Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2018/033

Scientific title of trial: CAPSTONE: Phase III Confirmatory Assessment Protocol: rVA576 Safety and Efficacy in Three-Part, Two-Arm, Randomized Open Label Evaluation in patients with Paroxysmal Nocturnal Haemoglobinuria (PNH)

Date of commencement (enrolment of first participant): 12/02/2019

Progression:6 months □1 year2 years ⊠3 years □

At completion \square

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**/ recruitment suspended / recruitment terminated

Number assessed for eligibility: 7

Number recruited and allocated/randomized: 5

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

Arm 1:1

Arm 2:4

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

Arm 1:N/A Arm 2:N/A

3. Trial output

Date of trial completion ("last patient, last visit"): 28 Aug 2020

Final sample size: 06 subjects from Sri Lankan and globally 10 subjects

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	

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	

Moillians

Dr. Senani Williams Co-ordinating Principal Investigator

Date:21st of October 2020