Inaugural Southern California Genitourinary Cancer Research Forum

Panel: Prostate Studies (Localized, Salvage/BCR, mHSPC, mCRPC)

Moderator: Rana McKay, MD

Speakers:

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Disclosures

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- *Consultant for AstraZeneca, Aveo, Bayer, Bristol-Myers Squibb, Calithera, Caris, Dendreon, Eisai, Exelixis, Johnson & Johnson, Lilly, Merck, Myovant, Novartis, Pfizer, Sanofi, SeaGen, Sorrento Therapeutics, Telix, and Tempus; and Grant/Research Support from AstraZeneca, Bayer, Bristol-Myers Squibb, Exelixis, Oncternal, and Tempus.*

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This presentation and/or comments will be free of any bias toward or promotion of the above referenced companies or their product(s) and/or other business interests.

This presentation and/or comments will provide a balanced, non-promotional, and evidence-based approach to all diagnostic, therapeutic and/or research related content.

This presentation has been peer-reviewed and no conflicts were noted.

The off-label/investigational use of Cabozantinib + Atezolizumab, AMG509, and ARV766 will be addressed.

Disclosures

Arash Rezazadeh Kalebasty, MD

- *Consultant for AstraZeneca, Exelixis, Bayer, Bristol Myers Squibb, EMD Serono, Genentech, Gilead Sciences, Immunomedics, Novartis, and Pfizer; On the Speakers Bureau for Amgen, Astellas, AstraZeneca, AVEO Oncology, Bristol Myers Squibb, Eisai, EMD Serono, Exelixis, Genentech/Roche, Gilead Sciences, Janssen (Johnson & Johnson), Medivation (Pfizer), Merck, Myovant Sciences (Sumitomo America, Inc.), Novartis, Pfizer, Novartis, Sanofi, and Seagen; and Grant/Research Support from Astellas Pharma, AstraZeneca, Bayer, BeyondSpring Pharmaceuticals, Bristol Myers Squibb, Eisai, Epizyme (Ipsen Biopharmaceuticals), Exelixis, Genentech, Immunomedics (Gilead Sciences), Janssen, MacroGenics, and Seagen.*

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This presentation and/or comments will be free of any bias toward or promotion of the above referenced companies or their product(s) and/or other business interests.

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Cultural Linguistic Competency (CLC) & Implicit Bias (IB)

STATE LAW:

The California legislature has passed Assembly Bill (AB) 1195, which states that as of July 1, 2006, all Category 1 CME activities that relate to patient care must include a cultural diversity/linguistics component. It has also passed AB 241, which states that as of January 1, 2022, all continuing education courses for a physician and surgeon **must** contain curriculum that includes specified instruction in the understanding of implicit bias in medical treatment.

The cultural and linguistic competency (CLC) and implicit bias (IB) definitions reiterate how patients' diverse backgrounds may impact their access to care.

EXEMPTION:

Business and Professions Code 2190.1 exempts activities which are dedicated solely to research or other issues that do not contain a direct patient care component.

The following CLC & IB components will be addressed in this presentation:

- *Importance of addressing bias and barriers to care based on socioeconomic status and differences in responses that have been noted based on race.*
- *Patients who are underinsured can be treated with older generation drugs.*

Prostate cancer - Localized

Trials in progress

Prostate cancer - Localized

Study Title	Study Design	Other Details
NCT05498272 (NePtune)	A Phase 2 Study of Neoadjuvant PARP Inhibition Followed by Radical Prostatectomy in Patients With Unfavorable Intermediate-Risk or High-Risk Prostate Cancer With BRCA1/2 Gene Alterations	• UCSD
NCT04025372 (INTREPId)	INTermediate Risk Erection PreservatIon Trial: A Randomized Trial of Radiation Therapy and Darolutamide for Prostate Cancer	• UCSD
NCT06067269 (HEATWAVE)	Hormone Therapy (Apalutamide) and Image-guided Stereotactic Body Radiation Therapy for the Treatment of Patients With Prostate Cancer	• UCLA
NCT04037254 (NADIR)	Randomized Phase II Trial of Niraparib With Standard Combination Radiotherapy and Androgen Deprivation Therapy (ADT) in High Risk Prostate Cancer	• Cedars Sinai
NCT04530552	Clinical Study of Bioactivity of Low Dose Apalutamide in Prostate Cancer Patients Scheduled for Prostatectomy	• USC

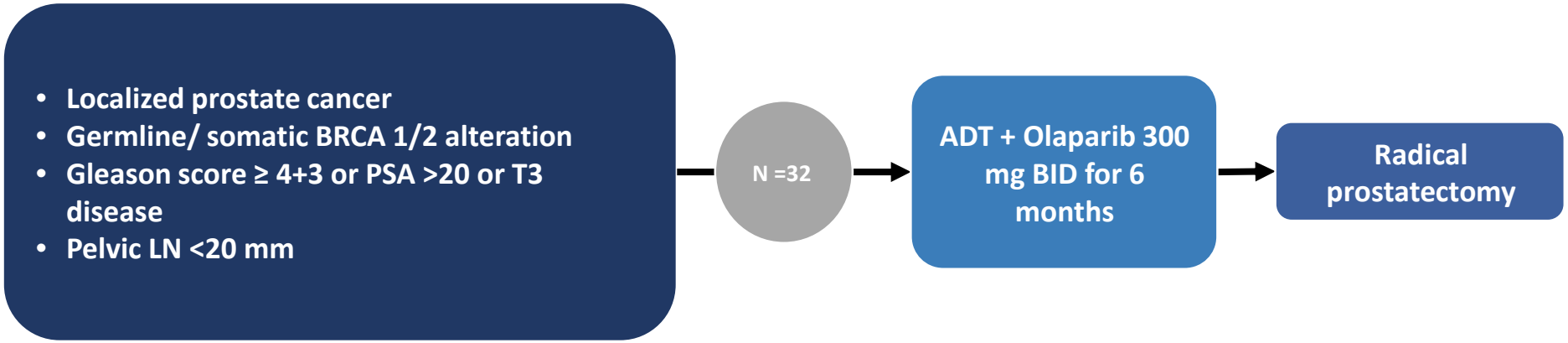
Localized Pca

UC San Diego

NePtune

Phase 2, single arm

NCT 05498272



MOA:

