Attralus Receives FDA and EMA Orphan Designation for AT-01 (Iodine (I-124) Evuzamitide), an Investigational Diagnostic for the Management of AL and ATTR Amyloidosis

SAN FRANCISCO – December 19, 2022 – Attralus, Inc., a clinical stage biopharmaceutical company developing transformative medicines to improve the lives of patients with systemic amyloidosis, announced today that the European Commission (EC) and European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has granted orphan designation for AT-01 (iodine (I-124) evuzamitide) as a diagnostic for the management of both immunoglobulin light chain amyloidosis (AL) and transthyretin (ATTR) amyloidosis. In addition, the U.S. Food and Drug Administration (FDA) has granted orphan drug designation for AT-01 as a diagnostic for the management of AL amyloidosis. The FDA previously granted orphan drug designation for AT-01 as a diagnostic for the management of ATTR.

"We are thrilled to receive orphan designation for AT-01 in ATTR and AL in both the US and EU," said Gregory Bell, M.D., Chief Medical Officer at Attralus. "AT-01 has the potential to be the first amyloid-specific imaging agent designed to detect amyloid in key organs, including the heart, kidney and liver, and become an essential tool to streamline diagnosis and provide a comprehensive assessment of disease burden."

AT-01 utilizes the Company's pan-amyloid binding peptide as an amyloid-specific imaging agent to detect and quantify amyloid in multiple types of systemic amyloidosis and key organs involved by PET/CT imaging. The Phase 1/2 trial, conducted by the University of Tennessee Medical Center, evaluated the ability of AT-01 to detect amyloid deposits by PET/CT imaging in patients with diverse forms of systemic amyloidosis, including AL. The trial enrolled a total of 57 subjects including 25 patients with AL amyloidosis.

"Historically, the diagnosis of systemic amyloidosis has been a challenging process for patients, and current diagnostics do not capture the full disease burden at the time of diagnosis. An amyloid-specific imaging agent has the potential to transform the diagnosis of patients," said Isabelle Lousada,

Founder and CEO of the Amyloidosis Research Consortium. "Beyond diagnosis, the potential to provide a means to monitor disease progression and response to therapy in patients with systemic amyloidosis such as ATTR and AL would be transformative in the lives of those patients."

The EMA grants orphan designation to incentivize the development of treatments for rare diseases. To qualify, a medicine must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating, with a prevalence in the EU of no more than 5 in 10,000 patients, and for which no satisfactory method of diagnosis, prevention or treatment already exists, or in cases where the medicine must be of significant benefit to those affected by the condition. Sponsors who obtain orphan designation benefit from protocol assistance, a type of scientific advice specific for designated orphan medicines, and market exclusivity once the medicine is on the market. Fee reductions are also available depending on the status of the sponsor and the type of service required.

FDA Orphan Drug Designation program is granted 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 benefits to sponsors designed to support the development of drugs and biologics for small patient populations with unmet medical needs. These benefits include tax credits for clinical costs, exemptions from certain FDA fees and potential seven years of marketing exclusivity.

About AT-01 Pan-Amyloid Diagnostic

AT-01 (iodine (I-124) evuzamitide) utilizes the company's pan-amyloid binding peptide as an amyloid-specific imaging agent 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 AT-01 under a commercial license agreement with the University of Tennessee Research Foundation. Similar PAR-peptide technology is utilized in AT-02 and AT-04, two of the company's therapeutic candidates.

About Amyloid Light Chain (AL) 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. Amyloid Light Chain (AL) is caused by a bone marrow disorder in which the light chain proteins become misfolded and accumulate as amyloid fibrils, in the heart, kidneys, liver, nerves and other organs. AL is progressive, debilitating, and often fatal. There is a significant unmet need for new therapies and diagnostics in systemic amyloidosis, especially AL.

About Transthyretin Amyloidosis (ATTR)

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. Transthyretin amyloidosis (ATTR) is caused by a protein called transthyretin, or TTR, produced in the liver that misfolds and accumulates, as amyloid fibrils, in the heart, nerves, kidneys and other organs. ATTR is progressive, debilitating and often fatal. There is a significant unmet need for new therapies and diagnostics in systemic amyloidosis, especially ATTR.

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 San Francisco.

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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