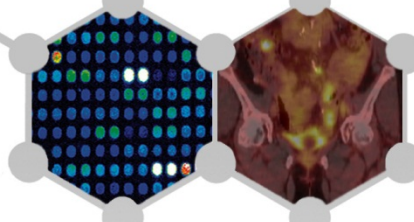
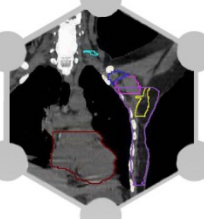


NRG ONCOLOGY

Advancing Research. Improving Lives.™



Phase II Trial of Radium-223 Dichloride in Combination with Paclitaxel in Patients with Bone Metastatic Breast Cancer [ETCTN #10302]

Jyoti Malhotra, MD, MPH
Salma Jabbour, MD
Rutgers Cancer Institute of New Jersey

2021 Winter NRG Radiation Oncology Virtual Meeting
January 29th, 2021

10302: Hypothesis

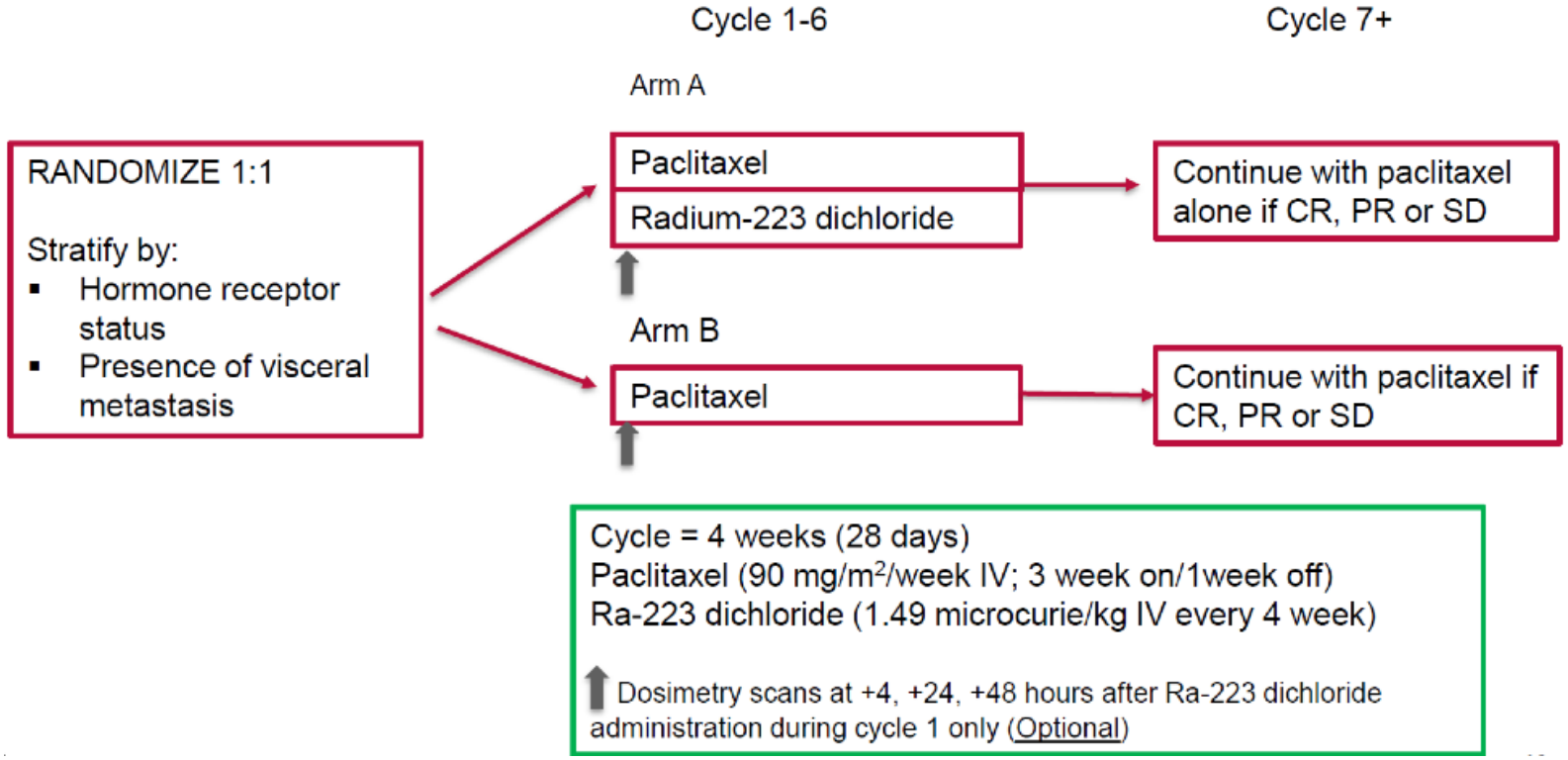
- Radium-223 dichloride is a calcium mimetic that localizes to bone metastases and induces double-strand DNA breaks.
- We hypothesize that the combination of Ra-223 and paclitaxel will have synergistic anti-tumor activity in bone metastases

Primary Objective

- Progression-free survival (PFS)

10302: Study Schema

Randomized, open-label, phase II trial in patients
70 patients will be randomized (35 patients in each arm).
For response assessment, imaging every 8 weeks (CT scan and bone scan)



NRG ONCOLOGY™

10302: Study Eligibility

- Age≥18 years, ECOG 0-2
- Metastatic breast cancer with bone only or bone dominant disease (HER-2 positive tumors excluded)
- Visceral metastases allowed if
  - three or less (≤ 2 cm in size) and asymptomatic and
  - all lymphadenopathy ≤ 3 cm
- Adequate counts, liver and renal function
- ≤ 3 lines of chemo in metastatic setting
- Progressed on prior hormonal and CDK therapy (unless intolerable toxicity or contraindication)

NRG ONCOLOGY™

10302: Accrual

Sites open to enrollment	Sites pending
▪ Dartmouth University ▪ Ohio State University ▪ Rutgers Cancer Institute ▪ University of California- Davis ▪ University of Kansas ▪ University of Virginia ▪ Wayne State/Karmanos Cancer Institute	▪ City of Hope ▪ University of Miami ▪ University of Pittsburgh ▪ Wake Forest University

Lead site activated June 2020, other sites Nov 2020 onwards
Accrual: 1
Goal: 3/month

NRG ONCOLOGY™

Logistical and management Issues

Site Specific:

- Sites have to be certified as Targeted Radiopharmaceutical Facility (TRF) with CTEP and need local radiation safety approvals as well
- Ability of local site to administer Radium-223 and chemotherapy on same day

Patient specific

- Accrual barriers due to COVID-19 pandemic: weekly visits, myelosuppressive therapy
- Dosimetry scans require SPECT machine at local site (optional study done at 4, 24, 48 hours)
- ePRO require patient to use their own device (download app) or enter data on tablet provided at local site

Acknowledgements

NCI: Charles Kunos, MD, PhD
Radium-223 Project Team Leaders: Jacek Capala, MD; Jeff Michalski, MD

#10302 study team
Radiation Oncology: Salma Jabbour, MD
Breast medical oncology: Nancy Chan, MD
Nuclear Medicine: Murray Becker, MD
Statistician: Yong Lin, PhD
Dosimetry Medical Physicists: George Sgouros & Eric Frey

All participating sites and investigators