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# Soliton's RAP Device Received Institutional Review Board Approval of Non-Significant Risk Designation

**HOUSTON, TX / ACCESSWIRE / March 8, 2019** /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"), discusses that their RAP device received institutional review board ("IRB") approval as a non-significant risk device. Subsequent to receiving this status, the Company conducted several human clinical trials to study the use of the RAP device to accelerate tattoo fading and initiated a proof-of-concept trial in humans for the reduction of cellulite.

Soliton's RAP device accelerates tattoo removal in part by providing dermal clearing of laser-generated vacuoles during laser treatment. This designation by the IRB allows the Company to use its device in human clinical trials.

The Institutional Review Board (IRB) is an FDA registered constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

"The NSR designation makes it very straight forward for us to conduct clinical trials with our technology," commented Dr. Chris Capelli, Soliton's President and CEO. " This applies not only to the clinical data we are presenting to the FDA with regard to accelerating tattoo removal, but potential future indications like cellulite reduction. We believe this allows us to move more quickly in developing Soliton RAP."

## **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 will use rapid pulses of designed acoustic shockwaves to dramatically accelerate the removal of unwanted tattoos. The Company is based in Houston, Texas, and is actively engaged in bringing its Rapid Acoustic Pulse ("RAP") device to the market. The Company believes this "Soliton" method can not only dramatically accelerate tattoo removal, but also has the potential to lower removal cost for patients, while increasing profitability to practitioners. Soliton has discovered other capabilities of the RAP technology during preclinical testing, including the potential to assist existing fat reduction technology in the reduction of fat as

well as reducing the appearance of cellulite by creating mechanical stress at the cellular level and inducing significant collagen growth.

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 Soliton RAP to receive FDA clearance, as well as reduce the appearance of cellulite in humans. 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 "Risk Factors" in the Form 1-A we filed with the SEC on February 13, 2019. 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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