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# Soliton Receives FDA Clearance of Special 510(k)

## - Commercialization Milestone Towards Mid-2020 Strategic Tattoo Removal Launch -

HOUSTON, March 11, 2020 /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 U.S. Food and Drug Administration ("FDA") clearance of the Company's Special 510(k) Premarket Notification regarding its Generation II Rapid Acoustic Pulse ("RAP") device.

"The FDA clearance of our Generation II RAP device marks yet another milestone on Soliton's path towards commercialization, specifically this year's strategic launch for tattoo removal," stated Christopher Capelli, MD, founder, President and CEO of Soliton. "We initially intend to provide this generation of the device to approximately 20-25 of the top dermatologists within the United States and look forward to the resulting physician feedback and market data regarding cartridge utilization."

The Generation II RAP device delivers the same tattoo-removal technology as the Generation I device but is slightly modified for improved ease of use in the physician's office. The Generation II RAP device constitutes the underlying technology of the RAP device that will be deployed in the strategic U.S. tattoo removal commercial launch planned for mid-2020. Similar technology was utilized in the Company's pivotal cellulite and proof of concept keloid scar trials. Only the tattoo removal indication was reviewed by the FDA in this submission and cleared for marketing.

The Special 510(k) filing was submitted to the FDA on February 10, 2020 and states the device is indicated as an accessory to the 1064 nm Q-Switched laser for black ink tattoo removal in Fitzpatrick Skin Type I-III patients. Clinical trials have demonstrated that using the

Company's RAP device, in conjunction with a Q-switched laser, allows for multiple passes of laser treatment in a single treatment session, resulting in accelerated fading in comparison to stand-alone laser treatment.

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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 launch its product 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, 2019 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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