- **Olaparib**: PARP inhibitor

Endpoints

Primary: pCR or minimum residual disease (tumor ≤5 mm)

Secondary: PSA, surgical staging, surgical margin rate, safety, time to Test recovery

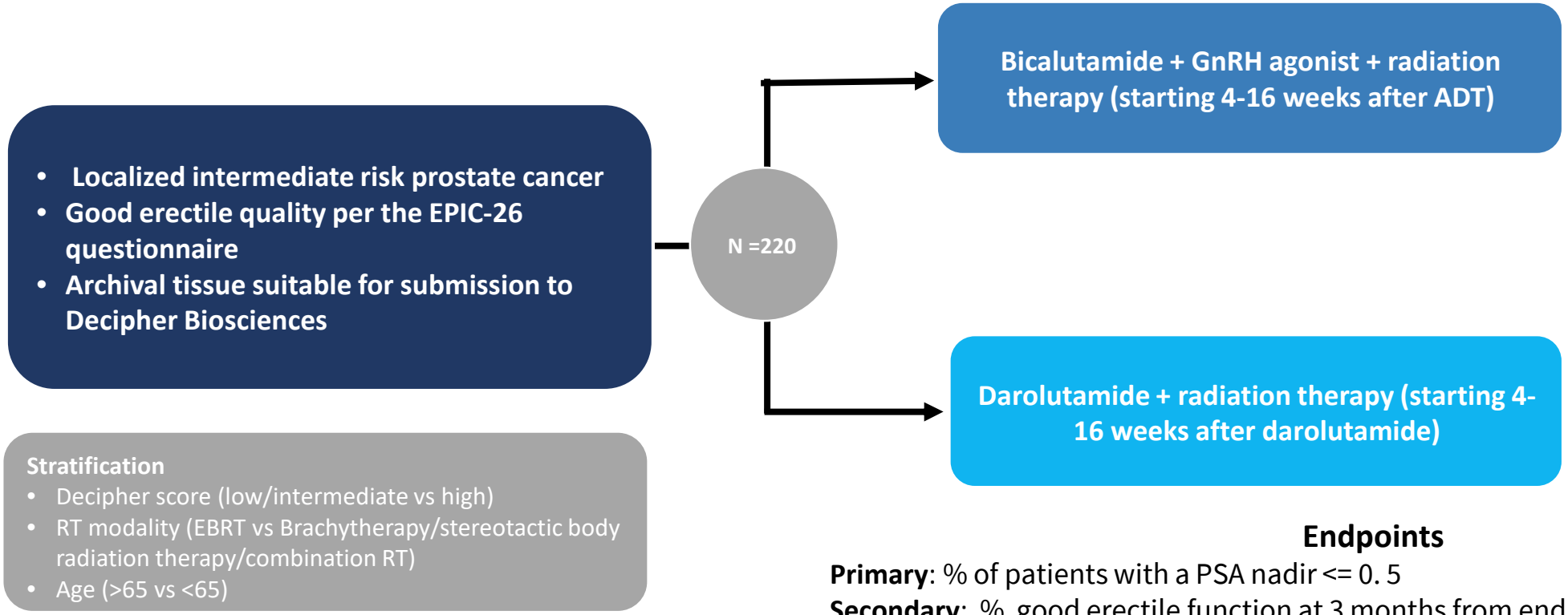
Localized Pca

UC San Diego

INTREPId

NCT 04025372

Phase 2b, randomized control trial, open label, multicenter



Endpoints

Primary: % of patients with a PSA nadir <= 0. 5

Secondary: % good erectile function at 3 months from end of treatment, PSA PFS, MFS

Localized

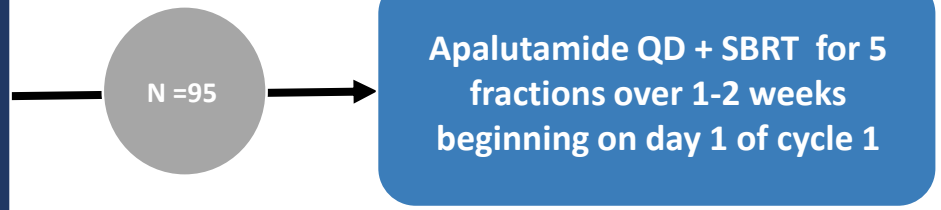
UCLA

HEATWAVE

Phase 2, single arm

NCT 06067269

- NCCN unfavorable intermediate-risk prostate (2 of the following: PSA 10-20 ng/mL, clinical T category 2b-2c, or ISUP group 2; OR any 1 of with ISUP grade group 3 disease; OR any 1 with 50% or more cores with prostate cancer)
- Have a Decipher genomic classifier score
- Have at least one dominant intraprostatic lesion visible on multiparametric MRI
- Have undergone a PSMA PET
- Testosterone >= 150 ng/dL
- ECOG 0-1



Endpoints

Primary: % patients achieving PSA of < 0.2 ng/mL

Secondary: time to BCR, PROs, radiographic persistence of disease on PSMA/PET and MRI, acute and late toxicities

