Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2012/003

Scientific title of trial: An open label, randomised phase III trial of BIBW 2992 and vinorelbine versus trastuzumab and vinorelbine in patients with metastatic HER2-overexpressing breast cancer failing one prior trastuzumab treatment

Date of commencement (enrolment of first participant):

Progression: 6 months ☐ 1 year ☐ 2 years ☐ 3 years ☐ 4 years **X**

At completion ☐

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1. Baseline data

Date of commencement: 11 March 2012

Any changes to the trial design/ methodology/ protocol after commencement: Stared with protocol version 4. There were 4 revisions during the study and the current protocol version is 8.0.

Any changes to trial outcomes after commencement: Investigational drug discontinued on 26 Apr 2013 as per the DMC recommendation.

2. Current status

Recruitment status: recruitment terminated

Number assessed for eligibility: 13

Number recruited and randomized: 5

Number allocated to each intervention/arm: Investigational Arm: 4 Control Arm: 1

Losses/exclusions after randomization: None

3. Trial output

Summary of Interim/Final data (if available): Interim Clinical Trial Report dated 04-Jun-2014.

Presentations of results at scientific meetings: San Antonia Breast Cancer Symposium, Dec 9-13, 2014.

Publications: NA

for .....

Dr. Nadarajah Jeyakumaran

Principal Investigator

Date: 17/10/2016