UPCOMING STUDIES

BALOXAVIR Trial

PI: Dr. Nelson Lee (Infectious Diseases)  CO-PI: Dr. Wendy Sligl
ClinicalTrials.gov: NCT02954354
Study Sponsor: F. Hoffman-La Roche Ltd

The purpose of this Phase III, randomized, double-blind, placebo-controlled, multicenter study is to assess the efficacy, safety, and pharmacokinetics of baloxavir marboxil in combination with a standard-of-care (SOC) neuraminidase inhibitor (NAI), compared with a matching placebo in combination with a standard-of-care neuraminidase inhibitor in approximately 366 hospitalized adults with influenza world-wide.

We plan to enroll up to 5 patients in General Systems ICU.

Study Intervention:

- **Experimental Arm:** Baloxavir marboxil administered along with SOC NAI.
  - Baloxavir marboxil will be administered as a weight-based dose (40mg for patients 40-79kg & 80mg for patients≥ 80kg) on Days 1 and 4, and also Day 7 if clinical improvement has not occurred at Day 5 as determined by the study PI.

- **Control Arm:** Matching placebo along with SOC NAI

Inclusion Criteria:

- Diagnosis of influenza A and/or B by a positive lab test within 24 hours
- Onset of new general symptoms is within 96 hours

Exclusion Criteria:

- Patients who have received more than 48 hours of antiviral treatment for influenza prior to screening
- Patients expected to die or be discharged within 48 hours
- Patients weighing < 40kg
- Patients with severe renal impairment (eGFR >30mL/min/1.73m², receiving CRRT, IHD or PD)
- Patients with abnormal liver function test within 24 hours of screening

Anticipated To Start Recruitment in January 2020

COMPLETED STUDIES

A special congratulations to the Research Team and Dr. Sean Bagshaw for completing enrollment in STARRT-AKI!

General Systems ICU enrolled 41 patients and CVICU in the Mazankowski Heart Institute enrolled 4 patients from January 2016 to August 2019.

In total, 102 patients were enrolled in the Edmonton Zone and Red Deer.

3019 patients were enrolled from 166 sites world-wide.

We continue to look forward to seeing the many publications from the trial.

WINTER CLOSURE

In accordance with the University of Alberta Winter Closure the Research Office will be closed from:

December 24th – January 1st

Enrollment Updates:

- STARRT-AKI: GS-ICU: 41
- CV-ICU: 4
- BALANCE: 68
- LOVIT: 3
- FORECAST: 1

For more information about our research contact Dr. Sean Bagshaw, Director of Research at 780-248-1256, Nadia Baig, Research Manager at 780-492-3817, or visit our website at www.ualberta.ca/critical-care/research