

## **Autism Spectrum Disorder (ASD) “Fever Effect” Pilot Study Enrollment Announced**

SAN DIEGO, CA – June 12, 2018 – AVACEN Medical, Inc. (AVACEN), announced that it will be sponsoring a 12-family blinded, double placebo-controlled pilot study of ASD children ages 6-16 who will be using the AVACEN 100 dry heat therapy, FDA-cleared, medical device which simulates the effect of a low-grade fever by non-invasively infusing heat into the circulatory system.

The Fielding Graduate University IRB approved study is entitled: “*The Fever Effect: Do kids with autism do better when they use a device to warm their blood? Effects of a six-week AVACEN Treatment Method on Autism Spectrum Disorder*”. Enrollment will begin immediately.

The purpose of conducting a pilot study is to examine the feasibility of an approach that is intended to be used in a follow-up larger scale study. This larger randomized, double-blind, placebo-controlled, study will examine improvements in the Childhood Autism Rating Scale (CARS-2) and the Parental Stress Scale. In addition, the study will evaluate the reductions in anxiety and sleep problems reported by parents of ASD children and adolescents using the AVACEN 100 medical device\*.

Researchers have wondered about the so-called "fever effect" since at least 1980, when a viral infection swept through a therapeutic nursery for children with autism at Bellevue Psychiatric Hospital in New York. Hospital staff reported that the children were more social, alert, and talkative while feverish (Sullivan, 1980). When their fevers faded, so did those behavioral improvements. Unraveling the fever effect could lead to innovative ways to improve the lives of individuals affected by autism spectrum disorder.

The Autism Society estimates that 70 million people worldwide have ASD. Research on the costs associated with ASD conducted in the United States (e.g. Croen, et al. 2006) determined that the average cost for children with ASD were twice as high as other children for hospitalization, clinic visits, and prescription medications.

Thomas G Muehlbauer, CEO of AVACEN Medical stated, “Autism has a devastating impact on those who suffer from ASD, and their personal support systems.” He added,

“That’s why this pilot study will also be evaluating the potential benefit of the AVACEN 100 for the entire family that may be affected by ASD.”

With over 4 million estimated treatments and zero reported adverse events, the AVACEN 100 is the only known OTC non-invasive medical device with proven systemic efficacy that can safely warm the body from the inside out.

### **About AVACEN 100 Patents**

The US Patent Office has issued 4 Patents to AVACEN. The patents cover innovations embodied in the AVACEN 100 system, which is expected to allow multiple therapeutic uses to alleviate symptoms associated with a circulatory, neurological, lymphatic, or endocrinal dysfunction, or any combination thereof.

Patents have also been issued for China, Australia, Japan, UK, France, Germany, Spain, Sweden and Canada. Patents are pending in other countries.

### **About AVACEN Medical**

AVACEN Medical is dedicated to the innovation and design of safe, easy to use, noninvasive drug-free alternatives for the management of pain associated with numerous chronic and acute conditions including the temporary relief of minor muscle and joint pain and stiffness associated with arthritis and potentially other conditions that can cause joint pain, such as CRPS, Reynaud’s, and Lyme Disease. Founded in 2009, AVACEN Medical is headquartered in San Diego. Contact: Ryan Jeffcoat at (888) 428-2236 x 711 or [info@AVACEN.com](mailto:info@AVACEN.com).

**E.U. and Health Canada Approval: A heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; the temporary relief of widespread pain associated with fibromyalgia; muscular relaxation; and the temporary increase of microcirculation.**

**U.S. FDA-Clearance: A heat therapy system indicated for the temporary relief of minor muscle and joint pain and stiffness; the temporary relief of joint pain associated with arthritis, muscle spasms, minor strains and sprains; muscular relaxation; and the temporary increase of local circulation where applied.**

**IMPORTANT NOTES: The AVACEN 100 is not for sale in the U.S. or E.U. for any non-cleared or non-approved indication mentioned in this document.**

\*AVACEN recommends that parents contact a physician before using the AVACEN 100 on those under 18 years of age.