

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/ 2018/029

Scientific title of trial: Combined Phase 3, Double-blind, Randomized, Placebo-Controlled Studies Evaluating the Efficacy and Safety of Filgotinib in the Induction and Maintenance of Remission in Subjects with Moderately to Severely Active Crohn's Disease

Date of commencement (enrolment of first participant):

Progression: 6 months 1 year 2 years 3 years
At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Protocol amendment # 7, dated 22 Aug 2019 was updated to Protocol amendment # 8, dated 03 September 2020

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: pending/ **recruiting**/ recruitment complete/ recruitment suspended / recruitment terminated

Number assessed for eligibility: 28

Number recruited and allocated/randomized: 11

Number allocated/randomized to each intervention/arm (please edit as relevant):

Cohort A: 10

Cohort B: 01

Subjects who meet protocol eligibility criteria will be assigned to the respective Cohort and subsequently randomized in a blinded fashion in a 1:1:1 ratio to 1 of 3 treatments as follows:

Cohort A (Biologic-Naïve)*

Treatment 1 (n = 220): filgotinib 200 mg and placebo-to-match (PTM) filgotinib 100 mg, once daily

Treatment 2 (n = 220): filgotinib 100 mg and PTM filgotinib 200 mg, once daily

Treatment 3 (n = 220): PTM filgotinib 200 mg and PTM filgotinib 100 mg, once daily

Cohort B (Biologic- experienced)

Treatment 1 (n = 220): filgotinib 200 mg and placebo-to-match (PTM) filgotinib 100 mg, once daily

Treatment 2 (n = 220): filgotinib 100 mg and PTM filgotinib 200 mg, once daily

Treatment 3 (n = 220): PTM filgotinib 200 mg and PTM filgotinib 100 mg, once daily

Losses/exclusions after allocation/randomization (please edit as relevant): 02 (Early End of Treatment)

3. Trial output

Date of trial completion ("last patient, last visit"): N/A

Final sample size: N/A

Summary of Interim/Final data (if available):

N/A

Abstract presentations of results at scientific meetings

Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
N/A	N/A
N/A	N/A

Publications

Note: please include a URL link or scanned copy of the publication

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
N/A	N/A
N/A	N/A



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Prof Arjuna De Silva
Co-ordinating Principal Investigator

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