



# caladrius

BIOSCIENCES

*Developing Regenerative Therapies  
that Reverse Chronic Disease*

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# Indication: COVID-19 induced lung damage

- Human coronavirus disease-19 (COVID-19) is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).
- Evidence suggests that the endothelium of the pulmonary vasculature is a target of the virus and that vascular injury contributes to the severe lung damage that follows.<sup>1,2</sup>
- Moreover, autopsy data reveals that the early natural response to this injury includes angiogenesis, the body's attempt to repair the damaged lung vasculature.<sup>2</sup>
- Prior data from the SARS epidemic also suggests that CD34+ cells in the lung could be a target of SARS-CoV-2 infection and that destruction of lung CD34+ progenitors could account for the inability of patients with severe lung damage to recover fully.<sup>3</sup>

## Our solution: CLBS119

- CLBS119 is a proprietary formulation of CD34+ cells that has been shown in pre-clinical and clinical studies to induce the formation of new capillaries in tissues where the microcirculation has been compromised.
- The FDA has authorized Caladrius' IND for the study of CLBS119 for the repair of COVID-19 induced lung damage.
- The initial proof-of-concept study will include:
  - Efficacy endpoints of clinical measures such as supplemental oxygen requirements, pulmonary function, resolution of lung infiltrates, time to recovery and biomarkers of inflammation.
  - Safety endpoints of examination of adverse events, laboratory investigations, physical examinations, vital signs and occurrence of death.
- Study initiation target: 3Q 2020.

<sup>1</sup> Varga Z, et al., *Lancet*. 2020;395(10234):1417-1418

<sup>2</sup> Ackermann et al, *NEJM* 2020. 57(6): p. 651-661

<sup>3</sup> Chen Y, et al. *J Exp Med*. 2007;204(11):2529-2536.