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News Release

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European Society of Cardiology (ESC) Congress 2026:

Phase III REVEAL Study with Investigational PET Radiotracer Iodine 124 Evuzamitide Presented as Late-Breaker at ESC 2026

- Pivotal study met primary endpoints in the assessment of sensitivity and specificity for the diagnosis of cardiac amyloidosis based on visual scan interpretation
 - Phase III results in patients with suspected cardiac amyloidosis were presented at the European Society of Cardiology (ESC) Congress 2026 and simultaneously published in *The Journal of the American Medical Association*
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Berlin, Germany, August 30, 2026 – Bayer today announced first detailed results from the Phase III REVEAL study, an investigator-initiated study by Brigham and Women's Hospital, that evaluated the investigational positron emission tomography (PET) radiotracer iodine 124 evuzamitide (I 124 evuzamitide) for the diagnosis of cardiac amyloidosis.¹ The pivotal study met its primary endpoints in the assessment of sensitivity and specificity for the diagnosis of cardiac amyloidosis based on visual scan interpretation.¹ Secondary endpoints, which assessed diagnostic performance in light-chain amyloidosis (AL) as well as in transthyretin amyloidosis (ATTR) based on visual scan interpretation, also met the predefined success criteria in the overall population. I 124 evuzamitide is an investigational compound and has not been approved by any health authority for use in any country for any indication.

These results were shared in a late-breaking oral presentation at the [European Society of Cardiology Congress 2026](#) (ESC) in Munich, Germany, on August 30, 2026, and simultaneously published in *The Journal of the American Medical Association*.

"For people with cardiac amyloidosis, obtaining an accurate diagnosis can be challenging," said REVEAL principal investigator Dr. Sharmila Dorbala, Director of Nuclear Cardiology, Brigham and Women's Hospital, Director of Amyloidosis Research,

Mass General Brigham Heart & Vascular Institute. “These challenges can lead to delays, underdiagnosis or misdiagnosis in the course of the disease .”

“ Bayer is proud to present this new research on cardiac amyloidosis at ESC,” said Dr. Erin Bowman, Senior Medical Director of Molecular Imaging and Theranostics at Bayer. “The presentation of this data reflects our ongoing commitment to advancing research for patients affected by this disease.”^{2,3}

Key Highlights of the Phase III REVEAL Study Results and Design

REVEAL was a multicenter, open-label, single-arm Phase III study conducted at 18 centers in the United States, evaluating 170 adults with suspected cardiac amyloidosis.

- Primary analyses from the Phase III REVEAL study showed the investigational PET radiotracer I 124 evuzamitide met the primary efficacy endpoints of sensitivity (the ability to identify individuals who have the condition) and specificity (the ability to identify individuals who do not have the condition) for the diagnosis of cardiac amyloidosis based on visual scan interpretation from three independent readers.
 - o Sensitivity
 - Reader 1: 94% (95% confidence interval [CI], 85% to 98%)
 - Reader 2: 94% (95% CI, 85% to 98%)
 - Reader 3: 90% (95% CI, 81% to 95%)
 - o Specificity
 - Reader 1: 84% (95% CI, 75% to 91%)
 - Reader 2: 85% (95% CI, 76% to 92%)
 - Reader 3: 89% (95% CI, 81% to 95%)
- Based on the majority read (agreement between at least two out of three readers), sensitivity was 94% (95% CI, 85% to 98%) and specificity was 86% (95% CI, 77% to 92%).
- Secondary efficacy endpoints, which assessed diagnostic performance in light-chain amyloidosis (AL) as well as in transthyretin amyloidosis (ATTR) based on visual scan interpretation, also met the predefined success criteria for the total population of patients with suspected cardiac amyloidosis.
 - o For the ATTR type, sensitivity from the majority read was 96% (95% CI, 87% to 100%) and specificity was 86% (95% CI, 77% to 92%).
 - o For the AL type, sensitivity from the majority read was 95% (95% CI, 76% to 100%) and specificity was 86% (95% CI, 77% to 92%).

- Among the 170 patients who received I 124 evuzamitide, 55 (32.4%) experienced at least one treatment-emergent adverse event (TEAE) from Day 1 to Day 30. Of these, 11 (6.5%) patients experienced a serious TEAE unrelated to I 124 evuzamitide; only one TEAE (fatigue) was considered related to I 124 evuzamitide.
- The most common TEAEs, occurring in >1% of participants, were upper respiratory tract infection (2.9%), dizziness (2.4%), nausea (1.8%), vomiting (1.8%), syncope (1.8%), hyperglycemia (1.8%) and skin laceration (1.8%).
 - There were no deaths or evuzamitide related TEAEs leading to discontinuation during the study period.

About Iodine 124 Evuzamitide

Iodine 124 evuzamitide (I 124 evuzamitide) is an investigational PET radiotracer – a radioactive diagnostic imaging agent injected into the body before a PET scan to assist with visualization – being studied in patients with suspected cardiac amyloidosis. I 124 evuzamitide, also known as AT-01, is one of two investigational amyloid radiotracers that [Bayer acquired from Attralus, Inc.](#)⁴ The acquisition expands Bayer's radiology pipeline with complementary tracers targeting systemic amyloid disease.

