

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2024/033**

Scientific title of trial: **A Parallel-Group Treatment, Double-Blind, 2-Arm Study to Investigate the Comparative Efficacy, Safety, and Immunogenicity Between Intravenous AVT16 and Entyvio® in Male and Female Subjects Aged 18 to 80 Years Inclusive with Moderate to Severe Active Ulcerative Colitis**

Date of commencement (enrolment of first participant): **10 – Jan -2025**

Progression: 6 months ☐ 1 year ☒ 2 years ☐ 3 years ☐

At completion ☐

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: pending/ **recruiting**/ recruitment complete: follow up continuing/
recruitment complete: follow up complete/ recruitment suspended / recruitment
terminated

Number assessed for eligibility: 20

Number recruited and allocated/randomized: 3

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

Arm 1:

Arm 2:

Losses/exclusions after allocation/randomization (please edit as relevant): **Pending**

Arm 1:

Arm 2:

3. Trial output

Date of trial completion ("last patient, last visit"): **Pending**

Final sample size: **Pending**

Summary of Interim/Final data (if available):

Not available.

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).
Not applicable	

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)
Not applicable	

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