ASX ANNOUNCEMENT

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Saluda Medical Receives Regulatory Approval for EVA™ Sensing Technology in Europe with recognition in Australia

Saluda Medical, Inc. (ASX:SLD, "Saluda" or the "Company"), a commercial-stage medical device company focused on developing treatments for chronic neurological conditions using its novel closed-loop neuromodulation platform, today announced that, as expected, its next-generation EVA™ Sensing Technology has now received CE certification for commercialisation in Europe with recognition of this approval in Australia. This follows FDA approval of EVA in December 2024.

EVA Sensing Technology builds on the Evoke® System, the first closed-loop spinal cord stimulation (SCS) device capable of reading and responding to the spinal cord's evoked compound action potentials (ECAPs) in real time, enabling truly personalised therapy and optimised patient outcomes.

EVA Sensing Technology automates manual programming steps and objectively scans and analyses a patient's spinal cord to deliver therapy with optimised precision. By removing clinical guesswork and anchoring therapy to each patient's unique spinal cord physiology, EVA Sensing Technology sets a new standard for personalised pain management.

"*This approval is in line with our expectations and builds on the successful commercialisation we've seen in the U.S., this expansion allows us to bring a proven technology enhancement to more markets,*" said Barry Regan, CEO, Saluda Medical. "*This reinforces our commitment to driving innovation and improving outcomes for patients worldwide.*"

"*EVA Sensing Technology builds on the positive outcomes we have seen with the Evoke® System's closed-loop therapy compared to traditional SCS,*" Harold Nijhuis, MD, Pain Specialist, Antonius Hospital, Netherlands. "*It delivers objective neural metrics aligned with maximum analgesic benefit while streamlining programming to improve efficiency and enhancing the patient experience.*"

A limited commercial release in Europe and Australia will begin in the first calendar quarter of 2026, followed by a full commercial release later in the year. The timing of this approval and launch is in line with the Company's internal expectations.

This announcement has been authorised for release by Saluda Medical's Disclosure Committee.

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About Saluda Medical

Saluda Medical, Inc. (ARBN 691 140 360) is a commercial-stage medical device company focused on developing treatments for chronic neurological conditions using its novel neuromodulation platform. The Company's closed-loop, dose-control platform senses and measures neural responses to stimulation and automatically adjusts therapy based on real-time neurophysiological feedback. The Company's first product, the Evoke® System, 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, and is designed to treat chronic neuropathic pain by providing spinal cord stimulation (SCS) therapy that senses and measures neural activation to optimize therapy and reduce patient and clinician burden. 12-month results from the EVOKE study, the first and only prospective, multi-center, parallel-arm, double blind, randomized controlled pivotal study with a voluntary crossover arm in SCS, that demonstrated clinically superior pain relief to open-loop therapy, were published in The Lancet Neurology, 24-month results were published in JAMA Neurology, and 36-month data, that demonstrated sustained pain relief, were published in Regional Anesthesia and Pain Medicine. To learn more, including risks and important safety information, visit www.saludamedical.com/us/safety/. Saluda and Evoke are registered trademarks owned by Saluda Medical Pty Ltd.

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