



# Attralus Presents Positive New Data at 2021 American Society of Hematology Annual Meeting

- *AT-03 potently binds human AL and ATTR fibrils and is capable of binding diverse forms of systemic amyloid deposits in mouse models*
- *AT-03 enhances macrophage-mediated phagocytosis of AL amyloid extracts ex vivo and in an in vivo mouse model*
- *SAP-scFc, a precursor construct to AT-03, demonstrated significant amyloid reduction in a mouse model of AA amyloidosis*
- *AT-01 uptake was observed in amyloidosis of the heart and other major organ sites in AL patients*

SOUTH SAN FRANCISCO, Calif. – December 13, 2021 – Attralus, Inc., a clinical stage biopharmaceutical company developing transformative medicines to improve the lives of patients with systemic amyloidosis, today announced encouraging new preclinical data for AT-03, the company's first-in-class pan-amyloid removal (PAR) therapeutic being developed for the treatment of systemic amyloidosis. Attralus also announced new clinical data from the University of Tennessee from its Phase 1/2 trial of <sup>124</sup>I-AT-01, the company's pan-amyloid binding peptide in development as a radiotracer for the diagnosis of systemic amyloidosis. These data were included in poster presentations at the American Society of Hematology (ASH) Annual Meeting taking place December 11-14, 2021, in Atlanta, GA.

"These new data are encouraging and reinforce our confidence in the potential of our pan-amyloid removal technology to treat all types of systemic amyloidosis, as well as our pan-amyloid binding peptide radiotracer as the first amyloid-specific non-invasive diagnostic for systemic amyloidosis," said Gregory Bell, M.D., Chief Medical Officer of Attralus. "We look forward to building on these promising data as we advance our AT-03 and AT-01 development programs."

### **AT-03 Preclinical Study**

The objective of this study was to characterize the preclinical profile of AT-03, including its binding to amyloid extracts and fibrils, biodistribution in mouse models of amyloidosis, mechanism of action (promotion of macrophage-mediated phagocytosis), and efficacy (amyloid clearance).

#### *Results Summary*

- AT-03 is a fusion protein that potently binds human AL and ATTR amyloid extracts and is capable of binding diverse forms of systemic amyloid deposits in mouse models of the disease.
- AT-03 demonstrated high affinity binding to amyloid extracts and mediates phagocytosis which is significantly enhanced with serum complement.
- AT-03 enhances macrophage-mediated phagocytosis of AL amyloid extracts *ex vivo* and in an *in vivo* mouse model.
- SAP-scFc, a precursor construct to AT-03, demonstrated significant splenic amyloid reduction in a mouse model of AA amyloidosis.

"Current treatments for systemic amyloidosis reduce new amyloid formation and slow progression, but do not remove existing toxic amyloid fibril deposits," said Christophe Sirac, Ph.D., Professor, University of Limoges. "These data demonstrate the potential of AT-03 to specifically bind to and remove toxic amyloid fibrils."

### **AT-01 Phase 1/2 Trial**

The Phase 1/2 trial evaluated the ability of AT-01 to detect amyloid deposits by PET/CT imaging in adults with a confirmed diagnosis of AL amyloidosis. The trial enrolled 23 patients with systemic AL amyloidosis and 5 healthy patients. All patients received an IV infusion of <2 mg of AT-01 (<2 mCi) and images were acquired at 5-6 hours post injection using a Biograph PET/CT with a low dose CT. Efficacy endpoints included patient- and organ-based sensitivity of AT-01 uptake in the heart, liver, spleen, and kidney.

### *Results Summary*

- Patients with AL amyloidosis exhibited uptake of AT-01 in the heart, kidneys, spleen, liver, pancreas, lung, bone marrow and other sites, consistent with amyloid distribution in this patient population.
- The patient-based sensitivity (patients with visual uptake in at least one anatomic site) was 96% (22/23).
- <sup>124</sup>I-AT-01 detected cardiac amyloid in 13 of 14 (93%) of patients with presumed cardiac amyloid by clinical criteria. <sup>124</sup>I-AT-01 detected hepatic amyloid in 3 of 3 of patients with clinical hepatic amyloid disease and renal amyloid in 7 of 10 patients with clinical renal amyloid disease.
- In healthy subjects, radioactivity was observed in the parotid, salivary and thyroid glands, saliva, stomach lumen and urine in the ureters and bladder, consistent with the biodistribution of free radioiodide. No uptake was observed in the heart.

