Saluda Medical Receives FDA Approval for Evoke® System MRI Labeling

Patients implanted with the Evoke® System now eligible for full-body MRI scans

MINNEAPOLIS, Sept. 26, 2023 /PRNewswire/ -- Saluda Medical, Inc. ("Saluda Medical"), a global medical device company revolutionizing the field of neuromodulation with an emerging portfolio of therapies driven by advanced closed-loop technologies, today announced that the U.S. Food and Drug Administration (FDA) has approved MRI conditional labeling for the Evoke® System, the first and only precision, dose-control spinal cord stimulation (SCS) therapy powered by SmartLoop™ technology. This approval applies to all commercially implanted Evoke® System patients in the United States as well as patients formerly enrolled in the ECAP Study.

The Evoke® system's MRI labeling is one of the most comprehensive in the SCS space. The approval provides patients implanted with the Evoke® System the ability to undergo 1.5 or 3.0T head and extremity and 1.5T full-body MRI scans across the most implant locations in the industry. Imaging can be done in both prone and supine positions. Specific scan conditions and safety information are provided in the Evoke® SCS System MRI Guidelines manual.

"This approval marks an important step in meaningfully expanding patients' eligibility and access to the paradigm-shifting Evoke therapy," said Jim Schuermann, President and CEO of Saluda Medical. "The Evoke® System has been MRI-approved since 2019 in Europe and Australia and since 2022 for patients in the ECAP Study, a U.S. IDE study with 300 patients enrolled. With this approval, every current and future Evoke® system patient across every region where the device is currently marketed will be able to undergo MRI scans."

About Saluda Medical

Saluda Medical is a global company transforming patients' lives with disruptive neural sensing technologies designed to revolutionize the field of neuromodulation. The company's first product, the Evoke® System, is the only SmartLoop™ therapy with physiologic ECAP-controlled closed-loop spinal cord stimulation (SCS) system and is indicated as an aid in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome, intractable low back pain, and leg pain. The Evoke® System automatically reads, records, and responds to the nerves' response to stimulation 4+million times a day to provide continually optimized therapy and is proven to be superior to open-loop SCS for the treatment of overall trunk and/or limb pain. 12-month results from the EVOKE study, the first double-blind randomized controlled trial (RCT) used in support of Premarket Approval (PMA) in spinal cord stimulation history, were published in *The Lancet Neurology* and 24-month results have since been published in *JAMA Neurology*. Furthermore, unprecedented 36-month data from the EVOKE Study demonstrated enduring and consistent pain relief with the Evoke® System. To learn more, including risks & important safety information, visit www.saludamedical.com/us/safety/.

Media Contact:
Stella Kim
+1 (651) 270-3084
Stella.kim@saludamedical.com

Investor Contact:
Brian Johnston
Gilmartin Group
(332) 895-3222
brian@gilmartinir.com