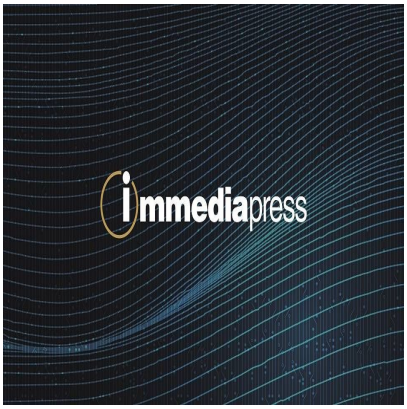

Supira Medical Announces FDA Approval for SUPPORT II Pivotal Trial, Advances in Cardiogenic Shock, and Appointment of D. Keith Grossman to Board of Directors

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

Milestones underscore clinical progress and strengthen commercial foundation

LOS GATOS, Calif., April 8, 2026 /PRNewswire/ â?? Supira Medical, Inc. (Supira), a clinical-stage company focused on transforming the percutaneous ventricular assist device (pVAD) market, today announced FDA approval to initiate the SUPPORT II Pivotal Trial. The trial is designed to support a future PMA submission and represents a critical step toward U.S. market entry.

SUPPORT II (SUpira System in Patients Undergoing High-Risk Percutaneous COronaRy InTervention (HRPCI)) is a prospective, randomized controlled study designed to assess the safety and efficacy of the companyâ??s next-generation pVAD in patients undergoing HRPCI. The study will enroll up to 385 patients at up to 40 U.S. sites and is led by national co-principal investigators Dr. Ajay Kirtane, Professor of Medicine at Columbia University, Vagelos College of Physicians and Surgeons/New York-Presbyterian Hospital, and Dr. David Kandzari, Chief of the Piedmont Heart Institute and Chief Scientific Officer for Piedmont Healthcare, Atlanta, GA.

â??In HRPCI, the decision to use hemodynamic support is often influenced by access, deliverability, and the balance between support and procedural efficiency,â?• said Dr. Kandzari. â??A system that can provide effective circulatory support with a smaller profile has the potential to expand the available treatment population and improve effectiveness.â?•

â??The appropriate use of a pVAD allows physicians to safely perform procedures of the highest complexity, offering HRPCI to patients who previously had limited options,â?• said Dr. Kirtane. â??The initiation of this pivotal randomized trial of a novel, lower-profile hemodynamic support device is an important step in advancing the care of some of our highest risk patients.â?•

Advances in Cardiogenic Shock

Separately from SUPPORT II, the company has been pursuing opportunities to improve treatment options for patients experiencing cardiogenic shock. Recent case experience outside the U.S. includes the initial series of cardiogenic shock patients, utilizing percutaneous axillary access to enable patient ambulation with an active 10Fr pVAD.

Together, these milestones highlight what the next generation of temporary mechanical circulatory support can potentially enable; expanding access options, supporting mobility, and advancing how physicians manage critically ill patients.

For interventional cardiologists and heart failure specialists, full hemodynamic support with flexibility in percutaneous access site and the potential for patient mobility during support represent important steps toward improving the overall care pathway for cardiogenic shock.

Appointment of Medical Device Industry Veteran D. Keith Grossman as Independent Board Member

In parallel with these clinical milestones, Supira announced the appointment of D. Keith Grossman to its Board of Directors. Mr. Grossmanâ??s 40-year leadership experience in the medical technology industry, including a foundational role in the mechanical circulatory support space, will reinforce the companyâ??s focus on scaling toward market readiness and growth.

â??Keith brings a valuable combination of operational discipline, commercial insights, and strategic perspective,â?• said Dr. Nitin Salunke, President and CEO of Supira Medical. â??His addition as an independent member of our Board reflects our commitment to building an organization that is not only clinically differentiated but also positioned to execute at scale.â?•

â??Supira has established a compelling clinical and technological foundation that is uniquely positioned to change the growing and still under-penetrated pVAD landscape,â?• said Mr. Grossman. â??I look forward to supporting the company as it advances its pivotal trial and prepares to become a leading presence among treatment options for high-risk PCI and cardiogenic shock patients.â?•

About Supira Medical, Inc.

Supira Medical is focused on the development of a next-generation pVAD for use in high-risk patients undergoing interventional procedures and experiencing cardiogenic shock. To date, the Supira System has been used in 99 patients. To learn more about Supira Medical, please visit www.supiramedical.com.

pVADs are important for supporting cardiovascular function during HRPCI and in patients experiencing cardiogenic shock. HRPCI patients have complex coronary anatomy, compromised hemodynamics, and multiple comorbidities, while cardiogenic shock is a high-mortality condition where the heart is too weak to pump sufficient blood to vital organs, usually resulting from a heart attack or heart failure.

The Supira System is an investigational device and is not approved for sale in the U.S. or anywhere in the world. The device is limited by federal law to investigational use.

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