"More than 80% of patients with systemic amyloidosis remain undiagnosed. The diagnosis of amyloidosis is a long, complex process, and current diagnostics do not capture the full disease burden at the time of diagnosis," said Jonathan Wall, Ph.D., Co-founder & Interim Chief Scientific Officer, Attralus. "Non-invasive PET/CT imaging with <sup>124</sup>I-AT-01 has the potential to improve detection of amyloid throughout the body, including the heart, kidney, spleen, and liver providing a more comprehensive picture of the disease."

### **Poster Presentation Details**

**Abstract Title:** Pre-Clinical Characterization of a Novel Fusion Protein (AT-03), with Pan-Amyloid Binding and Removal

- **Presenter:** Christophe Sirac, Ph.D., Professor, University of Limoges
- **Session:** 605. Molecular Pharmacology and Drug Resistance: Lymphoid Neoplasms: Poster I
- **Date/Time:** December 11, 2021, 5:30 p.m. – 7:30 p.m. ET
- **Location:** Georgia World Congress Center, Hall B5

**Abstract Title:** Detection of Systemic AL Amyloidosis by <sup>124</sup>I-p5+14 PET/CT imaging – Providing the Complete Picture for Diagnosis

- **Presenter:** Jonathan Wall, Ph.D., Distinguished Professor and Director of the University of Tennessee Graduate School of Medicine's Amyloidosis and Cancer Theranostics Program
- **Session:** 803. Emerging Diagnostic Tools and Techniques: Poster II

- **Date/Time:** December 12, 2021, 6:00 p.m. – 8:00 p.m. ET
- **Location:** Georgia World Congress Center, Hall B5

For additional information, please visit the ASH Annual Meeting [website](#).

### **About AT-01 Pan-Amyloid Diagnostic**

AT-01 utilizes the company's pan-amyloid binding peptide as an amyloid-specific radiotracer to image all types of systemic amyloidosis by PET/CT imaging. In initial clinical trials, AT-01 has been shown to detect multiple types of amyloid deposits, including AL and ATTR, in major organs such as the heart, kidney, liver and spleen. Attralus obtained exclusive rights to commercialize <sup>124</sup>I-AT-01 under a commercial license agreement with the University of Tennessee Research Foundation.

### **About AT-03 PAR Therapeutic**

AT-03 is a fusion of the company's PAR-SAP (Serum Amyloid Protein) technology with a single-chain Fc. The PAR-SAP component mediates binding to all types of amyloid deposits, and the single-chain Fc stimulates the immune system to remove amyloid deposits that are bound by AT-03. Attralus obtained exclusive rights to develop, manufacture and commercialize AT-03 under license agreements with University of Limoges.

### **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. Systemic amyloidosis is significantly underdiagnosed due to low awareness, lack of specific symptoms, and no current disease-specific diagnostics. The two most common forms of systemic amyloidosis are immunoglobulin light-chain-associated (AL) amyloidosis and transthyretin-associated amyloidosis (ATTR). There is a significant unmet need for new therapies and diagnostics in systemic amyloidosis.

### **About Attralus**

Attralus is a clinical stage biopharmaceutical company focused on creating transformative medicines 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 universal 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 South San Francisco.

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements related to Attralus' continued development of AT-01 and AT-03, including the efficacy and therapeutic potential of AT-01 and AT-03. Words such as "demonstrated," "may," "anticipate," "estimate" 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:

Luke Heagle

Real Chemistry

(910) 619-5764

[lheagle@realchemistry.com](mailto:lheagle@realchemistry.com)