

**FOR IMMEDIATE RELEASE**

**AngelMed Announces FDA Approval of the Enhanced Real-Time Cardiac Monitor for Acute Coronary Syndrome (ACS) Events**

*AngelMed Guardian® System prompts high-risk ACS patients to seek medical care*

EATONTOWN, N.J., June 28, 2021 -- [Angel Medical Systems, Inc.](#), (dba AngelMed) a proactive diagnostics company focused on the advancement of long-term management of high-risk coronary disease, announced today the FDA approval of the second-generation AngelMed Guardian® device. The AngelMed Guardian System is the world's first implantable cardiac detection monitor and patient-warning system for acute coronary syndrome (ACS) events, including silent heart attacks. The new, second-generation device is enhanced with ease-of-use adaptations and an updated, long life battery that could potentially double the life of the implanted device.

The AngelMed Guardian device is implanted subcutaneously by a cardiologist during a low-risk, outpatient surgical procedure. Using a patented algorithm, the AngelMed Guardian continuously records the heart's electrical activity, 24 hours a day, monitoring for electrical changes that can indicate an impending ACS event. The AngelMed Guardian device provides a more effective diagnosis of a life-threatening condition when compared to patient symptoms alone.<sup>1</sup>

"Patients who have had a prior ACS event often remain at high-risk of a recurrent event. Even those patients who are on alert for another potential cardiac event may delay seeking treatment," said Dr. C. Michael Gibson M.D., Boston Clinical Research Institute. "The AngelMed Guardian System has demonstrated the ability to identify the earliest signs of an ACS event, including heart attacks, more effectively than patients' symptoms alone, and in patients who do not experience symptoms at all."

"The improved AngelMed Guardian device will have a meaningful effect on the current standard of patient cardiology care for ACS events. Our dedicated team and supporting physicians have worked tirelessly to bring this disruptive technology to market," said AngelMed Chief Executive Officer, Brad Snow. "As the first real-time detection device for high-risk heart attack patients, the AngelMed Guardian System provides critical data at the point of care, along with peace of mind for physicians and patients alike."

"Our key learnings based on hundreds of thousands of hours of clinical monitoring data for many ambulatory patients with cardiovascular disease provides a technology platform for future offerings. Our patient-centric approach will drive our research and development," said Dave Keenan, AngelMed chief operating officer.

Every 40 seconds, someone in the U.S. suffers a myocardial infarction or heart attack.<sup>2</sup> The most important risk factors for another cardiovascular event in post-heart attack patients are

age, medical history, comorbidities, and the severity of their first ACS event.<sup>3</sup> Despite proactive ongoing efforts over the last decade from the medical community to better educate the public on signs and symptoms of a heart attack, the time from symptom onset to arrival at a hospital remains static at eight hours.<sup>4</sup>

For more important safety information, please visit: <http://www.angel-med.com/>.

### **About Angel Medical Systems, Inc.**

[Angel Medical Systems, Inc.](http://www.angel-med.com/), is a proactive diagnostics company committed to advancing life-sustaining, personalized patient care, including the long-term management of high-risk coronary disease. Angel Medical Systems maintains a robust portfolio of U.S. patents relating to detecting cardiac events, including silent heart attacks.

<sup>1</sup> Food and Drug Administration Website. Summary of Safety and Effectiveness Data. <https://www.fda.gov/media/96475/download> . Accessed May 6, 2021

<sup>2</sup> Centers for Disease Control and Prevention. (2012, August). *NCHS data brief: Prevalence of Uncontrolled Risk Factors for Cardiovascular Disease: United States, 1999–2010* (No. 109). Retrieved from <https://www.cdc.gov/nchs/data/databriefs/db103.pdf>.

<sup>3</sup> Amsterdam EA, Wenger NK, Brindis RG, et al. 2014 AHA/ACC guideline for the management of patients with non-ST-elevation acute coronary syndromes: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2014;130(25):2354-2394. doi: 10.1161/CIR.000000000000133.

<sup>4</sup> Holmes DR, Krucoff MW, Mullin C, et al. Implanted monitor alerting to reduce treatment delay in patients with acute coronary syndrome events. *J Am Coll Cardiol*. 2019;22:2047-2055. doi: 10.1016/j.jacc.2019.07.084.

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