UNIVERSITY OF CALGARY

Summary of Study for clinician use

TRIAL: CORIPREV-LR

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OVERVIEW OF DESIGN:

This study is a Phase III, open-label, 1:1 cluster-randomized (ring design) versus no intervention, multicenter study evaluating the efficacy of a 14-day course of oral lopinavir/ritonavir (LPV/r, brand name Kaletra®) as post-exposure prophylaxis (PEP) against microbiologically confirmed SARS-CoV-2 infection **among individuals with a significant unprotected exposure to a confirmed case.** Enrollment must occur within 48 hours of study staff being notified of the potential ring.

ELIGIBILITY

Participant eligibility depends on key criteria:

- Not known to be positive for SARS-CoV-2
- Non-vaccinated individuals 6 months and older
- Had high-risk close contact with a confirmed COVID-19 case (index) in the past 1-7 days:
  - For symptomatic index cases, contact period includes one day prior to symptom onset
  - For asymptomatic index cases, contact must have occurred within 14-days of the case's first positive SARS-CoV-2 test.
- Not breastfeeding
- Not using Kaletra® for the treatment of HIV
- Not allergic to Kaletra® or its components

Study Drug: Lopinavir/Ritonavir (LPV/r)

- 200/50mg Tablets — 2 Tablets twice daily = 4 tablets total for 14 days
- 80/20 mg/mL oral solution — Dosing based on weight. Solution taken twice daily for 14 days

Study Duration: 90 Days

Study Visits: 5 to 7 (virtual/ 1 in person) visits over 90 days

- Visits include Screening/Day 1, Day 7, Day 14, Day 35, Day 90 and possible symptoms-based visit
- Participant will do self-testing for SARS-CoV-2 up to 4X during first 2 weeks
- Samples collected for: SARS-CoV-2 serology & antibodies, microbiome analysis, Lopinavir drug levels
- Daily symptom and adherence diary for first 2 weeks
- Electronic surveys for demographics, activities of daily living and psychological impact of COVID-19

If you have eligible persons in your practice – persons who have had a high-risk exposure to a COVID-19 case, please provide them the study email and phone number to discuss the study further.