Clinical Trials Summary for out of hours Important Reference

Lancashire Teaching Hospitals NHS Foundation Trust

Acronym study title	**WO43919 - INAVO121 in HR+ Metastatic Breast Cancer** A PHASE III, MULTICENTER, RANDOMIZED, OPEN-LABEL STUDY EVALUATING THE EFFICACY AND SAFETY OF INAVOLISIB PLUS FULVESTRANT VERSUS ALPELISIB PLUS FULVESTRANT IN PATIENTS WITH HORMONE RECEPTORPOSITIVE, HER2-NEGATIVE, PIK3CA MUTATED, LOCALLY ADVANCED OR METASTATIC BREAST CANCER WHO PROGRESSED DURING OR AFTER CDK4/6 INHIBITOR AND ENDOCRINE COMBINATION THERAPY
Study Details	Study WO43919 is a Phase III, multicenter, randomized, open-label, global study designed to evaluate the efficacy and safety of inavolisib plus fulvestrant compared with alpelisib plus fulvestrant in patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2) -negative, PIK3CAmutated, locally advanced (LA) or metastatic breast cancer (mBC), who progressed during or after CDK4/6i-based therapy. Open label study **Inavolisib** 3mg or 9mg immediate-release tablet Oral 9mg OD, dose may be reduced up to two times if required due to intolerable side effects, full details are given in the protocol Unlicensed
Principal Investigator PI Sub PI's	**Dr Martin Hogg (PI)** **Dr Elaine Young (Sub-I)**
Research Nurse Team	Haiyan.Huang@lthtr.nhs.uk
Drug therapy	Study WO43919 is a Phase III, multicenter, randomized, open-label, global study designed to evaluate the efficacy and safety of inavolisib plus fulvestrant compared with alpelisib plus fulvestrant in patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2) -negative, PIK3CAmutated, locally advanced (LA) or metastatic breast cancer (mBC), who progressed during or after CDK4/6i-based therapy. Open label study **Inavolisib** 3mg or 9mg immediate-release tablet Oral 9mg OD, dose may be reduced up to two times if required due to intolerable side effects, full details are given in the protocol Unlicensed Treatment:

	– Experimental: inavolisib plus fulvestrant: inavolisib 9 mg tablet taken PO QD on Days 1–28 of each 28-day cycle, plus fulvestrant 500 mg administered by IM injection on Days 1 and 15 of Cycle 1 and then on Day 1 of each subsequent 28-day cycle until radiographic progression per BICR-assessed RECIST v1.1, unacceptable toxicity, withdrawal of consent, death, or predefined study end. – Control: alpelisib plus fulvestrant: alpelisib 300 mg (2 × 150 mg tablets) taken PO QD on Days 1–28 of each 28-day cycle, plus fulvestrant 500 mg administered by IM injection on Days 1 and 15 of Cycle 1 and then on Day 1 of each subsequent 28-day cycle until radiographic progression per BICR–assessed RECIST v1.1, unacceptable toxicity, withdrawal of consent, death, or predefined study end. For AEs and SAEs please refer to the investigator brochure  RO7113755_Investigator's Brochure_22-A
In the event that a patient calls this hotline for advice	Refer to SoC protocol for additional information regarding SoC treatment. Advise patient to seek medical assistance via nearest available healthcare provider depending upon severity of symptoms. Advise patient to keep all relevant trial paperwork with them for review by treating clinician. Patients requiring admission may be reviewed by the on-call Oncology SpR/Consultant. Day time contact number: Principal Investigator: Martin.hogg@lthtr.nhs.uk **Tel: 01772 522699** Research Nurse: Haiyan.Huang@lthtr.nhs.uk Tel:01772 524656 If out of hours escalation is required, please alert PI/Co-I on the above details. Treatment interruption/modification may be required.