



much looking forward to the results of the ongoing Phase 3 REVEAL study in suspected cardiac amyloidosis patients. We are excited by the potential of <sup>124</sup>I-evuzamitide to become a new standard of care for diagnosing systemic amyloidosis.”

“Detection and quantification of amyloid burden in the heart is an unmet clinical need for patients with diverse types of systemic amyloidosis,” said Jonathan Wall, Ph.D., Distinguished Professor, University of Tennessee Graduate School of Medicine. “AT-05 is a promising new reagent candidate for the facile detection of ATTR and AL cardiac amyloid using gamma imaging and may serve as a useful tool for the early detection of amyloidosis by community cardiologists, having the potential to be an invaluable tool to both detect early cardiac and extracardiac deposits.”

### Poster Presentations –

- **Poster 905-21: DIAGNOSTIC PERFORMANCE OF CARDIAC AND WHOLE-BODY <sup>124</sup>I-EVUZAMITIDE (AT-01) PET/MRI IN SYSTEMIC AMYLOIDOSIS - Ahmad Masri**
  - **Date:** March 29, 2025, 11:18 – 11:25 a.m. CDT
  - **Presenter:** Ahmad Masri, M.D., Oregon Health and Science University
  - **Highlights**
    - This study included 97 patients (57 had cardiac transthyretin amyloidosis, 20 had cardiac light chain amyloidosis, 3 had ApoA1 or ApoA4, 8 had systemic amyloidosis but no cardiac involvement, and 17 had no evidence of systemic amyloidosis).
    - <sup>124</sup>I-evuzamitide PET/MRI demonstrated 100% sensitivity and specificity in detecting cardiac amyloidosis. No false positive or false negative cases were observed.
    - <sup>124</sup>I-evuzamitide PET/MRI demonstrated uptake in multiple organs with amyloid deposition, including the kidneys, liver, spleen and lungs.
  
- **Poster 997-13: RELIABILITY OF <sup>124</sup>I-EVUZAMITIDE IMAGING AND QUANTITATIVE AGREEMENT IN PATIENTS WITH AL AND ATTR SYSTEMIC AMYLOIDOSIS**
  - **Date:** March 31, 2025, 10:00 – 10:07 a.m. CDT
  - **Presenter:** Spencer Guthrie, MPH, Attralus, Inc.
  - **Highlights**
    - Twenty-seven (n=27) patients were included (64% AL, and 36% with ATTR amyloidosis).
    - Subjects received 1 mCi of <sup>124</sup>I-evuzamitide by IV infusion and were scanned with PET/CT on Day 1 and Week 6 to determine reliability and repeatability of quantitative measures across the heart, kidneys and other organs.

- Using automated quantification methods, for cardiac uptake, the SUV mean and %ID mean yielded excellent reliability (ICC=0.95) and bias of 1 with 95% upper and lower LOA of 0.81 and 1.23, indicating that ~20% change in the <sup>124</sup>I-evuzamitide cardiac uptake represents a real change. The mean features provided reliable analytics (ICC ≥0.9) with good agreement for every organ measured.
- **Poster 997-19: AUTOMATED QUANTIFICATION OF AL AND ATTR SYSTEMIC AMYLOID BURDEN USING <sup>124</sup>I-EVUZAMITIDE, A NOVEL PAN-AMYLOID RADIOTRACER**
  - **Date:** March 31, 2025, 10:36 – 10:43 a.m. CDT
  - **Presenter:** Spencer Guthrie, MPH, Attralus, Inc.
  - **Highlights**
    - This study included 95 CA patients (n=37 AL-CA and n=58 ATTR-CA) and 16 healthy volunteers, pooled from four independent clinical studies. The 3-dimensional volumes of the liver, spleen, kidneys, pancreas, and adrenals were segmented in the CT data using an automated trained deep learning algorithm.
    - <sup>124</sup>I-evuzamitide uptake was observed: in the liver in 15 of the n=37 (41%) AL patients and 5 of the n=58 (9%) ATTR patients; in the spleen in 22 (59%) AL and 9 (16%) ATTR patients; in the kidney in 18 (49%) AL and 3 (5%) ATTR patients; in the pancreas in 25 (68%) AL and 18 (31%) ATTR patients.
    - This new radiotracer candidate affords a novel noninvasive approach to characterize cardiac and extracardiac organ amyloid burden, including in organs that have been less characterized such as the pancreas and adrenals.
- **Poster PB123: DETECTION OF CARDIAC AMYLOIDOSIS, AND MORE, USING SPECT/CT IMAGING OF TECHNETIUM-99M-LABELED PEPTIDE p5+14 (AT-05)**
  - **Date:** March 31, 2025, 9:36 – 9:43 a.m. CDT
  - **Presenter:** Jonathan Wall, Ph.D., University of Tennessee Graduate School of Medicine
  - **Highlights**
    - This study includes 18 cardiac amyloidosis patients and 5 healthy controls.
    - Subjects were administered a single IV injection of <sup>99m</sup>Tc-p5+14 (<22 mCi). SPECT/CT and planar images were acquired at 1 h and 3 h post injection.
    - No cardiac uptake of <sup>99m</sup>Tc-p5+14 was seen in healthy subjects.
    - Cardiac uptake was observed in both planar and SPECT/CT images acquired at 1 h and 3 h post injection.
    - Comparison of <sup>99m</sup>Tc-p5+14 and <sup>99m</sup>Tc-PYP in the same ATTR patient suggests that the myocardium uptake-to-blood pool ratio is 3-fold higher for the peptide tracer at 1 h post injection.

