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News Release

Not intended for UK Media

Investigational PET tracer iodine 124 evuzamitide from Bayer met primary endpoints in Phase III study in patients suspected to have cardiac amyloidosis

- The Phase III REVEAL study met its primary endpoints demonstrating sensitivity and specificity of iodine 124 evuzamitide (I 124 evuzamitide) positron emission tomography computed tomography (PET/ CT) for the diagnosis of cardiac amyloidosis based on visual scan interpretation[1]
- I 124 evuzamitide, an investigational radiotracer for the diagnosis of cardiac amyloidosis, was previously granted U.S. FDA Breakthrough Therapy Designation for positron emission tomography (PET) imaging in patients with suspected or known cardiac amyloidosis[2]
- The compound also previously received Orphan Drug status in the U.S. and EU[3]
- Cardiac amyloidosis typically takes between 2-4 years from symptom onset to diagnosis,[4] yet there is no single non-invasive test for reliable detection and diagnosis of the disease
- Bayer plans to discuss the data and submission for regulatory approval with the FDA and other health authorities

Positive Topline Data Results

Berlin, Germany/ Whippany, N.J., May 7, 2026 – Bayer today announced positive topline results from the Phase III REVEAL study, an investigator-initiated study by Brigham and Women's Hospital that evaluated the investigational PET/CT radiotracer I 124 evuzamitide.[1, 5] The study met the primary endpoints of sensitivity (the ability of a test to identify individuals who have the condition) and specificity (the ability of a test to identify individuals who do not have the condition) for the diagnosis of cardiac amyloidosis based on visual scan interpretation.[1] Bayer plans to present the complete results at an upcoming scientific congress.

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.[5]

The compound was previously granted Breakthrough Therapy Designation for PET imaging in patients with suspected or known cardiac amyloidosis as well as Orphan Drug status for both light-chain amyloidosis (AL) and transthyretin amyloidosis (ATTR) in the U.S. and the EU. [2,3] Bayer plans to discuss the data and submission for regulatory approval with the FDA and other health authorities. I 124 evuzamitide is an investigational compound and has not been approved by any health authority for use in any country for any indication.

Why This Data Matters

“Cardiac amyloidosis is often under- or misdiagnosed,[6] impacting patients’ ability to begin appropriate treatment earlier, when it may help prevent further organ damage,” said REVEAL principal investigator Dr. Sharmila Dorbala, Director of Nuclear Cardiology at Brigham and Women’s Hospital. “These I 124 evuzamitide data demonstrate the potential of a single test to help health care providers identify or exclude cardiac amyloidosis. Clinically, a sensitive, specific and quantitative PET tracer could help distinguish cardiac amyloidosis from other causes of heart failure, differentiate amyloid subtypes when used alongside appropriate laboratory testing, and track changes in cardiac amyloid burden over time.”

I 124 evuzamitide is one of two investigational amyloid radiotracers that Bayer acquired from Attralus, Inc. The compound is also known as AT-01. The acquisition, announced in early 2026, expanded Bayer’s radiology pipeline with complementary tracers targeting systemic amyloid disease and reinforced the company’s strategy to build a leading position in precision imaging for cardiovascular and other serious conditions.

“As a leader in radiology, we are committed to bringing forward options for earlier diagnosis of diseases such as cardiac amyloidosis for the benefit of patients,” said Dr. Konstanze Diefenbach, Head of Radiology Research & Development at Bayer’s Pharmaceuticals Division. “We are very excited about the positive topline results of the REVEAL study and are looking forward to sharing the data with the scientific community.”

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] As the disease is underdiagnosed, current estimates state the condition impacts approximately 400,000 patients worldwide[8], though the number is likely greater. Without appropriate diagnosis and treatment, cardiac amyloidosis can lead to heart failure, frequent hospitalizations and early mortality.

Currently, there is no single, non-invasive test that can reliably detect and diagnose cardiac amyloidosis or quantify and monitor myocardial amyloid burden. Despite increasing disease awareness by health care providers, a prolonged diagnostic journey is common, with patients often consulting several specialists and receiving multiple imaging procedures before an accurate diagnosis.

About The REVEAL Study

The REVEAL (**"R**esearch with I 124 **EV**uzamitide to **E**lucidate Cardiac **A**my**L**oidosis") study[5] is an investigator-initiated Phase III clinical trial of the investigational diagnostic imaging agent I 124 evuzamitide in patients with suspected cardiac amyloidosis with Brigham and Women's Hospital in Boston, MA, as 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 care (SoC) diagnosis. Secondary analyses assessed diagnostic performance in ATTR and AL subtypes. The imaging test used in this study was a positron emission tomography computed tomography (PET/CT) scan.

REVEAL is a multicenter, open-label, single-arm Phase III study conducted at 19 centers in the United States, evaluating 170 adults with suspected cardiac amyloidosis.

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. SoC diagnosis was independently adjudicated by clinical amyloidosis experts, blinded to PET results, using routine diagnostic data collected up to 60 days after imaging.

Diagnostic sensitivity and specificity of I 124 evuzamitide were determined using SoC diagnosis as the reference standard.

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] Bayer is committed to advancing this field through technologies and strategic collaborations.

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.

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