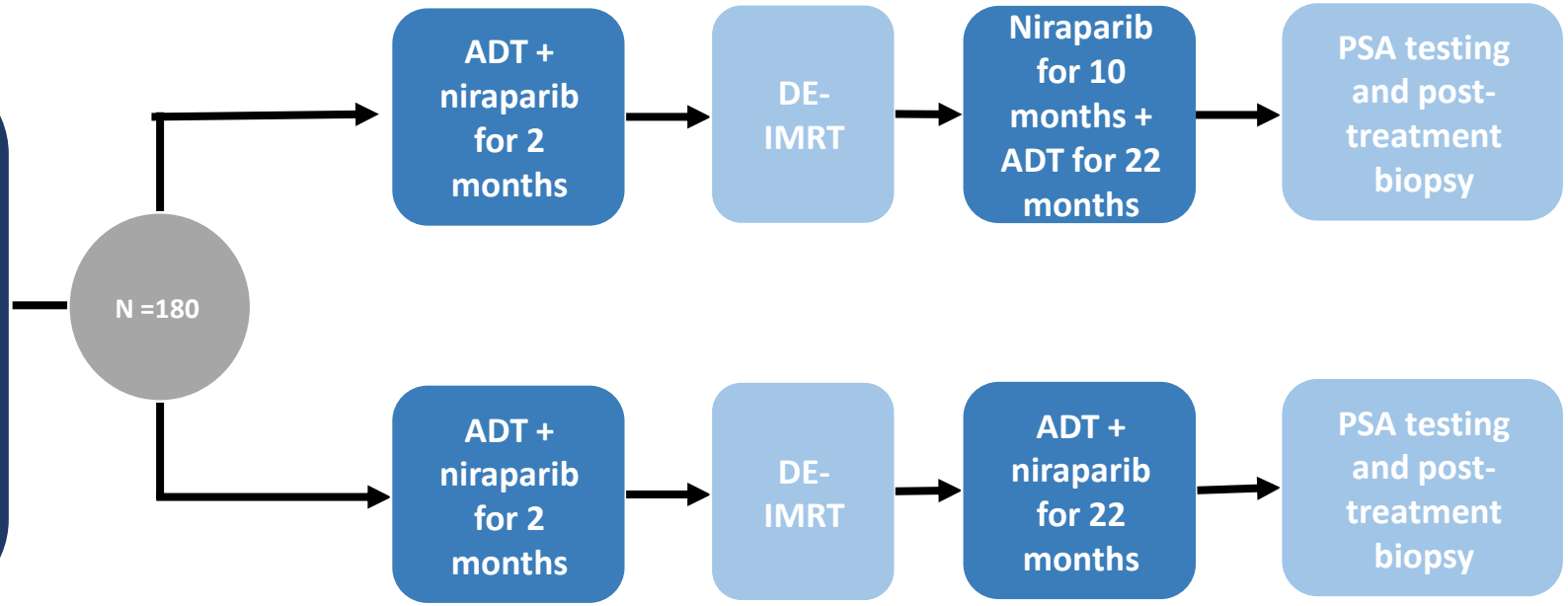
Localized

NADIR

NCT 04037254

Phase 2, randomized control trial, open-label, parallel assignment

- Histologically confirmed (within 180 days prior to registration) adenocarcinoma of the prostate at high risk for recurrence: Gleason ≥ 9, PSA ≤ 150 ng/mL, any T-stage; OR Gleason 8, PSA < 20 ng/mL, and ≥ T2; OR Gleason 8, PSA ≥ 20-150 ng/mL, any T-stage; OR Gleason 7, PSA ≥ 20-150 ng/mL, any T-stage
- No distant metastases on conventional imaging
- ECOG 0-1



Endpoints

Primary: maintenance DFS

Secondary: OS, PCa specific survival, pCR, BC PFS, TTDM, AEs, time to local/regional or distant progression

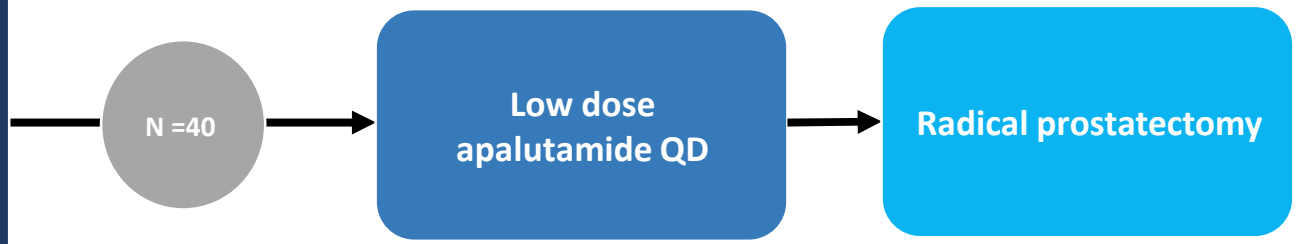
Localized

LOW DOSE APALUTAMIDE ON PSA LEVEL

NCT 04530552

Phase 2a, single arm, open label

- Organ confined adenocarcinoma of the prostate suitable for prostatectomy
- Gleason score =< (4+4), however no Gleason pattern 5
- Current serum PSA =< 20 ng/ml
- TSH within the institutional normal range
- Testosterone > 200 ng/dl



Endpoints

Primary: change in PSA levels

Secondary: reversibility of testosterone levels, plasma apalutamide concentrations, HRQOL,

Prostate cancer – N1

Study Title	Study Design	Other Details
NCT04857502	99mTc-PSMA-I&S Biodistribution in Patients With Prostate Cancer	• UCLA
NCT04134260 (NRG-GU008/ INNOVATE)	Randomized Phase III Trial Incorporating Abiraterone Acetate with Prednisone and Apalutamide and Advanced Imaging Into Salvage Treatment for Patients with Node-Positive Prostate Cancer After Radical Prostatectomy	• USC

UCLA

99mTc-PSMA-I&S Biodistribution

NCT 04857502

Phase 1, single arm

- PCa (primary or recurrent disease)
- Received a 68Ga-PSMA-11 positron emission tomography (PET)/computed tomography (CT) for staging or restaging
- Men with evidence of lymph nodes (LNs)-positive disease on 68Ga-PSMA-11 PET/CT
- Men who are scheduled for pelvic LN dissection (PLND)

Endpoints

Primary: biodistribution of 99mTc-PSMA-I&S in normal and malignant tissues

Secondary: 99mTc-PSMA-I&S accumulation within tumor lesions observed by in-vivo SPECT will be correlated with PSMA expression, best time-point for 99mTc-PSMA-I&S radioguided surgery

NRG-GU008/ INNOVATE

NCT 04134260

Phase 3, randomized controlled trial, open label

- Localized prostate cancer with negative PSMA/PET for distant disease
- pT any, pN(+)
- ECOG 0-1
- Detectable PSA after RP (PSA > 0ng/ml)
- Patients who have already started on post-prostatectomy GnRH agonist/antagonist for =< 180 days prior to registration are eligible

N =586

ADT for 24 months + EBRT (5 days per week over 5-6 or 7-8 weeks)

ADT + apalutamide + abiraterone/prednisone for 24 months + EBRT (5 days per week over 5-6 or 7-8 weeks)

Endpoints

Primary: MFS

Secondary: QoL, OS, bPFS, TT to loco regional progression, AEs

Prostate cancer - Biochemical recurrence

Study Title	Study Design	Other Details
NCT00779168	A Phase Ib Trial of Mushroom Powder in Biochemically Recurrent Prostate Cancer	• COH

