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Caelum Biosciences Announces Collaborations with the Amyloidosis Advocacy Community and Support of Amyloidosis Awareness Month

BORDENTOWN, N.J., March 01, 2021 (GLOBE NEWSWIRE) -- Caelum Biosciences, Inc. ("Caelum"), a clinical-stage biotechnology company developing treatments for rare and life-threatening diseases, today announced its collaboration with and support of the amyloidosis advocacy community as Amyloidosis Awareness Month begins. The campaign was created to spread awareness about this rare disease and its symptoms to help prompt earlier diagnosis for patients.

In honor of the month and Rare Disease Day, Caelum has made several commitments to the amyloidosis community that seek to raise awareness, educate, support and empower patients diagnosed with amyloidosis and their families. Caelum has provided an unrestricted donation to the Amyloidosis Support Groups; provided support for the Amyloidosis Foundation patient travel grant program, which provides travel expense assistance to medical appointments for newly diagnosed patients and their caregivers; and made a donation to the Cardiac Amyloidosis in Athletes Foundation.

In addition, throughout the month of March, Caelum will be recognizing the ["Light the Night for Amyloidosis"](#) campaign that drives awareness about amyloidosis by encouraging participants to light up their entryways with red bulbs during the month.

Amyloidosis represents several different types of diseases where an abnormal protein, amyloid, is produced. Amyloid protein fibers can cause significant health problems as they attach and deposit into organs, tissues, nerves and other places in the body. The most common type, AL amyloidosis, is a rare systemic disorder caused by an abnormality of plasma cells in the bone marrow. Symptoms of AL amyloidosis vary by patient, depending on which organs are affected by the amyloid deposits, but can include impairment of many organs, nerves and soft tissues, among them the kidneys, heart, digestive system and nervous system. Chronic kidney disease, arrhythmia, nausea, diarrhea, constipation, peripheral neuropathy and autonomic neuropathy are potential symptoms of the disease.

"Caelum is proud to work with the amyloidosis community to increase awareness of this devastating set of diseases," said Michael Spector, President and Chief Executive Officer of Caelum. "We are grateful for the patients who participate in our clinical trials and their

families, as it is with their ongoing commitment that we hope to improve the current standard of care by advancing a treatment that directly addresses the organ dysfunction caused by amyloid deposition.”

[Caelum's Cardiac Amyloid Reaching for Extended Survival \(CARES\) clinical program](#) is evaluating CAEL-101, a first-in-class monoclonal antibody designed to improve organ function by reducing or eliminating amyloid deposits in the tissues and organs of patients with AL amyloidosis. Enrollment is ongoing in two parallel Phase 3 studies – one in patients with Mayo stage IIIa disease and one in patients with Mayo stage IIIb disease (ClinicalTrials.gov Identifier: [NCT04512235](#) and [NCT04504825](#)), both of which provide a travel stipend for participating patients. The company also has a Phase 2 clinical study that is evaluating the safety and tolerability of CAEL-101 in patients with AL amyloidosis (ClinicalTrials.gov Identifier: [NCT04304144](#)).

About CAEL-101

CAEL-101 is a first-in-class monoclonal antibody (mAb) designed to improve organ function by reducing or eliminating amyloid deposits in the tissues and organs of patients with AL amyloidosis. The antibody is designed to bind to misfolded light chain protein and amyloid and shows binding to both kappa and lambda subtypes. In a Phase 1a/1b study, CAEL-101 demonstrated improved organ function, including cardiac and renal function, in 27 patients with relapsed and refractory AL amyloidosis who had previously not had an organ response to standard of care therapy. CAEL-101 has received Orphan Drug Designation from both the U.S. Food and Drug Administration and European Medicine Agency as a therapy for patients with AL amyloidosis.

About AL Amyloidosis

AL amyloidosis is a rare systemic disorder caused by an abnormality of plasma cells in the bone marrow. Misfolded immunoglobulin light chains produced by plasma cells aggregate and form fibrils that deposit in tissues and organs. This deposition can cause widespread and progressive organ damage and high mortality rates, with death most frequently occurring as a result of cardiac failure. Current standard of care includes plasma cell directed chemotherapy and autologous stem cell transplant, but these therapies do not address the organ dysfunction caused by amyloid deposition, and up to 80 percent of patients are ineligible for transplant. AL amyloidosis is a rare disease but is the most common form of amyloidosis. There are approximately 22,000 patients across the United States, France, Germany, Italy, Spain and the United Kingdom. AL amyloidosis has a one-year mortality rate of 47 percent, 76 percent of which is caused by cardiac amyloidosis.

About Caelum Biosciences

Caelum Biosciences, Inc. (“Caelum”) is a clinical-stage biotechnology company developing treatments for rare and life-threatening diseases. Caelum’s lead asset, CAEL-101, is a novel antibody for the treatment of patients with amyloid light chain (“AL”) amyloidosis. In 2019, Caelum entered a collaboration agreement with Alexion Pharmaceuticals, Inc. (“Alexion”) under which Alexion acquired a minority equity interest in Caelum and an exclusive option to acquire the remaining equity in the company. Caelum was founded by Fortress Biotech, Inc. (NASDAQ: FBIO). For more information, visit www.caelumbio.com.

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