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: **No**

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: 18

Number recruited and allocated/randomized: 03

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	

for;

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Date: 28 Apr 2025