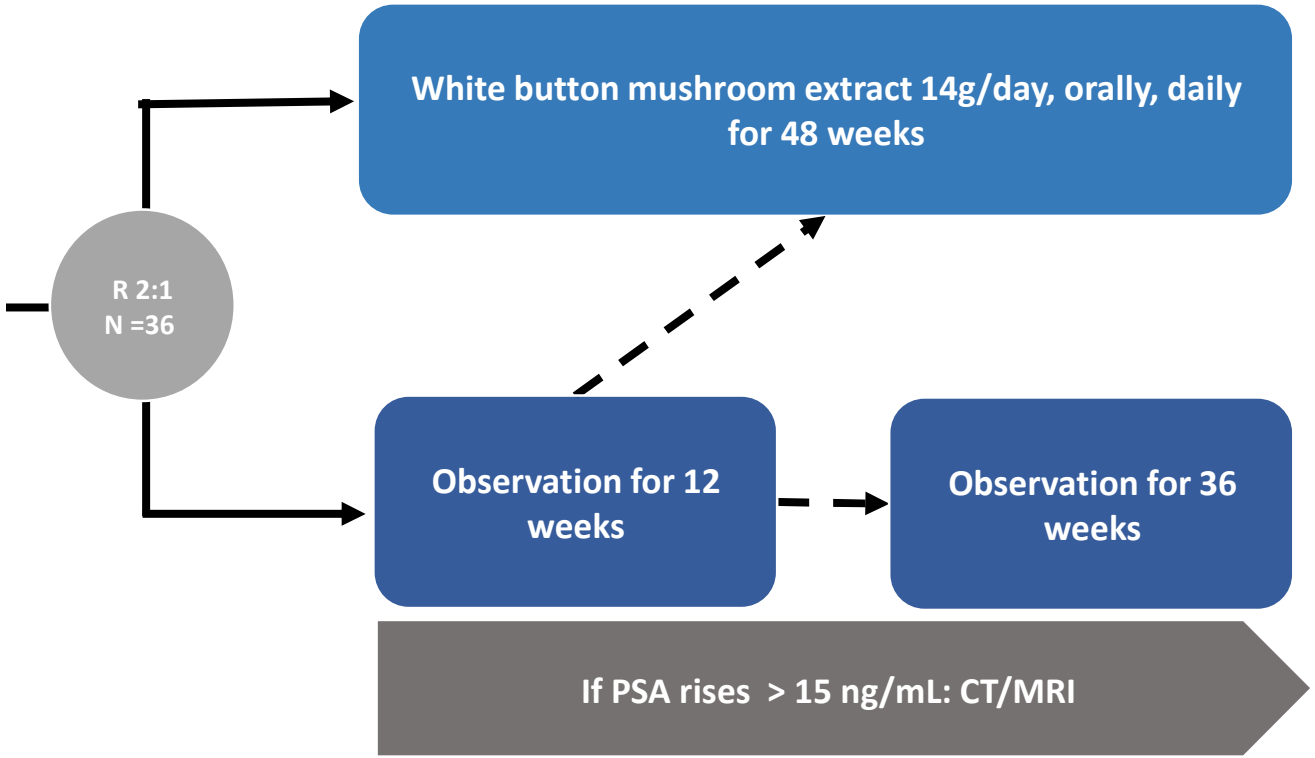
Biochemical recurrence

WHITE BUTTON MUSHROOM

NCT 00779168

Phase 1, randomized trial, open-label

- Localized prostate cancer with negative PSMA/PET for distant disease
- May have received any number of local therapies (radical prostatectomy, external beam radiation therapy, radioactive seed implantation, cryotherapy)PSA failure (>= 0.2 ng/ml that has increased above nadir following prostatectomy, 2.0 if radiation)
- At least 3 PSA measurements over a minimum of 3 months
- ECOG 0-2



Endpoints

Primary: PSA levels from baseline to 12 weeks

Prostate cancer - mHSPC

Study Title	Study Design	Other Details
NCT04734730	Phase II Study of Talazoparib With Androgen Deprivation Therapy and Abiraterone in Castration Sensitive Prostate Cancer	• COH
NCT05241860 (A-DREAM)	A Phase II Trial of ADT Interruption in Patients Responding Exceptionally to AR-Pathway Inhibitor in Metastatic Hormone-Sensitive Prostate Cancer (MHSPC)	• UCI
NCT05053152	Testing the Addition of the Drug Relugolix to the Usual Radiation Therapy for Advanced-Stage Prostate Cancer	• Cedars Sinai
NCT05832086	Intermittent Fasting Using a Fasting-Mimicking Diet to Improve Prostate Cancer Control and Metabolic Outcomes	• Cedars Sinai, COH
NCT03678025 (SWOG1802)	Phase III Randomized Trial of Standard Systemic Therapy (SST) Versus Standard Systemic Therapy Plus Definitive Treatment (Surgery or Radiation) of the Primary Tumor in Metastatic Prostate Cancer	• USC, COH
NCT03456843 (SIMCAP)	Phase 2.5 multi-institution randomized prospective clinical trial evaluating the impact of cytoreductive radical prostatectomy combined with best systemic therapy on oncologic and quality of life outcomes in men with newly diagnosed metastatic prostate cancer	• USC, COH

Talazoparib with ADT and Abiraterone

Phase 2, single arm, open label

NCT 04734730

- Metastatic HSPC (measurable disease not required)
- KPS 60-100
- 6 months since completion of ADT in the neoadjuvant and/or adjuvant setting, and it must not have lasted for more than 36 months
- No more than 60 days from first LHRH injection (or surgical castration)
- Testosterone >150 ng/mL within 28 days prior to registration
- Abiraterone for no more than 3 weeks

→ N =70 → LHRH + abiraterone acetate 1000 mg daily + prednisone 5 mg daily + talazoparib 1 mg daily → Follow up after drug discontinuation until disease progression or death

