Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2015/004

Scientific title of trial: A Phase 3 Randomized Double-blind Study Comparing TR701 FA and Linezolid in Ventilated Gram-positive Nosocomial Pneumonia

Date of commencement (enrolment of first participant): In Sri Lanka sites initiated in May 2015. Globally first patient was randomized on 19 Jun 2014.

Progression:	6 months 🛛	1 year	2 years	3 years

At completion

1. Baseline data

Date of commencement:

- Sites Initiated in May 2015. No screening in Sri Lanka yet.
- Any changes to the trial design/ methodology/ protocol after commencement:
 - Yes. (Information updated in protocol amendment sheet separately)

Any changes to trial outcomes after commencement:

No

2. Current status

Recruitment status:

- recruiting
- Number assessed for eligibility: beside 122 randomized patients worldwide, there were 21 Screen failures so far = so 143 patients assessed for eligibility; Sri Lanka
 None

Number recruited and randomized:

• Globally 122: Sri Lanka- None

Number allocated to each intervention/arm:

• TBC at the end of trial, since it is double-blinded

Losses/exclusions after randomization:

• 26 (USA 2, Russia 6, Ukraine 8, Georgia 9, Guatemala 1)

3. Trial output

Summary of Interim/Final data (if available):

• Not available at this time

Presentations of results at scientific meetings: NA at this time

Publications:

• Not available at this time

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Name and signature of Responsible Registrant Coordinating Principal Investigator Dr Asantha de Silva MBBS, MD (Anesthesiology), FRCA (Lond) Date: 25 9-2015