Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2020/024

Scientific title of trial: An open-label, multi-center, extension study to evaluate the longterm safety, tolerability and preliminary efficacy of evenamide as add-on treatment in patients with treatment-resistant schizophrenia (TRS) not responding adequately to their current antipsychotic medication.

Date of commencement (enrolment of first participant):

Progression: 6 months

1 year

2 years

3 years x

At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes (Protocol Version: 5.3, 15 July 2022)

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Completed

Number assessed for eligibility:15

Number recruited and allocated/randomized:15

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

Arm 1:07

Arm 2:08

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

Arm 1:01

Arm 2:02

3. Trial output

Date of trial completion ("last patient, last visit"): 12 Nov 2023

Final sample size:15

Summary o	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. Shehan Williams Principal Investigator

Date: 16 Nov 2023