Attralus Announces Enrollment of First Patient in Phase 3 Trial for the Pan-Amyloid Diagnostic ^{124}I-evuzamitide (AT-01) for Cardiac Amyloidosis

- *Phase 3 – REVEAL study for iodine* ^{124}I-evuzamitide (AT-01) *in patients with suspected cardiac amyloidosis has begun enrollment by Brigham and Women's Hospital, Boston MA, in conjunction with Attralus.*
- *Attralus is developing* ^{124}I-evuzamitide *as the first non-invasive pan-amyloid PET imaging agent specifically designed for the diagnosis and management of patients with all types of systemic amyloidosis.*
- *Cardiac amyloidosis is underdiagnosed and there remains a significant unmet need for a more sensitive and specific imaging test that can diagnose patients earlier in the disease process.*
- ^{124}I-evuzamitide *has received Breakthrough Therapy Designation from the Food and Drug Administration (FDA) for PET imaging in patients with suspected or known cardiac amyloidosis.*
- ^{124}I-evuzamitide *has been granted orphan drug designations as a diagnostic for the management of ATTR and AL amyloidosis by both the US FDA and the European Commission.*
- *Enrollment is expected to be completed by the end of 2025.*

Naples, FL – January 15, 2024 – Attralus, Inc., a clinical stage biopharmaceutical company developing transformative products to improve the lives of patients with systemic amyloidosis, and Brigham and Women's Hospital, Boston, MA, are pleased to announce the enrollment of the first patient in the **R**esearch with ^{124}I-**EV**uzamitide to **E**lucidate Cardiac **A**my**L**oidosis

(REVEAL) study – A Phase 3 clinical trial of the investigational diagnostic imaging agent, ^{124}I-evuzamitide (AT-01), in patients with suspected cardiac amyloidosis. The trial is designed to determine the sensitivity and specificity of ^{124}I-evuzamitide imaging to diagnose cardiac amyloidosis. “This study seeks to add significant value for patient care," says Dr. Sharmila Dorbala, Principal Investigator and Sponsor of the REVEAL study. “^{124}I-evuzamitide PET/CT imaging offers an exciting opportunity to noninvasively detect various types of amyloid deposition in the heart and other organs. As cardiac amyloidosis has high morbidity and mortality, early diagnosis is crucial. With effective FDA-approved treatments now available, a scan that can definitively detect amyloidosis or exclude it would be a major step forward to reduce diagnostic delays and improve patient outcomes.”

^{124}I-evuzamitide has been granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for positron emission tomography (PET) imaging in patients with suspected or known cardiac amyloidosis. FDA granted BTD for ^{124}I-evuzamitide based on clinical data from Attralus-sponsored and investigator-initiated studies evaluating the use of ^{124}I-evuzamitide in patients with systemic amyloidosis, representing experience in more than 200 trial participants. It is one of the first investigational diagnostic imaging agents to receive BTD from the FDA, and the only diagnostic imaging agent that has received BTD for cardiac amyloidosis. Additionally, Orphan Drug Designations have been granted to ^{124}I-evuzamitide as a diagnostic for the management of ATTR and AL amyloidosis by both the US FDA and the European Commission.

“There are no FDA-approved diagnostic imaging agents for cardiac amyloidosis. The diagnosis of cardiac amyloidosis can be a challenging and time-consuming process for patients, with many going years without an accurate diagnosis, and losing critical time in the process”, said Spencer Guthrie, Chief Operating Officer, Attralus. “Early diagnosis in this disease leads to better patient outcomes. We remain committed to bringing ^{124}I-evuzamitide to the market as quickly as possible and look forward to working closely with the FDA and Dr. Dorbala to bring ^{124}I-evuzamitide to patients.”

About REVEAL study

- The study will enroll up to 200 participants with suspected cardiac amyloidosis in the United States. Cardiac amyloidosis may include ATTR, AL or other types of cardiac amyloidosis such as ApoA1 or ApoA4.
- The primary objective is to evaluate the efficacy of ^{124}I-evuzamitide for diagnosing cardiac amyloidosis. The co-primary endpoints are 1) To determine the sensitivity of PET/CT imaging with ^{124}I-evuzamitide for the diagnosis of cardiac amyloidosis based on visual scan interpretation by independent PET readers and 2) To determine the specificity of PET/CT imaging with ^{124}I-evuzamitide for the diagnosis of cardiac amyloidosis based on visual scan interpretation by independent PET readers.
- The secondary objective is to evaluate the safety of a single intravenous administration of ^{124}I-evuzamitide.
- There are a number of exploratory objectives including, but not limited to, evaluating the ability to ^{124}I-evuzamitide to detect extracardiac organ involvement and to differentiate AL from ATTR amyloidosis.

Additional information about the REVEAL trial will be posted to clinicaltrials.gov.

About ^{124}I-evuzamitide (AT-01) Pan-Amyloid Diagnostic

^{124}I-evuzamitide is the first non-invasive pan-amyloid PET imaging agent specifically designed for systemic amyloidosis. ^{124}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, ^{124}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 ^{124}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 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 AT-01. 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.

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