Endpoints

Primary: PSA nadir <0.2 at 12 months

Secondary: ORR, PSA response, rPFS, PROs

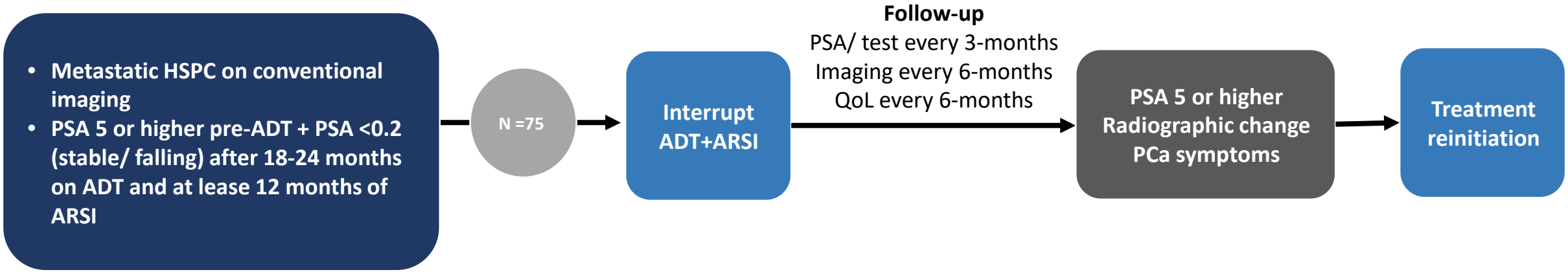
mHSPC

UCI

A-DREAM

NCT 05241860

Phase 2, single arm of ADT interruption in patients responding exceptionally



Endpoints

Primary: treatment free at 18 months (with normal testosterone)
Secondary: rPFS, TTNT, OS, cost

Oligometastatic mHSPC

NRG PROMETHEAN

Phase 2,

NCT 05053152

- mHSPC with 1 - 5 oligometastatic lesions in bone and/or nodal/soft tissue on PSMA/ PET
- No local tumor recurrence
- PSA ≤10.0 ng/ml
- Must have ≥3 PSA values within the last two years since end of primary treatment
- Serum total testosterone ≥ 100 ng/dL

N =260

Placebo PO QD on days 1-180 + SBRT for 1-3 weeks

Relugolix PO QD on days 1-180 + SBRT for 1-3 weeks

Endpoints

Primary: rPFS

Secondary: PET-PFS, MFS, OS, sexual function, fatigue

INTERMITTENT FASTING

NCT 05832086

Phase 2, randomized two-armed, multi-site study

- Metastatic HSPC (adenocarcinoma prostate histologically confirmed by biopsy AND metastatic disease confirmed biopsy, or MRI scan)
- Men receiving or planning to start first-line intensified ADT with abiraterone, apalutamide, enzalutamide, or darolutamide with or without current or prior chemotherapy

R 1:1
N =138

- Intermittent fasting using a fasting mimicking diet
- Standard Anti-Cancer Diet

Endpoints

Primary: response to cancer treatment
Secondary: time to development of castration resistance, metabolic toxicity

SWOG1802

Phase 3, randomized controlled trial

NCT 03678025

- mHSPC ≥ M1a
- No local tumor recurrence
- PSA ≤10.0 ng/ml
- Must have ≥3 PSA values within the last two years since end of primary treatment
- Serum total testosterone ≥ 100 ng/dL

N =260

- Systemic standard of care + definitive treatment (surgery and radiation)
- Systemic standard of care

Endpoints

Primary: OS

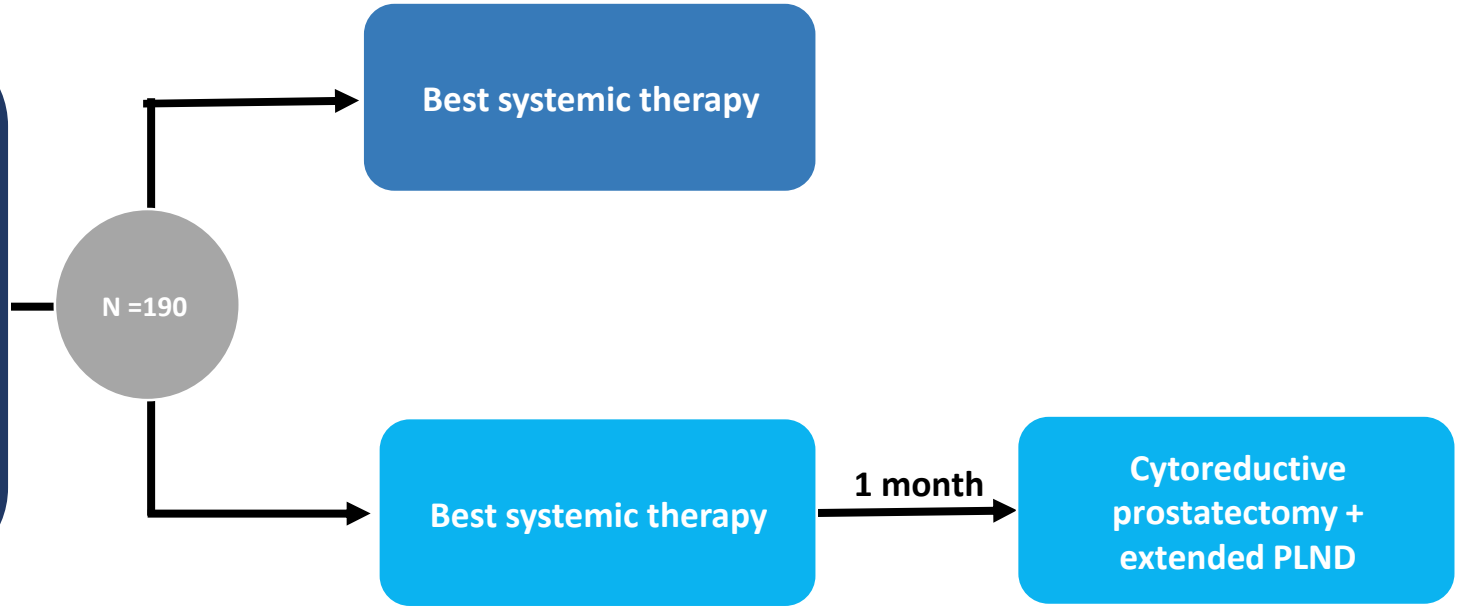
Secondary: rate of symptomatic local progression, PFS

SIMCAP

Phase 2.5, multi-institution, randomized controlled trial

NCT 03456843

- mHSPC ≥ M1a
- ADT< 6 months
- Serum total testosterone ≥ 100 ng/dL
- If solitary lesion, metastasis confirmed with either biopsy or two independent imaging modalities
- No previous local therapy for prostate cancer
- Prostate deemed resectable by surgeon
- Plans to start or has already started antiandrogen therapy (ADT) no longer than 6 months prior to consent



