

FDA clears new indication for Myoscience's iovera^o system to relieve pain and symptoms associated with osteoarthritis of the knee

FREMONT, CA (March 17, 2017) – California-based Myoscience, Inc. announced that the U.S. Food & Drug Administration (FDA) has cleared its iovera^o device for the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days. The iovera^o technology is a non-opioid and non-systemic treatment for blocking pain signals from peripheral nerves.

Osteoarthritis compromises the quality of life of more than 27 million Americans, with approximately 25% of knee osteoarthritis sufferers complaining of pain while performing daily activities (walking, climbing stairs, kneeling, etc.)¹. The effect of this disease on the United States economy is estimated to be \$60 billion per year². Also, Center for Disease Control and Prevention (CDC) states that the US is in the throes of an opioid epidemic, and that the total number of opioid-related deaths may be underestimated.

"The iovera^o technology has the potential to change the current paradigm of pain management for osteoarthritis", said Dr. Vinod Dasa. "The patients that I have treated with this technology have experienced immediate and long-lasting pain relief; and are grateful to have an option that is non-narcotic and non-systemic."

The FDA clearance was based on a recent prospective, multi-center, sham-controlled, randomized, double-blind study of 180 subjects. The study concluded that patients treated with the iovera^o device reported statistically significant greater reduction in pain and improvement in symptoms (p=0.001) when compared to patients who received the sham treatment³. Also, patients who received the iovera^o treatment reported pain relief lasting up to 90 days, accompanied by reduced stiffness and improved physical function.

The [full study results are published in the Osteoarthritis and Cartilage journal](#).

Cary Vance, President and CEO of Myoscience, stated that "The addition of osteoarthritis to the indications for the iovera^o treatment will help in extending our innovative non-opioid therapy to more patients, especially in the growing baby-boomer population. I anticipate this technology to become the non-narcotic and non-systemic solution of choice to manage knee pain."

The iovera^o treatment uses the body's natural response to cold to treat peripheral nerves. A sensory nerve will stop sending pain signals immediately after receiving targeted cold therapy via the iovera^o treatment. The effect on the nerve is transient, providing pain relief until the nerve regenerates and its sensory function is fully restored. This pain relief is achieved without the use of habit-forming drugs such as opioids.

For additional information, please visit www.iovera.com or email us directly at contact@myoscience.com.

**Dr. Vinod Dasa, MD, is a member of Myoscience's Medical Advisory Board*

¹ Source: A National Public Health Agenda for Osteoarthritis. CDC. February 4, 2010.

² Buckwalter, JA, et al. The Impact of Osteoarthritis. Clin Orthop Related Res. Oct 2004. 427(427 Suppl):S6-S15.

³ Radnovich R, et al., Cryoneurolysis to Treat the Pain and Symptoms of Knee Osteoarthritis: A Multicenter,

ABOUT MYOSCIENCE

Silicon Valley, California-based Myoscience is a privately-held medical device company committed to making its platform technology, the iovera^o system, the standard of care for the treatment of peripheral nerves. The iovera^o treatment is powered by the Focused Cold Therapy[®] delivery system, a patented miniaturization of traditional cryotherapy. The iovera^o system is 510k cleared in the U.S. for the blocking of pain, the relief of pain and symptoms associated with osteoarthritis of the knee for up to 90 days and general surgical use. For more information, please visit www.iovera.com.

ABOUT OSTEOARTHRITIS

According to reports from the CDC, approximately 27 million Americans suffer with osteoarthritis. While 1 in 2 people develop osteoarthritis during their lifetime, obesity increases the risk of knee osteoarthritis to 3 in 5. Quality of life is routinely affected, with 25% of knee osteoarthritis sufferers reporting trouble performing simple daily activities, such as walking, climbing, kneeling or stooping. (Source: A National Public Health Agenda for Osteoarthritis. CDC. February 4, 2010)

ABOUT THE KNEE OSTEOARTHRITIS STUDY

The knee osteoarthritis study is a prospective, multicenter, randomized, double-blind, sham-controlled trial to evaluate the effectiveness and safety of the iovera^o device for the temporary relief of pain associated with knee osteoarthritis. Study population included male or female, ages 35-75 with chronic knee pain related to knee osteoarthritis.