- Extracardiac uptake of radiotracer was also observed in the lungs of patients with ATTR and the liver, spleen, salivary glands, lung, and tongue in AL patients.

For additional information, please visit the ACC.2025 [website](#).

To view posters and presentations, visit the Attralus [website](#).

### **About <sup>124</sup>I-*evuzamitide* (AT-01) Pan-Amyloid Diagnostic**

<sup>124</sup>I-*evuzamitide* is the first non-invasive pan-amyloid PET imaging agent specifically designed for systemic amyloidosis. <sup>124</sup>I-*evuzamitide* utilizes the company's pan-amyloid binding peptide labeled with iodine-124 as an amyloid-specific radiotracer to detect all types of systemic amyloidosis by PET/CT imaging. In clinical trials, <sup>124</sup>I-*evuzamitide* has been observed to detect multiple types of amyloid deposits, including ATTR and AL, in major organs such as the heart, kidney, liver, and spleen. Orphan drug designations have been granted to <sup>124</sup>I-*evuzamitide* as a diagnostic for the management of ATTR and AL amyloidosis by both the Food and Drug Administration (FDA) and the European Commission.

### **About Phase 3 REVEAL Study**

Research with <sup>124</sup>I-*EVuzamitide* to Elucidate Cardiac AmyLoidosis (REVEAL) study is an ongoing Phase 3 clinical trial of the investigational diagnostic imaging agent <sup>124</sup>I-*evuzamitide* in patients with suspected cardiac amyloidosis by Brigham and Women's Hospital in Boston, MA. The trial is designed to determine the sensitivity and specificity of <sup>124</sup>I-*evuzamitide* imaging to diagnose cardiac amyloidosis.

### **About AT-05, Pan-Amyloid Diagnostic**

AT-05 uses the same pan amyloid binding peptide as <sup>124</sup>I-*evuzamitide* but is labelled with technetium-99m (Tc-99m, <sup>99m</sup>Tc). AT-05 is designed to be used with single-photon emission computerized tomography (SPECT) to be more accessible to community cardiologists and thereby support broader screening of systemic amyloidosis. AT-05 is currently in a Phase 1 clinical trial.

### **About Systemic Amyloidosis**

Systemic amyloidosis encompasses a diverse group of rare diseases that occur due to accumulation of toxic amyloid deposits in tissues and organs, a consequence of aberrant protein misfolding events. These diseases are progressive, debilitating and often fatal. The majority of systemic amyloidosis patients have cardiac involvement, including the two most common forms, with ~95% of ATTR and 75% of AL patients having cardiac involvement. Other rare types of systemic amyloidosis such as AA, AApoAI, AApoAIV also have cardiac involvement. Cardiac amyloidosis is significantly underdiagnosed due to low awareness, non-specific symptoms, and lack of disease-specific diagnostics. There remains a significant unmet need for better diagnostics that may be able to more accurately diagnose patients earlier in the disease process.

## **About Attralus**

Attralus is a clinical stage biopharmaceutical company focused on creating transformative medicines and diagnostics to improve the lives of patients with systemic amyloidosis. The company's proprietary pan-amyloid removal (PAR) therapeutics are designed to directly bind to and remove toxic amyloid in organs and tissues. By targeting the disease-causing pathology in systemic amyloidosis diseases, PAR therapeutics have the potential to treat and reverse disease in patients with all types and stages of systemic amyloidosis. Attralus was founded by scientific experts in the field of amyloidosis and the company is headquartered in Naples, FL.

## **Forward-Looking Statements**

This press release contains forward-looking statements, including statements related to the efficacy, continued development, and potential of <sup>124</sup>I- evuzamitide and AT-05. Words such as “developing,” “potential,” “shown” and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Attralus' current expectations. Forward-looking statements involve risks and uncertainties. Attralus' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. Attralus expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Attralus' expectations with regard thereto or any change in events, conditions, or circumstances on which any such statements are based.

## **Contact:**

**Krishna Gorti, M.D. FRCS**

Corporate Development

[kgorti@attralus.com](mailto:kgorti@attralus.com)