Endpoints

Primary: FFS at two years (biochemical recurrence, progression, or death

Secondary: time to biochemical progression, cancer-specific survival, complication rate

Prostate cancer - mCRPC

Study Title	Study Design	Other Details
NCT05805371	A Phase 1b Study Evaluating Combinations With PSCA-Targeting Chimeric Antigen Receptor (CAR)-T Cells for Patients With PSCA+ Metastatic Castration-Resistant Prostate Cancer	• COH
NCT05204147	A Phase 1 Study of Actinium-225 Labeled Humanized Anti-CEA M5A Antibody in Patients With CEA Producing Advanced or Metastatic Cancers	• COH
NCT05156905	A Phase 1b Trial Investigating Docetaxel Combined With Cirmtuzumab in Patients With Metastatic Castration Resistant Prostate Cancer	• UCSD
NCT05502315 (CANOPY)	Study of Cabozantinib and Nivolumab in Metastatic Castration Resistant Prostate Cancer	• UCSD
NCT04363164	A Randomized Phase II Study Comparing Sequential High Dose Testosterone and Enzalutamide to Enzalutamide Alone in Asymptomatic Men With Castration Resistant Metastatic Prostate Cancer	• UCSD
NCT06136624	A Phase III Randomized, Open-label Study of MK-5684 versus Alternative Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration Resistant Prostate Cancer (mCRPC) Previously Treated with Next-generation Hormonal Agent (NHA) and Taxane-based Chemotherapy	• UCI

Prostate cancer - mCRPC

Study Title	Study Design	Other Details
NCT06136650	A Phase III, Randomized, Open-label Study of MK-5684 versus Alternative Abiraterone Acetate or Enzalutamide in Participants with Metastatic Castration-resistant Prostate Cancer (mCRPC) That Progressed on or After Prior Treatment with One Next-generation Hormonal Agent (NHA)	• UCI
NCT05828082	A Phase II Study of M1774 in Refractory SPOP-mutant Prostate Cancer	• UCI
NCT05398302	Radiologically Guided Biopsies of mCRPC to Identify Adaptive Mechanisms of Resistance in Patients Undergoing 177Lu-PSMA Radioligand Therapy	• UCLA
NCT06056791	An Open-label, Phase I/IIa Dose Escalation and Expansion Study to Determine the Safety and Clinical Activity of an Immune Priming Cell Therapy (INKmune) in Patients with Metastatic Castration Resistant Prostate Cancer (mCRPC) *final stages of approval	• UCLA
NCT05534646	Study of Apalutamide With Carotuximab in Metastatic, Castration-Resistant Prostate Cancer	• Cedars Sinai

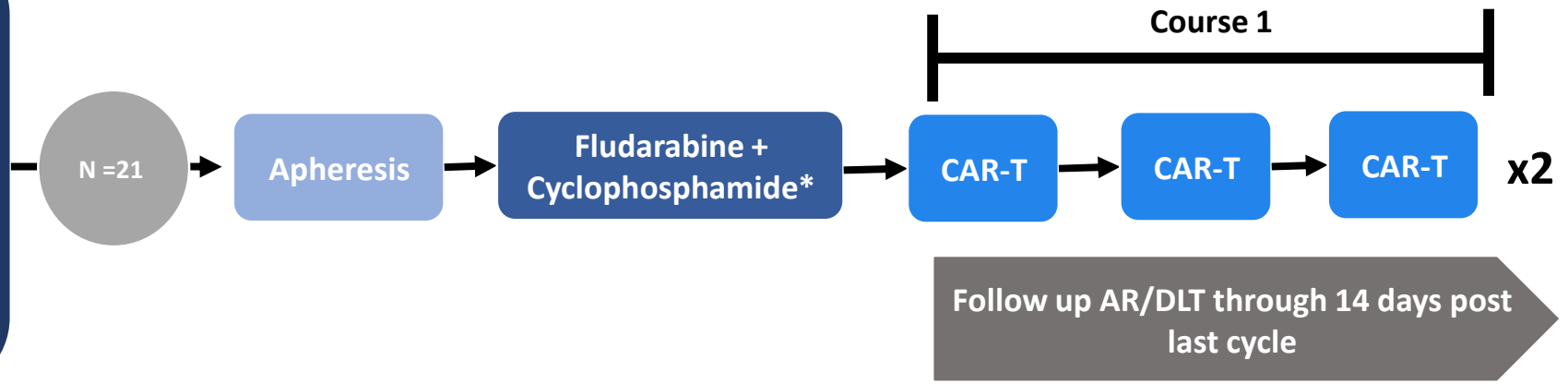
City of Hope

Combinations With PSCA-targeting CAR-T Cells for PSCA+

NCT 05805371

Phase 1b

- Metastatic CRPC (measurable disease not required)
- ECOG 0-2, KPS 70-100
- Documented PSCA+ tumor expression
- Disease progression on at least 1 advanced androgen-targeted therapy
- Prior radiotherapy is allowed
- No known contraindications to leukapheresis, steroids or tocilizumab



Endpoints

Primary: adverse events, PSA50

Secondary: OS, PFS, disease response

*Additional Flu/Cy cycles per PI discretion

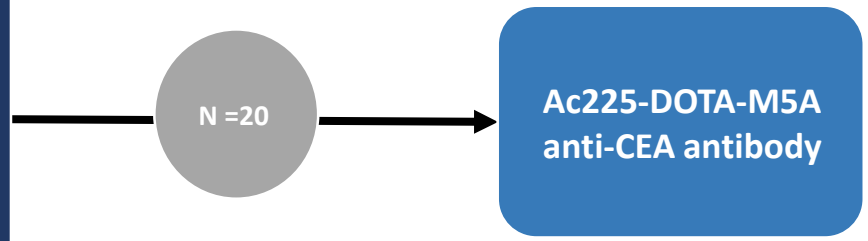
mCRPC

Actinium Ac225 anti-CEA mAb

Phase 1b, single arm

NCT 05204147

- NEPC with measurable disease
- Histologic diagnosis of a malignancy that expresses CEA
- Tumors that produce CEA as documented by either an elevated serum CEA above the institutional limit of normal or by immunohistochemical methods
- Advanced disease for which no standard or effective treatment is available
- KPS 60-100%
- estimated survival of at least 3 months



