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Soliton Announces Successful Completion of Safety Testing at SGS to Support FDA Filing for Second Generation Device

HOUSTON, Dec. 18, 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 Rapid Acoustic Pulse ("RAP") device successfully completed the IEC 60601 safety testing being conducted at SGS, the world's leading inspection, verification, testing and certification company. The testing was led by a team at Sanmina Corporation, a leading electronics manufacturing services provider.



This safety testing is a requirement of the supplemental 510(k) filing for the Company's RAP device for tattoo removal, improvement in the appearance of cellulite, keloid (scarring) and additional pipeline indications. The tests are intended to insure that devices meet standard safety metrics to protect users and patients. The supplemental 510(k) filing will provide an update to Soliton's current FDA 510(k) clearance, which was received in May 2019 for tattoo removal, with respect to the step changes made to the device to improve usability in the field.

Dr. Chris Capelli, Soliton's President, CEO and co-founder, commented, "We are pleased, but not surprised by the safety testing results of our RAP device. The safety of our second generation device mirrors that of our first, and these results reinforce this. We look forward to submitting this safety data in early 2020, simultaneous with the Special 510k filing of our second generation RAP device. This step is an important one in our plans to commercialize the device being launched for tattoo removal to a select and limited number of dermatologists in mid-2020."

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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 to submit the safety data for the second generation RAP device in early 2020, and to commercialize the device being launched for tattoo removal to a select and limited number of dermatologists in mid-2020. 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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