

Radiopharmaceuticals: Updates on Ongoing Clinical Trials

Phillip J. Koo, MD

Prostate Cancer and PSMA

- 139 studies

Diagnostic Trials



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Additional Applications

- Disease characterization
 - Prognosis
 - Treatment planning
 - Treatment response
 - Radiogenomics
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- Data Science/Machine Learning/AI

OSPREY

- 18F-DCFPyI PET/CT
- Progenics Pharmaceuticals
- Prospective Phase 2/3 Multi-Center
 - Cohort A: High Risk before prostatectomy and lymphadenectomy
 - Cohort B: Locally recurrent or metastatic disease
- 377
- Single group assignment
- December 2018

Discussion Points

- Acceptance
 - Change in Management
 - Outcomes
 - Delay in time to ADT
- Reimbursement
- Access
- Will M0 CRPC exist
 - M1 with traditional imaging vs. M1 with NCI
- Axumin vs. PSMA
 - PSMA non-expressors
- Treatment response

Therapeutic Trials



ERA 223

- Radium 223 plus abiraterone
- Increase in fractures
- Increase in deaths

EMA

- Radium 223 after 2 prior therapies or when other treatments cannot be taken
- Not to be used in combination with abiraterone and steroids
- Not recommended in patients with a low number of bone metastases called osteoblastic bone metastases.

PEACE III

- Phase III
- Radium plus enzalutamide
- Study completion April 2021

VISION Trial

- Endocyte Pharmaceuticals
- International, prospective, open label, multicenter, randomized Phase III
- Progressing mCRPC
 - 1 novel anti androgen AND 1 taxane
- 750 patients
- 2:1 randomization with best SOC
- OS
 - rPFS
 - RECIST
 - Time to SSE
- Two interim analyses planned
 - Study completion May 2021
 - Possible early approval

Lu-177 PSMA vs Cabazitaxel

- Phase 2, open label, randomized, 2 arm, multicenter trial
- 200
- Activity and safety
- Primary endpoint – PSA response rate
- Pain response, PFS, QoL, AE's
- Est Study Completion: 1/21

Discussion Points

- Toxicity
 - Xerostomia
 - Bone marrow failure
- Layering/Sequencing
 - Theranostics

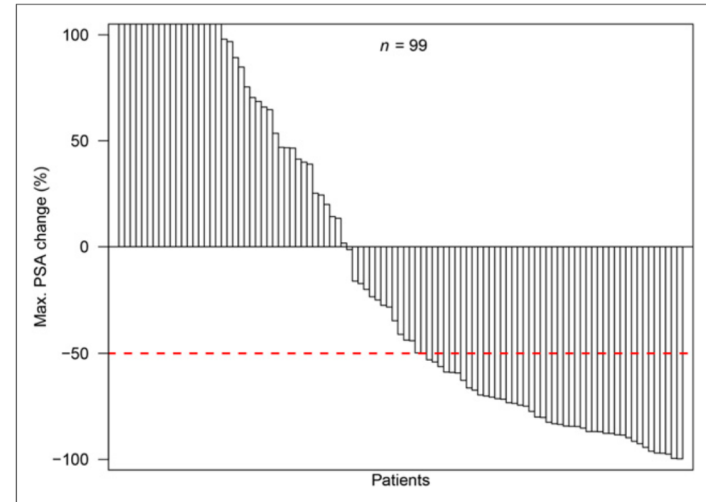


FIGURE 2. Waterfall plot of maximum PSA change (%) from baseline over total follow-up period. PSA increase > 100% was cropped due to simplification.

Theranostics in Action