Endpoints

Primary: MTD

Secondary: clinical activity of the agent in metastatic CEA expressing cancer, organ biodistribution, pharmacokinetics

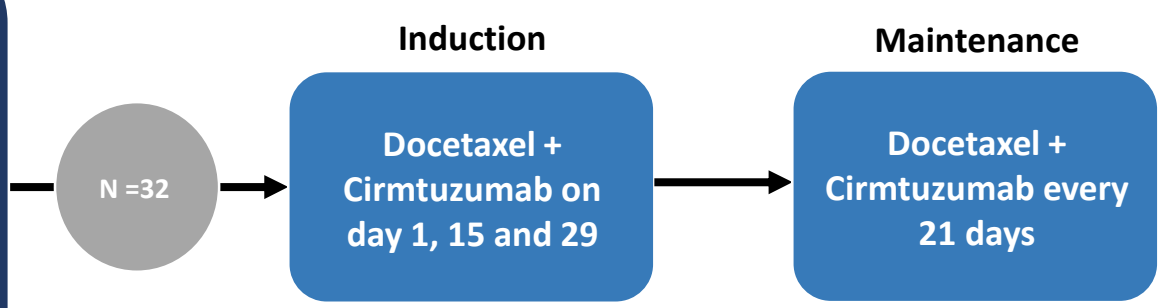
UC San Diego

Docetaxel Combined With Cirmtuzumab in mCRPC

NCT 05156905

Phase 1b, single arm

- Metastatic CPRC (measurable disease not required)
- KPS 80-100, ECOG 0-1
- Neuroendocrine component are eligible
- Castrate levels of serum testosterone < 50 ng/dL.
- Prior abiraterone and/or next generation androgen receptor antagonist (enzalutamide, apalutamide, or darolutamide) for hormone sensitive disease or CRPC
- Prior docetaxel for hormone sensitive disease is permitted



MOA:

- **Cirmtuzuab**: mAb anti-ROR1 (non-canonical Wnt pathway)

Endpoints

Primary: recommended phase 2 dose

Secondary: AEs, alk phos response, time to PSA progression, rPFS, OS, TT first skeletal evento

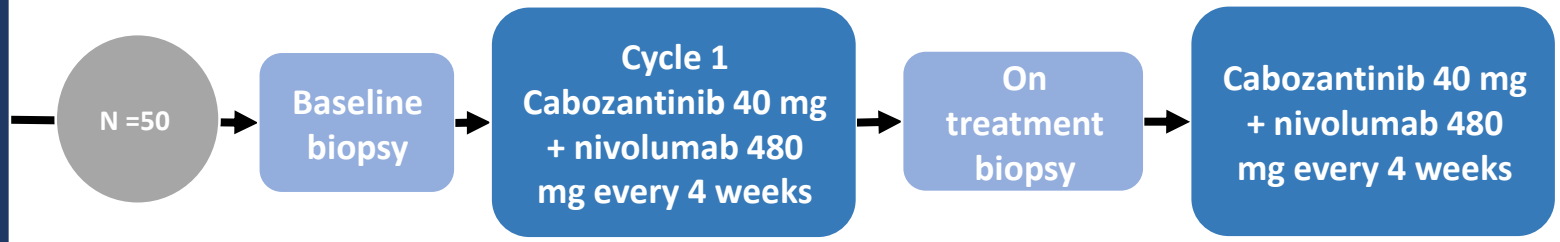
UC San Diego

CANOPY (HCRN GU21-517)

NCT 05502315

Phase 2, label, two-stage

- Metastatic CPRC (non measurable disease caped at 50%)
- ECOG 0-2
- Castrate levels of serum testosterone < 50 ng/dL
- Progressive disease as defined by PSA or radiographic progression
- Must have exposure to one prior taxane (or be taxane ineligible or refuse taxane) AND one prior AR-targeting agent (abiraterone, enzalutamide, apalutamide, darolutamide)



Endpoints

Primary: rPFS

Secondary: PSA, ORR, 6-month rPFS, 6-month PSA response, OS, time to PSA progression

