Corvidia Therapeutics Initiates Phase 2b Dose-Finding Study for Ziltivekimab

- *Investigational therapy targeting residual inflammatory cardiovascular risk in patients living with chronic kidney disease*
- *Phase 2b study called RESCUE based in US, enrolling more than 200 patients*
- *Approximately two million chronic kidney disease patients in the US also have inflammation, leading to elevated cardiovascular risk*

Waltham, MA, June 13, 2019 — Corvidia Therapeutics Inc., a clinical stage biotechnology company, announced today the initiation of patient screening for a Phase 2b dose-finding study of ziltivekimab. Previously known as COR-001, ziltivekimab is a proprietary anti-interleukin-6 ligand monoclonal antibody (anti-IL6 mAb), targeting residual inflammatory cardiovascular risk in patients living with advanced chronic kidney disease (CKD).

In two previous early phase clinical trials in chronic kidney disease patients with evidence of inflammation, ziltivekimab has demonstrated that it reduced C-reactive protein (CRP), a marker of inflammation. The trial called RESCUE (*Reduction in Inflammation in Patients with Advanced Chronic Renal Utilizing Antibody-Medicated IL-6 Inhibition*) is a randomized, double-blind, placebo-controlled dose-finding study of ziltivekimab. The trial explores three doses of ziltivekimab administered monthly.

"Dose-finding is a critical step that will teach us a great deal about how targeted anti-cytokine therapy can impact the IL-6-to-CRP axis so crucial for atherothrombosis," said Paul Ridker, MD, director of the Center for Cardiovascular Disease Prevention at Brigham and Women's Hospital, an expert in inflammation biology and a member of the Scientific Advisory Board of Corvidia Therapeutics. "This dose-finding data will also inform the design of a hard outcomes trial to test the hypothesis that IL-6-lowering will reduce cardiovascular event rates in patients with chronic kidney disease, which is based upon an observation in an 1800 patient CKD subset of the CANTOS trial." [i] Ridker is providing academic oversight for the RESCUE study.

A large portion of patients with chronic kidney disease continue to be at risk for adverse cardiovascular outcomes despite being on drugs that control LDL cholesterol and high blood pressure.[ii] At least two million of these patients demonstrate high levels of the inflammatory marker CRP, an independent indicator of cardiovascular risk [iii]. These patients also have high cardiovascular morbidity and mortality[iv]; ziltivekimab is being evaluated for its ability to address this inflammatory condition.

"We are pleased to initiate the RESCUE trial, marking the next phase of development of ziltivekimab," said Michael Davidson, MD, chief scientific officer of Corvidia Therapeutics. "Treating inflammation has the potential to be the next major advance in cardiovascular risk reduction and we are excited to lead the way. We also look forward to working with the FDA on the development of ziltivekimab for a patient population with a high unmet need."

The RESCUE study will enroll 240 patients living with CKD stages three to five with evidence of inflammation, with the primary endpoint being inflammation (CRP) reduction at six months. Study enrollment will occur in 50 centers across the United States. Corvidia Therapeutics is expecting to report data results from the RESCUE study in the second half of 2020. For more information on the trial, visit www.clinicaltrials.gov

About Corvidia Therapeutics Inc.

Corvidia Therapeutics Inc. is a clinical stage biotechnology company based in Waltham, Massachusetts developing ground-breaking therapies for cardio-renal disease. Corvidia's pipeline programs are presently focused on the next generation of therapies. Among our portfolio of novel therapeutic candidates, we have an experimental therapy in Phase 2b development addressing inflammation in CKD. Corvidia's other preclinical programs are in various stages of development. For more information, please visit www.corvidiatx.com

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