

# SS Innovations Conducts Interactive Meeting with the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) and Updates its Expected FDA Approval Timeline

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FORT LAUDERDALE, Fla., Sept. 11, 2024 (GLOBE NEWSWIRE) -- SS Innovations International, Inc. (the "Company" or "SS Innovations") (OTC: SSII), developer of innovative surgical robotic technologies dedicated to making world-class robotic surgery affordable and accessible to a global population, today issued an update on its progress and timeline in obtaining U.S. Food and Drug Administration ("FDA") approvals to market the SSi Mantra Surgical Robotic System ("SSi Mantra") in the United States.

Early this year, the Company completed its first interactive pre submission meeting with the FDA for the SSi Mantra. The Company received valuable feedback from the FDA regarding its planned regulatory strategy, biocompatibility assessment, reprocessing validation, and clinical data requirements and, based on this feedback, will proceed with a de novo pathway for the pre-market submission of the SSi Mantra for numerous indications in parallel.

The Company plans to have follow-on pre-submission meetings in the upcoming months and anticipates submitting the SSi Mantra for an investigational device exemption (IDE) application in the first quarter of 2025 to initiate clinical trials.

The Company is planning to simultaneously conduct clinical trials for various indications including abdominal, pelvis, thoracic and cardiac.

The Company believes that it will be able to meet the clinical trial requirements relatively quickly because (i) the SSi

Mantra's safety, efficacy, and performance has already been demonstrated in ongoing clinical use in India, where it has performed all the types of surgical procedures for which approval is being applied for; and (ii) under applicable FDA protocols, procedures performed in India can be included in the clinical trials. The Company plans to also conduct some of the clinical trials in the United States, particularly for Cardiac, where it has already identified potential testing sites.

The Company estimates that, barring any unanticipated developments, it should be able to secure its pre-market approvals by the end of 2025.

#### About SS Innovations International, Inc.:

SS Innovations International, Inc. (OTC: SSII) is a developer of innovative surgical robotic technologies with a vision to make the benefits of robotic surgery affordable and accessible to a larger part of the global population. SS Innovation's product range includes its proprietary "SSi Mantra" surgical robotic system, and "SSi Mudra" its wide range of surgical instruments capable of supporting a variety of surgical procedures including robotic cardiac surgery. SS Innovations' business operations are headquartered in India and the Company has plans to expand the distribution of its technologically advanced, user-friendly, and cost-effective surgical robotic solutions, globally. For more information, visit SS Innovation's website at [ssinnovations.com](https://ssinnovations.com) or [LinkedIn](#) for updates.

#### About SSi Mantra:

Supporting advanced, affordable, and accessible robotic surgery, the SSi Mantra Surgical Robotic System provides the capabilities for multi-specialty usage including cardiothoracic, head and neck, gynecology, urology, general surgery and more. With its modular arm configuration, 3D 4K vision open-console design and superior ergonomics, the system engages with the surgeon and surgical teams to improve safety and efficiency during procedures. The SSi Mantra system has received Indian Medical Device regulatory approval (CDSCO) and is clinically validated in India in more than 80 different types of surgical procedures. SS Innovations has commenced the regulatory approval process in the United States and the European Union and anticipates receiving FDA approval to market and CE Mark approval in the latter half of 2025.

#### Forward-Looking Statements:

This press release may contain statements that are not historical facts and are considered forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. The words "anticipate," "assume," "believe," "estimate," "expect," "will," "intend," "may," "plan," "project," "should," "could," "seek," "designed," "potential," "forecast," "target," "objective," "goal," or the negatives of such terms or other similar expressions to identify such forward-looking statements. These statements relate to future events or SS Innovations' future financial

performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

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