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Soliton Receives FDA 510(k) Clearance of its Acoustic Shockwave RAP Device

HOUSTON, May 28, 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 received clearance from the U.S. Food & Drug Administration ("FDA") to market its Rapid Acoustic Pulse ("RAP") device for tattoo removal. The device is indicated as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal on the arms, legs and torso in Fitzpatrick Skin Type I-III individuals.

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"Receiving clearance from the FDA, while inline with our expectations, is nonetheless gratifying and validating, representing a bedrock for the commercialization plan of our RAP technology," commented Dr. Chris Capelli, President, CEO and co-founder of Soliton.

"This clearance to market allows us to begin the transition from R&D to expanded product development and commercialization within the tattoo removal segment.

Development of our breakthrough shockwave device, which was recently awarded "Best in Show" by the American Society for Laser Medicine and Surgery (ASLMS), has taken us over 5 years and more than $25 million in research and development to create. This required collaborating with a wide range of industry-leading experts, including engineers responsible for the Space Shuttle ignition system, scientists specializing in the plasma physics involved in nuclear fusion and physicysts specializing in acoustic engineering.

Our device, which is now covered by 8 patent families with 68 patents issued or pending, safely converts 3,000 volts at 3,000 amps (9,000,000 watts of power) into finely-controlled acoustic shockwaves at a rate of up to 100 pulses per second through our replaceable treatment cartridge. While this is a significant amount of power being converted into an acoustic pulse, it is extremely brief in time, with both a very short rise time and a similarly short fall time. This results in microscopic mechanical disruption to the targeted cellular level structures and vacuoles. Importantly, the negative pressure component of each acoustic pulse is attenuated so therapy can be provided without creating the cavitation, heat or collateral tissue damage that would give the patient the sensation of significant pain. As a result, Soliton's RAP technolocy can provide meaningful results with little potential for bruising or other treatment related downtime.

In the clinical trials submitted to the FDA as part of the 510(k) application that was just cleared, we demonstrated that our RAP device can enable tattoo removal in just 2-3 office visits. In contrast, a separate independent study of 397 tattoo owners, demonstrated that the standard of care laser-only method required 10 or more office visits to achieve acceptable

results.

Taking into consideration that the tattoo removal industry is estimated to grow to approximately $4.8 billion annually by 2023, we are eager to further our commercialization plans and move towards our launch and revenue generation as early the first half of 2020.

Importantly, this FDA clearance represents only the first of many indications we are pursuing with our RAP technology. We believe our RAP technology offers the potential for significant breakthrough treatments in a variety of aesthetic market segments. We look forward to building upon this initial FDA clearance in combination with compelling results from various clinical trials in these other aesthetic segments to advance the influence of our RAP technology."

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 the Soliton RAP technology to prove safe and effective for our targeted indications and to achieve FDA clearance for this technology. 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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