additional treatment, suggesting that the scars continued to improve over time. Furthermore, the treatment of fibrotic scars using the RAP device was proven safe and tolerable during this POC study.

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About Soliton, Inc.

Soliton, Inc. is a medical device company with a novel and proprietary platform technology licensed from The University of Texas on behalf of MD Anderson Cancer Center. 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 filed a 510(k) application with the FDA for clearance of its RAP device to improve the appearance of cellulite and is investigating potential additional capabilities of the RAP technology. 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

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, whether the planned collaborative trial will be commenced on a timely basis, if at all, and the ability of the RAP device to successfully treat fibrotic scars. 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, 2019 we filed with the SEC on March 2, 2020 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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