

# Attralus Receives European Medicines Agency Committee for Orphan Medicinal Products (COMP) Positive Opinions for AT-02 for the Treatment of Both ATTR and AL Amyloidosis

- AT-02 has been granted COMP positive opinions for orphan medicinal product designations in the EU for both ATTR and AL amyloidosis
- AT-02 is the Company's lead pan-amyloid removal therapeutic candidate in development
- AT-02 is currently being evaluated in a Phase 1 and Phase 2 trial in ATTR and AL amyloidosis patients to support its use as an immunotherapy for treatment of systemic amyloidosis

**BURLINGAME, Calif.** – July 29, 2024 – Attralus, Inc., a clinical stage biopharmaceutical company developing transformative medicines to improve the lives of patients with systemic amyloidosis, announced today that the European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) has adopted positive opinions for orphan medicinal product designations for AT-02 for the treatment of the two most common forms of systemic amyloidosis, transthyretin-associated amyloidosis (ATTR) and immunoglobulin light-chain-associated (AL) amyloidosis.

AT-02, the company's lead pan-amyloid removal therapeutic candidate, is currently being evaluated in a three-part Phase 1 clinical trial and a Phase 2 open label extension trial in ATTR and AL amyloidosis patients to support its use as an immunotherapy in patients with systemic amyloidosis. These designations granted for each of the two indications support the unique properties of AT-02 to potentially treat ATTR and AL amyloidosis, as well as other types of systemic amyloidosis. AT-02 is the first and only therapeutic to receive positive opinions for orphan medicinal product designation for both ATTR and AL amyloidosis from the COMP.

"We are pleased to receive positive opinions on our requests for orphan medicinal product designations from the COMP for AT-02 in ATTR and AL, further supporting our efforts to develop a potentially transformative therapy for systemic amyloidosis," said Gregory Bell, M.D., Chief Medical Officer at Attralus. "Current approved therapies for systemic amyloidosis target precursor protein production, reducing the formation of *new* amyloid, but there is a significant unmet need for new therapies that can remove the existing toxic amyloid fibrils that cause organ damage and mortality."

In the European Union (EU), orphan medicinal product designation is granted to drugs and biologics intended for treating, diagnosing, or preventing rare, life-threatening or chronically debilitating conditions. To qualify, the condition's prevalence in the EU must be no more than five in 10,000 people. If satisfactory diagnosis, prevention, or treatment methods already exist for the disease, orphan designation may only be granted when the drug or biologic has the potential to provide significant benefit over existing therapies. Following the adoption of a positive opinion by the COMP, the legally binding final decision on the granting of orphan designation is issued by the European Commission. Following Commission Decision, orphan designation allows companies certain benefits, including a special category of scientific advice, reduced regulatory fees, research grants and up to ten years of market exclusivity in the EU if a product is approved. When combined with the EU Small or Medium-Sized Enterprise (SME) status granted to Attralus earlier this year, orphan-designated programs receive additional administrative and procedural assistance from the Agency's SME office and even greater fee reductions.

### About AT-02, Pan-Amyloid Removal Therapeutic

AT-02 is the company's lead pan-amyloid removal (PAR) therapeutic candidate for systemic amyloidosis. AT-02 is a humanized IgG1 monoclonal antibody genetically fused with the company's proprietary panamyloid binding peptide, enabling binding to multiple types of amyloid deposits. The Fc region of the antibody stimulates the immune system to remove amyloid deposits that are bound by AT-02. AT-02 uses a similar pan-amyloid peptide to <sup>124</sup>I-evuzamitide, the company's diagnostic agent, which has been shown in multiple clinical trials to selectively bind to amyloid deposits in the heart, liver, kidney, and other organs in multiple types of amyloidosis. As a result, the company expects AT-02 to bind specifically to amyloid in systemic amyloidosis patients. Preclinical data have shown the ability of AT-02 to bind to multiple amyloid types in major organs induce macrophage mediated amyloid phagocytosis and amyloid removal. AT-02 is currently being evaluated in a 3-part Phase 1 trial and a Phase 2 open label extension trial in ATTR and AL amyloidosis 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. Systemic amyloidosis is significantly underdiagnosed due to low awareness, lack of specific symptoms, and no current disease-specific diagnostics. There are approximately 17 different types of systemic amyloidosis, in the United States, the European Union and Japan. The two most common forms of systemic amyloidosis are transthyretin-

associated amyloidosis (ATTR) and immunoglobulin light-chain-associated (AL) amyloidosis. While currently approved treatments slow disease progression by targeting precursor proteins, there is a significant unmet need for new therapies that can remove toxic amyloid deposits across all amyloid types and improve organ function and patient quality of life.

## **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 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.

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