Regulatory Status of I 124 Evuzamitide

I 124 evuzamitide was previously granted [Breakthrough Therapy Designation](#) by the U.S. FDA for PET imaging in patients with suspected or known cardiac amyloidosis. It was also granted [Orphan Drug status](#) for both AL and ATTR in the U.S. and the EU.⁵ I 124 evuzamitide is currently under investigation and has not been approved by any health authority for use in any country for any indication. Bayer plans to discuss these data and submission for regulatory approval with the FDA and other health authorities.

About the REVEAL Study⁶

The REVEAL (“**R**esearch with **EV**uzamitide I 124 to **EL**ucidate Cardiac **AM**yloidosis”) study was an investigator-initiated Phase III clinical trial of the investigational diagnostic imaging agent I 124 evuzamitide in patients with suspected cardiac amyloidosis. Brigham and Women's Hospital in Boston, MA, was the study sponsor.

The main purpose of the study was to evaluate the efficacy and safety of the investigational radiotracer I 124 evuzamitide for diagnosing cardiac amyloidosis in participants with suspected cardiac amyloidosis compared to clinical standard of truth diagnosis based on available clinical data. Secondary analyses assessed diagnostic

performance in ATTR and AL subtypes. The imaging test used in this study was a positron emission tomography (PET) scan.

Participants received a single intravenous dose of I 124 evuzamitide, followed by cardiac and partial-body PET/CT imaging, 3-5 hours post-injection. All PET/CT images were independently read by experienced cardiac PET physicians, assessing visual presence or absence of cardiac tracer uptake, blinded to clinical data.

Cases were confirmed through an independent clinical adjudication committee, blinded to PET results, with expertise in cardiology, amyloidosis, and/or cardiac imaging. The committee established standard of truth using diagnostic data collected up to 60 days after imaging.

About Cardiac Amyloidosis

Cardiac amyloidosis is a severe, progressive disease caused by the accumulation of misfolded proteins (amyloid) in heart tissue, making it stiff and thick, which can impair its ability to pump blood effectively.⁷ Despite increasing disease awareness by health care providers, a prolonged diagnostic journey is common, with patients often consulting several specialists and receiving multiple tests and procedures before an accurate diagnosis.³ Without timely diagnosis and treatment, cardiac amyloidosis can lead to heart failure, frequent hospitalizations and early mortality.⁸ Currently, there is no single, non-invasive test that can reliably detect and diagnose cardiac amyloidosis or quantify and monitor myocardial amyloid burden.²

About Molecular Imaging

Molecular imaging allows clinicians to visualize and quantify biological processes at the molecular and cellular level in real time, enabling earlier disease detection and personalized treatment planning.⁹

About Radiology at Bayer

Building on a century of expertise, Bayer is committed to innovative products and high-quality services in diagnostic imaging to enhance patient care. Its leading radiology portfolio features contrast agents and devices for precise administration across modalities including computed tomography (CT), X-ray and magnetic resonance imaging (MRI), and positron emission tomography (PET). Bayer's comprehensive offerings also include informatics solutions. In 2025, Bayer's radiology products generated €2.2 billion in sales.

Bayer continues to advance research and innovation in medical imaging, including in molecular imaging and other promising fields.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, “Health for all, Hunger for none,” the company’s products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2025, the Group employed around 88,000 people and had sales of 45.6 billion euros. R&D expenses amounted to 5.8 billion euros. For more information, go to www.bayer.com.

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Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer’s public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

Bayer AG is a holding company with operating subsidiaries worldwide. References to “Bayer” or “the company” herein may refer to one or more subsidiaries as context requires.

¹ Data on file

² Briasoulis A, et al. Invasive and Non-Invasive Diagnostic Pathways in the Diagnosis of Cardiac Amyloidosis. *J Cardiovasc Dev Dis*. 2023 Jun 11;10(6):256. doi: 10.3390/jcdd10060256.

³ Dang D, et al. Gateway and journey of patients with cardiac amyloidosis. *ESC Heart Fail*. 2020 Oct;7(5):2418-2430. doi: 10.1002/ehf2.12793.

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- ⁴ Bayer. Bayer to expand into molecular imaging with acquisition of innovative pan-amyloid radiotracers from Attralus. Published January 12, 2026. Accessed July 24, 2026. Bayer press release
- ⁵ Bayer. Investigational PET Tracer Iodine 124 Evuzamitide from Bayer Met Primary Endpoints in Phase III Study in Patients Suspected to Have Cardiac Amyloidosis. Bayer. Published May 7, 2026. Accessed July 24, 2026. Bayer press release.
- ⁶ Clinicaltrials.gov. Research With I-124 EVuzamitide to Elucidate Cardiac AmyLoidosis (REVEAL). <https://clinicaltrials.gov/study/NCT06788535>
- ⁷ Cleveland Clinic. Cardiac amyloidosis: What you need to know. Updated October 13, 2025. Available at: <https://my.clevelandclinic.org/health/diseases/22598-cardiac-amyloidosis>
- ⁸ Dentamaro I, et al. Cardiovascular Prognosis in Stable Patients with Cardiac Amyloidosis: A Novel and Simple Risk Score. *J Clin Med*. 2026 Mar 7;15(5):2045. doi: 10.3390/jcm15052045.
- ⁹ Society of Nuclear Medicine & Molecular Imaging. What is Nuclear Medicine and Molecular Imaging? Accessed July 6, 2026. Available at: <https://snmmi.org/Patients/Patients/Fact-Sheets/What-is-Nuclear-Medicine-and-Molecular-Imaging.aspx>