



# **Attralus Therapeutic Zamubafusp Alfa (AT-02) Receives U.S. FDA Orphan Drug Designation for the Treatment of AL Amyloidosis**

**NAPLES, Fla., June 4, 2026** — Attralus, Inc., a clinical stage biopharmaceutical company developing transformative medicines to improve the lives of patients with systemic amyloidosis, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for zamubafusp alfa (AT-02) for the treatment of light chain (AL) amyloidosis, a rare, progressive, debilitating, and often fatal condition.

Zamubafusp alfa, the company's lead pan-amyloid removal candidate, has been evaluated in a completed Phase 1 study and is currently being studied in an ongoing Phase 2 open-label trial, both of which enrolled patients with AL amyloidosis.

"We are pleased to have received orphan drug designation from the U.S. FDA for zamubafusp alfa in AL amyloidosis," said Gregory Bell, M.D., Chief Medical Officer at Attralus. "Current approved therapies for AL target light-chain production, reducing the formation of new amyloid, but there is a significant unmet need for new therapies that can remove existing toxic amyloid fibrils that cause organ damage and mortality."

The FDA's Orphan Drug Designation applies to drugs and biologics intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or conditions affecting fewer than 200,000 people in the United States. Orphan drug designation provides sponsors with benefits designed to support the development of drugs and biologics for small patient populations with unmet medical needs and include tax credits for clinical costs, exemptions from certain FDA fees, and the potential for seven years of marketing exclusivity.

Zamubafusp alfa has also been granted three other orphan designations globally, including FDA orphan drug designation for the treatment of transthyretin-associated amyloidosis (ATTR). In addition, the European Medicines Agency's Committee for Orphan Medicinal Products (COMP) adopted positive opinions for orphan medicinal product designations for zamubafusp alfa for the treatment of transthyretin-associated amyloidosis (ATTR) and immunoglobulin light-chain-associated (AL) amyloidosis.

### **About Zamubafusp alfa (AT-02), Pan-Amyloid Removal Therapeutic**

Zamubafusp alfa is the company's lead pan-amyloid removal (PAR) therapeutic candidate for systemic amyloidosis. Zamubafusp alfa is a humanized IgG1 monoclonal antibody genetically fused with the company's proprietary pan-amyloid 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 zamubafusp alfa. Zamubafusp alfa uses a pan-amyloid peptide to bind specifically to amyloid in systemic amyloidosis patients. Preclinical data has shown the ability of zamubafusp alfa to bind to multiple amyloid types in major organs, induce macrophage mediated phagocytosis, and remove amyloid. Zamubafusp alfa is currently being evaluated in a completed Phase 1 study and an ongoing Phase 2 open label study that includes AL amyloidosis patients.

### **About AL Amyloidosis**

Immunoglobulin light-chain-associated (AL) amyloidosis is a progressive, systemic, multiorgan, orphan disease with significant morbidity. AL amyloidosis most commonly affects the heart and kidneys. Worldwide, an estimated 74,000 patients are living with AL amyloidosis. In the US, prevalence is approximately 25,000 with about 4,500 new patients diagnosed annually. AL amyloidosis is caused by small B-cell clones that produce a toxic light chain forming amyloid deposits in tissues. The combination of daratumumab, cyclophosphamide, bortezomib, and dexamethasone (dara-CyBorD) is the current standard of care, and achieving profound hematologic response is the early goal of treatment. There are no approved therapies that directly target amyloid removal. Amyloid-depleting therapies are needed to improve organ function. There is a significant unmet need for patients in hematologic remission who have persistent organ dysfunction (cardiac or renal).

### **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 Naples, FL.

### **Forward-Looking Statements**

This press release contains forward-looking statements, including statements related to the efficacy, continued development, and potential of zamubafusp alfa (AT-02). 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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