Attralus Receives Breakthrough Therapy Designation for its Pan-Amyloid Diagnostic PET Imaging Candidate 124I-evuzamitide (AT-01) for Cardiac Amyloidosis

- *^{124}I-evuzamitide (AT-01) is one of the first investigational diagnostic imaging agents to receive Breakthrough Therapy Designation (BTD) from the US Food and Drug Administration (FDA), and the only diagnostic imaging agent that has received BTD for cardiac amyloidosis.*
- *^{124}I-evuzamitide received orphan drug designations as a diagnostic for the management of ATTR and AL amyloidosis by both the US FDA and the European Commission.*
- *A Phase 3 study for ^{124}I-evuzamitide in patients with suspected cardiac amyloidosis is anticipated to begin in the first half of 2025.*

BURLINGAME, Calif. – August 5, 2024 – Attralus, Inc., a clinical stage biopharmaceutical company developing transformative products to improve the lives of patients with systemic amyloidosis, today announced that its investigational diagnostic imaging agent drug, ^{124}I-evuzamitide (AT-01), 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 (AT-01) based on clinical data from Attralus-sponsored and investigator-initiated studies evaluating the use of ^{124}I-evuzamitide in patients with cardiac amyloidosis, representing experience in more than 200 trial participants.

BTD is a program used by the FDA to expedite the development and review of a product when: (1) intended to treat or diagnose a serious or a life-threatening condition; and (2) when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints. BTD products are eligible for more intensive guidance from FDA to expedite development, including an organizational commitment by FDA and eligibility for Biologics License Application (BLA) rolling and priority review.

"We are highly encouraged by FDA's decision to grant Breakthrough Therapy Designation to ^{124}I-evuzamitide (AT-01), recognizing its potential as an innovative diagnostic agent for patients with systemic amyloidosis" said Gregory Bell, M.D., Chief Medical Officer, Attralus. "There are no FDA approved diagnostic imaging agents for cardiac amyloidosis. The diagnosis of cardiac amyloidosis is a challenging and time-consuming process for patients, with many going years without an accurate diagnosis, and losing critical time in the process. We remain committed to bringing ^{124}I-evuzamitide to the market as quickly as possible and look forward to working more closely with FDA to bring ^{124}I-evuzamitide to patients."

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

^{124}I-evuzamitide (AT-01) 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 imaging agent to image all types of systemic amyloidosis by PET/CT imaging. In clinical trials, ^{124}I-evuzamitide has been shown 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 Attralus

Attralus is a clinical stage biopharmaceutical company focused on creating transformative products 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 Burlingame, CA.

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.

Contact:
Krishna Gorti, M.D. FRCS
Corporate Development
kgorti@attralus.com