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Soliton Provides Special 510(k) and Commercialization Update

HOUSTON, April 15, 2021 /PRNewswire/ -- Soliton, Inc., (Nasdaq: SOLY) ("Soliton" or the "Company"), a medical device company with a novel and proprietary platform technology, today announced that the U.S. Food and Drug Administration ("FDA") has accepted its special 510(k) application previously submitted on March 31, 2021 for modifications to RESONIC™ device planned for commercial launch as complete. The company expects to hear if the FDA has cleared its special 510(k) application in the next 15-20 days unless the process takes slightly longer than normal given the COVID-related workload inside the FDA.

The changes submitted in the special 510(k) application include the development of an autoloading cartridge and an improved user interface. These modifications are geared towards providing for a more seamless user experience.

In addition, Soliton achieved several manufacturing milestones in anticipation for its planned 2Q21 initial launch of RESONIC for both cellulite and tattoo removal indications. The Company successfully completed all required safety testing including Quality System/Current Good Manufacturing Practice regulations for medical devices (21 CFR Part 820) inspection from the FDA.

Additionally, the Company expanded its sales team through the hiring of two Senior Practice Development Managers with previous experience in the aesthetics space. This role will be focused on in-practice execution of the introduction and support of the RESONIC device and RAP technology.

"With the FDA's acceptance of our special 510(k) application for improved commercial use and successful completion of all safety testing, we believe are well positioned to successfully bring RESONIC™ to market later this quarter," stated Brad Hauser, Soliton CEO and President. "We believe our commitment to improving the design and safety of our RAP technology is critical for Soliton's commercial success. We look forward to bringing these improvements to market with the support of our new seasoned Practice Development

Managers."

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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, RESONIC™, will use rapid pulses of acoustic shockwaves for the treatment of cellulite and as an accessory to lasers for the removal of unwanted tattoos. The Company is based in Houston, Texas, and is actively engaged in bringing RESONIC 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. The Company also believes the technology will provide the first non-invasive acoustic technology to target the underlying causes of dimples and ridges in cellulite. Soliton 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 cellulite.

For more information about the Company, please visit:http://www.soliton.com

Forward-Looking Statements

This press release includes 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 statements involve risks and uncertainties. These statements relate to future events, future expectations, plans and prospects. Forward-looking statements in this release include, but are not limited to, our ability to receive clearance from the FDA for our special 501k and to successfully launch the RESONIC™ technology. Although Soliton believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, actual results or outcomes may prove to be materially different from the expectations 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," "would," "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 in our filings with the Securities and Exchange Commission ("SEC"), including under the heading " Risk Factors" in our most recently filed Form 10-K filed with the SEC and as updated in our Form 10-Q filings and in our other 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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