

## ClearUP™ Sinus Pain Relief

### ClearUP™ Shows Reduction in Sinus Pain in Pivotal Trial

**NEARLY 75 PERCENT OF TRIAL SUBJECTS EXPERIENCED REDUCTION IN SINUS PAIN ON FIRST USE.**

**DATA DEMONSTRATES POTENTIAL FOR NEUROMODULATION AS A NEW NON-INVASIVE, DRUG-FREE SINUS TREATMENT.**

MENLO PARK, Calif., Oct. 8, 2018 /PrNewswire/ – [Tivic Health Systems Inc.](#) (Tivic Health™), a bioelectronic health-tech company, announced their first bioelectronic product, ClearUP™ Sinus Pain Relief (ClearUP™), successfully demonstrated a reduction in sinus pain in nearly 75 percent of study subjects during a 71-patient, double-blinded, randomized sham-controlled trial conducted at the Stanford Sinus Center of Stanford University Medical Center. The data was presented to Ear, Nose and Throat (ENT) and allergy physician specialists at an October podium presentation at the 2018 [American Rhinologic Society](#) (ARS) Annual Meeting. The journal paper for the ClearUP™ pivotal trial earned runner up for Best Clinical Paper at the annual meeting.

“Physicians have multiple options for effectively treating sinus-related conditions such as chronic sinus congestion, inflammation and infection. However, there are no good solutions specifically for sinus pain,” said [Jayakar Nayak, MD, Associate Professor of Otolaryngology Stanford Medical Center](#), principal investigator, Stanford University. “The results from this clinical trial demonstrate that ClearUP™ Sinus Pain Relief, a microcurrent neuromodulation device, reduces sinus pain after one 5-minute treatment. This is encouraging news for patients who frequently suffer from sinus pain that may be associated with allergic rhinosinusitis and sinusitis.”

[The ClearUP™ device](#) is not a pill, spray or flush. It’s a non-invasive, drug-free, handheld device. Trial subjects with self-reported sinus pain were recruited from a rhinology practice and from the surrounding community. A self-reported sinus pain score of 4 or greater was required for study enrollment. Each subject was randomly assigned to use an active (n=38) or sham (n=33) handheld ClearUP™ device. Each subject self-trained and self-administered a single treatment using either the active or sham ClearUP™ device for five minutes over their brow region, cheek

and nose. These areas are known to have a density of nerves and vasculature under the facial skin that link to the sinus passages. A 0-10 score for pain was collected before, and ten minutes after treatment.

Active microcurrent-treated patients had a mean pain score reduction of 29.6 percent, and active treatment resulted in a greater statistically significant reduction in pain compared to the placebo group (p=0.007).

Key data points from the clinical trial include:

- *74 percent of active-treated subjects experienced a reduction in sinus pain.*
- *Active-treated subjects experienced a 29.6 percent reduction in sinus pain after one 5-minute treatment.*
- *82 percent of active-treated subjects preferred the ClearUP™ device to their existing sinus pain treatments.*

“The positive outcome of this pivotal trial showing the benefits of ClearUP™ brings us one step closer to offering a new sinus pain relief option to the 34 million people who suffer from chronic sinusitis and the nearly 22 million who suffer from allergic rhinosinusitis,” said [Jennifer Ernst, CEO](#) of Tivic Health. “We’re looking forward to providing people with access to ClearUP™ in 2019 later this year, pending FDA clearance.”

Tivic Health is actively engaging with investor communities in preparation for the ClearUP™ Sinus Pain Relief launch following.

*FDA 510 K clearance is pending. ClearUP™ Sinus Pain Relief is an investigational technology. Claims have not been evaluated by the FDA. This device is not currently for sale in the U.S.*

#### **ABOUT TIVIC HEALTH SYSTEMS INC.**

Tivic Health Systems Inc. (Tivic Health™) is a bioelectronic device company dedicated to developing MICROCURRENT therapy solutions for chronic diseases and conditions. Tivic Health’s first product, ClearUP™ Sinus Pain Relief, targets sinus pain and pressure associated with chronic sinusitis, allergic rhinitis and other common sources of sinus pain.

Tivic Health, founded in 2016, is part of a neuromodulation industry projected to grow to \$6.2 billion industry by 2020.<sup>2</sup> The team is dedicated to harnessing the power of neuromodulation for home use products, empowering people to improve their health and quality of life.

For more information, visit [tivichealth.com](http://tivichealth.com) and follow us on [twitter.com/TivicHealth](https://twitter.com/TivicHealth).

#### **FORWARD LOOKING STATEMENT**

This news release contains forward-looking statements that are based on the current expectations and beliefs of Tivic Health Systems Inc. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including FDA submission, product launch and timing.

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