

TIVIC HEALTH SYSTEMS INC. RECEIVES ISO 13485:2016 CERTIFICATION FOR CLEARUP SINUS PAIN RELIEF

San Francisco, November 14, 2019 – [Tivic Health™ Systems Inc.](#), a commercial phase bioelectronic company, today announced it has received ISO 13485:2016 certification for its quality management system (QMS), following review by the British Standards Institute (BSI). ISO 13485:2016 is an internationally recognized quality standard for the medical device industry and demonstrates Tivic Health’s dedication to attain optimum level of medical device quality system to meet customer expectations and international regulatory requirements.

“Receiving ISO certification is a major milestone in our effort to obtain CE Mark Approval for ClearUP® Sinus Pain Relief,” said Jennifer Ernst, CEO of Tivic Health. “Quality and safety are vital in the development of medical devices. We are working to develop and bring to market well-designed products that give millions with chronic conditions access to health solutions that are easily accessible and affordable.”

ClearUP is an example of bioelectronic medicine, an emerging form of drug free, non-invasive medicine that uses low-level electrical stimulation, or neuromodulation, to treat chronic conditions. ClearUP is a small handheld device that is clinically proven and FDA cleared. It delivers a proprietary microcurrent waveform for treating sinus pain for the 50+ million in the US who suffer from allergic rhinitis – seasonal and year round allergies.

Funding

In July 2019, Tivic Health received an \$8 million series seed investment from Sand Hill Angels, Astia Angels, Golden Seeds, HBS Angels, Sierra Angels, Lateral Capital, Skylight Investments, a physician network and individual investors. The company has raised funds in a series of tranches. With initial investments in 2017 and 2018, the company completed product development and design, clinical studies, FDA clearance, production and early marketing.

About ClearUP

ClearUP’s proprietary technology emits low-level electrical stimulation called microcurrent to underlying sinus nerve fibers. Simply glide ClearUP around the outer cheek, nose and brow bone for a quick five-minute treatment. Low-level electrical

stimulation of the sinus nerve fibers has been shown to alleviate pain and pressure sensations and result in smaller blood vessel diameter and reduced edema (swelling). Studies show that 74 percent experienced relief after one treatment that lasts for up to six hours. ClearUP empowers sinus sufferers to manage their sinuses at home with self-care, a rapidly growing trend in healthcare.

ClearUP is available for purchase at \$149 on [Amazon](#), www.tivichealth.com, and online at Best Buy, CVS and Walgreens in November.

About Tivic Health Systems Inc.

Tivic Health Systems Inc. is a bioelectronic device company dedicated to developing microcurrent therapy solutions for chronic diseases and conditions. Founded in 2016, Tivic Health is part of a \$6.2B global neuromodulation industry and is dedicated to harnessing the power of neuromodulation for home use products and empowering people to improve their health and quality of life. @TivicHealth www.facebook.com/TivicHealth

Media Contact:

Cheryl Delgreco
Media Strategies, Inc.
cdelgreco@msipr.com
617-723-4004

