

CLINICAL TRIAL CONFIRMS NEW DEVICE IMPROVES BONE DENSITY IN CANCER SURVIVORS

11% increase in bone density in study published in the Journal of the American Medical Association (JAMA) Oncology.

Riviera Beach, FL. (April. 19, 2016) – Juvent (www.juvent.com) a leader in orthopedic regenerative therapies for bone and musculoskeletal health announced today very positive results from the St. Jude Children’s Hospital [Clinical Trial](#). [Kirsten K. Ness](#), PT, Ph.D., Principal Investigator, states “The first goal of treating low BMD (bone mineral density) in childhood cancer survivors is to manage potential underlying causes including endocrine disorders and nutritional deficiencies. In our study using LMS (Juvent® Dynamic Motion Therapy Platform), we managed endocrine problems and supplemented everyone on the study. Our randomized [study](#) was effective in improving total body and tibial BMD in children randomized to the device while children in the placebo group had decreases in BMD. Importantly, we had no adverse events with a year of twice daily 10 minute sessions. This portable device is safe and effective as an intervention for childhood cancer survivors who have low BMD and whose endocrine and nutrition status is well managed.”

Gunnar Andersson, M.D., Ph.D., Chairman Emeritus of Orthopaedic Surgery at Rush Presbyterian, past President of the Orthopaedic Research Society and Juvent Science Advisory Board (SAB) Member, stated “This is a very important study with a spectacular result from a short period, non-invasive intervention that has no side effects.”

Richard Treharne, Ph.D., a leading FDA regulatory expert and SAB Member, said "Randomized studies of orthopaedic devices are rare; with double-blind studies with placebo controls even rarer. To find any therapy that can increase total body bone mineral density is even more rare. The results from this study using a challenging patient population are striking, most encouraging, and warrant further study."

“This is our first cancer patient study. Our other successful pediatric bone studies improved bone density with Cerebral Palsy, Thalassemia and Scoliosis patient populations. We believe this study creates a new standard of care and will move this important technology into children’s hospitals and pediatric clinics to help the over 300,000 pediatric cancer survivors¹ who suffer from post-chemotherapy bone and joint damage. It also demonstrates the potential that this device could help the 14 million adult cancer survivors¹ who struggle with similar problems. We plan to submit this data to the FDA to secure a clearance for this new indication.” says company Chairman & CEO, Rush Simonson.

David Brumfield, a leading biomechanical engineer and SAB Member, said “Juvent’s platform offers an easy means of applying a proprietary, low-magnitude mechanical stimulation (LMMS; 0.3 g) calibrated to one’s own unique resonant frequency within a safe 32-37Hz range. As such, its use is more effective and safer than whole body vibration (WBV) devices which produce much larger magnitudes & frequencies with their associated side effects. This well-conducted study demonstrates that the safe and effective Juvent technology helped restore musculoskeletal health in these patients whose bone strength has been impaired by cancer treatments, thus improving the medical welfare of these who have already endured so much.”

“An 11% improvement in tibial BMD with no adverse events is a ‘home run’ by any criteria.” said Peter Simonson, a leading medical device developer, Georgia Tech mechanical engineer and Juvent President. “This study is another confirmation that the years of development of our patented software and mechanism was worth it. The software’s ability to automatically adapt to a user’s unique body mass and composition is the key” said Simonson.

“We are interviewing national distribution partners who are able to reach the 200+ children’s hospitals and therapists here in the U.S. We are also seeking funding to complete development and production of a low cost consumer unit. Over 50 million people who suffer from osteoarthritis in the U.S. could benefit from this safe, non-invasive technology.”, said Chairman & CEO Rush Simonson

Juvent’s Micro-Impact Platform® is registered as a FDA Class I medical exercise and rehabilitation device. Juvent uses a unique resonant technology to deliver thousands of low-magnitude and high-frequency micro-impacts that enter through the heels of the feet and move up the entire body. These micro-impacts safely stimulate the body’s muscles and bones to rebuild. Users stand on the Juvent for as little as 10 minutes per day and many begin to feel joint pain relief within days. Juvent’s platform is recommended and used by world-renowned trainers, doctors, physical therapists, and chiropractors. Juvent holds over 26 patents worldwide on its technology.

Juvent’s platform is also used in the athletic world for recovery and healing by leading organizations such as The David Leadbetter Golf Academy and the NFL Alumni Association (NFLA). Some of the champion athletes using Juvent in their daily training regimens include; Olympic Tennis Champion Mike Bryon, former NFL legend, Ray Lewis, Eric Wood, with the Buffalo Bills and tennis legend Mats Wilander.

Juvent is a Corporate Advisory Roundtable Member of the National Osteoporosis Foundation (NOF)

[JAMA Oncology Study](#) - *Effect of Low-Magnitude, High-Frequency Mechanical Stimulation on BMD Among Young Childhood Cancer Survivors - A Randomized Clinical Trial*

[ClinicalTrials.gov](#) - *Vibration Intervention For Bone Enhancement In Childhood Cancer Survivors*

[Kirstin K. Ness, PT, Ph.D](#) – *Principal Investigator at St. Jude Hospital for Children*

¹ *NIH, National Cancer Institute - [Childhood Cancer Survivor Study: An Overview](#)*

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About Juvent:

Juvent is a part of Regenerative Technologies Corporation, a privately held, Florida based company who manufactures the Juvent Micro-Impact Platform® here in the U.S. The platform provides non-invasive, micro-impact pulses to support bone health, lymphatic drainage, relieve joint and back pain, and enhance balance. The Class I medical exercise and rehabilitation device is the result of more than 20 years and \$45 million in R&D, with many peer-reviewed journals articles and 6 human clinical studies (completed or current) with backing from the National Institutes of Health (NIH), NASA, and the U.S. Army. Used by world-renowned medical doctors, trainers, physical therapists, and chiropractors, for more information, visit www.juvent.com or follow us on Twitter [@JuventHealth](#) and [Facebook](#).

In the U.S., the Juvent 1000N device is considered investigational for the treatment of osteoporosis or improvement/maintenance of bone mineral density (BMD).

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