

## Saluda Medical announces clinical study results of the chronic pain treatment

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Saluda Medical Pty Limited ("Saluda Medical") has announced data from two clinical studies evaluating the performance of the company's Evoke® ECAP-Controlled, Closed-Loop Spinal Cord Stimulation (SCS) System and its impact on pain relief for patients suffering from chronic pain. Evoke is designed to be the first closed-loop SCS system that measures the spinal cord's response to stimulation (via ECAPs, or evoked compound action potentials) and adjusts on every pulse to maintain activation within the patient's therapeutic window.

Results were reported in multiple plenary and oral presentations by leading pain specialists during the International Neuromodulation Society (INS) 14<sup>th</sup> World Congress in Sydney.

The Evoke and Avalon studies both demonstrated improvements in pain, function, sleep, and quality of life. These data substantiate the observation that considerable pain relief can impact a patient's entire life, including reduction in pain medications.

Steven M. Falowski, M.D., Director of Functional Neurosurgery at Neurosurgical Associates of Lancaster in Lancaster, PA and an investigator in the Evoke Study, said, "Two separate studies of the Evoke System show promising results. The U.S. Evoke study, the first double-blind randomized regulatory approval study in SCS, demonstrated better rates in pain relief and secondary outcomes for closed-loop compared to control. The Avalon study, an Australian prospective, single-arm study, provides long-term evidence for sustained pain relief with closed-loop. Both studies provide evidence supporting the novel design of the device where ECAPs are measured to monitor therapy delivery in real time. The technology provides an objective measure based on a neurophysiological response to control therapy delivery and provides insight into the mechanism of action. There were a plethora of talks featuring ECAPs at this congress and they highlight the potential clinical utility of this new technology."

Dr. Charles Brooker, Director of the Pain Management and Research Centre, Royal North Shore Hospital and Principal Investigator in the Avalon Study, highlighted, "With Evoke, study results suggest that pain relief continues to improve over time, which is not typically observed with fixed-output systems. With the capability of neurophysiology measurements, such as percentage time in the therapeutic window, we can now start to understand a complex condition objectively in addition to patient reported outcomes, an important advancement to the field of pain management."