

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2014/017

Scientific title of trial: A Phase III, Open-label, Randomized, Multi-center Study of the Effects of Leukocyte Interleukin, Injection [Multikine] Plus Standard of Care (Surgery + Radiotherapy or Surgery + Concurrent Chemoradiotherapy) in Subjects with Advanced Primary Squamous Cell Carcinoma of the Oral Cavity / Soft Palate Versus Standard of Care Only

Date of commencement (enrolment of first participant):17/Dec/2014

Progression: 6 months 1 year 2 years 3 years
At completion

1. Baseline data

Date of commencement: 17/Dec/2014

Any changes to the trial design/ methodology/ protocol after commencement: Yes.
Protocol amendment 04. Awaiting ERC approval

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: Recruitment is currently on hold. Please find attached the letter from sponsor regarding this

Number assessed for eligibility: 96 subjects from Sri Lanka

Number recruited and randomized: 46 Subjects from Sri Lanka

Number allocated to each intervention/arm: **Investigational arm: 25 Control arm: 18**

Losses/exclusions after randomization: 05 subjects have discontinued from Sri Lanka

3. Trial output

Summary of Interim/Final data (if available): NA

Presentations of results at scientific meetings: NA

Publications: N/A



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Coordinating Principal Investigator

Date: 14 OCT 2016