Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2020/023							
Scientific title of trial:							
A pilot, open-label, rater-blinded, randomized, parallel-group, multi-center study to evaluate the safety, tolerability, and preliminary efficacy of three add-on fixed doses of evenamide in patients with treatment-resistant schizophrenia (TRS) not responding adequately to their stable, therapeutically active dose of a single antipsychotic medication.							
Date of commencement (enrolment of first participant): 12 Feb 2021							
Progression:	6 months x	1 year □	2 years □	3 years □			
	At completion \square						
1. Baseline	data						
Any changes to the trial design/ methodology/ protocol after commencement: Yes. (Version 6.0, Amendment 5, 04 Feb 2021). This amendment will be notified to SLCTR upon receiving ERC & NMRA approvals.							
Any changes to trial outcomes after commencement: No							
2. Current status							
Recruitment status: recruiting							
Number assessed for eligibility:4							
Number recruited and allocated/randomized:3							
Number alloc	ated/randomized to e	ach intervention/arr	n (please edit as rele	evant):			
Arm 1	(7.5 mg bd):1						
Arm 2	(15 mg bd):2						
Losses/exclus	sions after allocation/	randomization (plea	se edit as relevant):				
Arm 1	Arm 1 (7.5 mg bd):1						
Arm 2 (15 mg bd):0							

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

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

Prof. Shehan Williams Principal Investigator

Date: 24 May 2021