



Caladrius Biosciences Opens Study of CLBS119 to Repair COVID-19-Induced Lung Damage

October 8, 2020

Patient screening begins immediately at NYU Langone Health

The study will explore the ability of CLBS119 to restore normal oxygen levels in patients who have recovered from the virus but require continued supplemental oxygen due to COVID-19-induced vascular damage

BASKING RIDGE, N.J. (October 8, 2020) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) (“Caladrius” or the “Company”), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, disease, announced that it has opened its proof-of-concept study of CLBS119 as a treatment for COVID-19-induced lung damage and begun screening prospective patients for inclusion at NYU Langone Health. This planned 12-patient open-label clinical trial is designed to evaluate the safety and efficacy of a single administration of CLBS119 (peripheral blood-derived autologous CD34+ cells) for the treatment and repair of COVID-19-induced lung damage in adults. The study will target patients who are experiencing hypoxia due to prior infection with SARS-CoV-2 and who require supplemental oxygen.

“Evidence suggests that severe lung damage due to COVID-19 may lead to long-term disability as a result of vascular damage. Although many therapies are targeting the SARS-CoV-2 virus or the reduction of severe inflammation caused by the virus during the acute phase of the illness, no therapy has been shown to repair COVID-19-induced long-term lung damage,” said Douglas W. Losordo, M.D., FACC, FAHA, Chief Medical Officer at Caladrius. “In previous clinical trials and preclinical models, CD34+ cells consistently have shown evidence of vascular repair in multiple organs including models of severe lung damage. This clinical study of CLBS119 will address the significant unmet medical need for COVID-19 survivors who still require supplemental oxygen. Our hypothesis is that CD34+ cells can regenerate the blood vessels damaged by COVID-19, thereby restoring lung function and capacity and reducing or eliminating the need for supplemental oxygen.

For more information on this study, please visit clinicaltrials.gov (identifier: NCT04522817). If you are a patient or a physician and have questions about eligibility for this study, please contact us at CLBS119@caladrius.com.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, disease. We are developing first- in-class cell therapy products based on the notion that our body contains finely tuned mechanisms for self-repair. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

The Company’s current product candidates include CLBS119, a CD34+ cell therapy product candidate for the repair of lung damage in patients with COVID-19 who are experiencing respiratory failure, for which the Company recently initiated a clinical trial as well as three developmental treatments for ischemic diseases based on its CD34+ cell therapy platform: HONEDRA® (formerly CLBS12), recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia (“CLI”) based on the results of an ongoing clinical trial; CLBS16, the subject of a recently completed positive Phase 2a clinical trial in the U.S. and slated to begin a comprehensive Phase 2b trial in the U.S. during 4Q20 for the treatment of coronary microvascular dysfunction (“CMD”); and CLBS14, a Regenerative Medicine Advanced Therapy (“RMAT”) designated therapy for which the Company has finalized with the U.S. Food and Drug Administration (the “FDA”) a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina (“NORDA”). For more information on the company, please visit www.caladrius.com.

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