Caelum Biosciences Granted Orphan Medicinal Product Designation from the European Commission for CAEL-101 for the Treatment of AL Amyloidosis

BORDENTOWN, NJ – December 2, 2019 – Caelum Biosciences, Inc. ("Caelum"), a company focused on developing treatments for rare and life-threatening diseases, today announced that the European Commission (EC) has granted orphan medicinal product designation to CAEL-101 (previously known as 11-1F4), a light chain fibril-reactive monoclonal antibody ("mAb"), for the treatment of amyloid light chain ("AL") amyloidosis. CAEL-101 is a first-in-class amyloid fibril targeted therapy designed to improve organ function by reducing or eliminating amyloid deposits in patients with AL amyloidosis. AL amyloidosis is a rare systemic disorder that causes misfolded immunoglobulin light chain protein to build up in and around tissues, resulting in progressive and widespread organ damage, most commonly to the heart and kidneys. CAEL-101 previously received orphan drug designation ("ODD") from the U.S. Food and Drug Administration ("FDA") as a therapy for patients with AL amyloidosis, and as a radio-imaging agent in AL amyloidosis.

Orphan Medicinal Product Designation in the European Union ("EU") is based upon a positive opinion from the European Medicines Agency's ("EMA") Committee for Orphan Medicinal Products and provides regulatory and financial incentives for companies to develop and market therapies to treat serious disorders affecting no more than five in 10,000 persons in the EU. Companies that obtain orphan medicinal product designation benefit from a number of incentives, including ten-year marketing exclusivity in the EU upon approval, as well as eligibility for protocol assistance, reduced fees and access to the EU's centralized marketing authorization procedure.

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, gradually affecting their function. This can cause progressive and widespread 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 CAEL-101 (mAb 11-1F4)

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 insoluble light chain amyloid protein, including 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 the

U.S. Food and Drug Administration as a therapy for patients with AL amyloidosis, and as a radio-imaging agent in AL 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 (mAb 11-1F4), is a novel antibody for the treatment of patients with amyloid light chain ("AL") amyloidosis. For more information, visit www.caelumbio.com.

Forward-Looking Statements
This press release may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements include, but are not limited to, any statements relating to our growth strategy and product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated include: risks relating to our growth strategy; our ability to obtain, perform under and maintain financing and strategic agreements and relationships; risks relating to the results of research and development activities; uncertainties relating to preclinical and clinical testing; risks relating to the timing of starting and completing clinical trials; our dependence on third-party suppliers; our ability to attract, integrate and retain key personnel; the early stage of products under development; our need for substantial additional funds; government regulation; patent and intellectual property matters; competition; as well as other risks described in our SEC filings. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

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