mCRPC

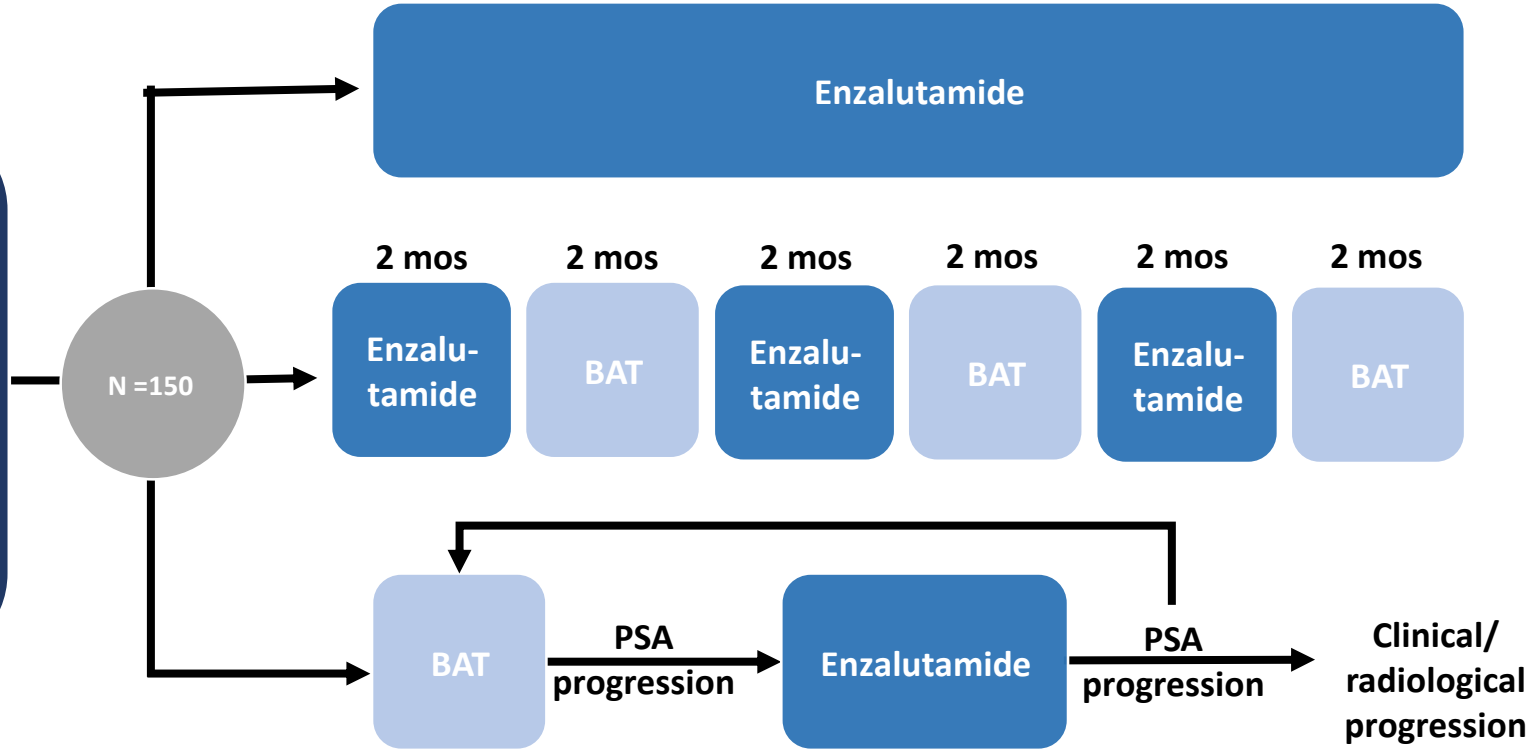
UC San Diego

STEP-UP trial

Phase 2, randomized control trial, 3 arm

NCT 04363164

- Asymptomatic mCRPC
- Disease progression on abiraterone (PSA or radiological progression)
- ECOG 0-2
- Documented castrate level of serum testosterone (<50 ng/dl)
- Screening PSA must be ≥ 1.0 ng/Ml
- No prior treatment with enzalutamide, apalutamide, darolutamide, or other investigational AR targeted



Endpoints

Primary: cPFS/rPFS

Secondary: safety, PSA RR, QoL, ORR, OS

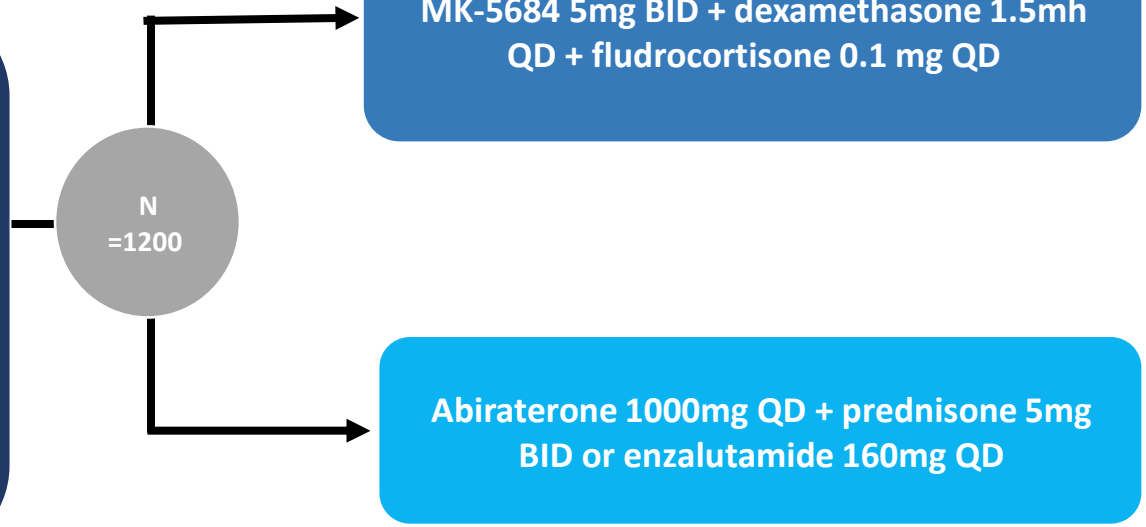
UCI

MK-5684 Versus Alternative NHA in mCRPC (prior taxane)

NCT 06136624

Phase 3, randomized control trial, open-label, parallel assignment

- mCRPC
- Disease that progressed during or after treatment with 1 NHA
- Has received 1 but no more than 2 taxane-based chemotherapy regimens for mCRPC and has had PD during or after treatmentECOG 0-1
- Castrate levels of serum testosterone < 50 ng/dL
- Progressive disease as defined by PSA or radiographic progression
- Prior treatment with PARPi and LuPSMA 177 or were deemed ineligible to receive treatment



MOA:

- **MK-5684**: oral, non-steroidal, selective inhibitor of CYP11A1 (first and rate-limiting enzyme of steroid biosynthesis)

Endpoints

Primary: OS, OS in AR LBD, rPFS

Secondary: time to initiation of the first subsequent anticancer therapy, ORR, DOR, time to pain progression, PSA RR, AE, time to first symptomatic skeletal-related event

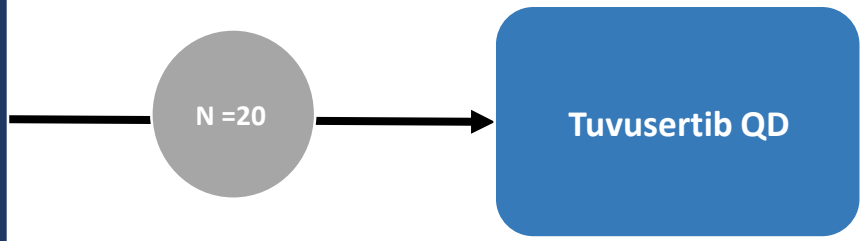
UCI

M1774 in Refractory SPOP-mutant PCa

Phase 1b, single arm

NCT 05828082

- **mCRPC**
- **ECOG 0-2**
- **Castrate levels of serum testosterone < 50 ng/dL**
- **Progressive disease as defined by PSA or radiographic progression**
- **Prior treatment with second generation anti-androgen and taxane- or lutetium-based therapy**
- ***SPOP* mutations in prostate cancer cells by NGS**



MOA:

- **M1774/ tuvusertib** : elective and orally active ATR inhibitor

Endpoints

Primary: ORR

Secondary: OS, PFS, Aes, SPOP-driven gene signature changes

mCRPC

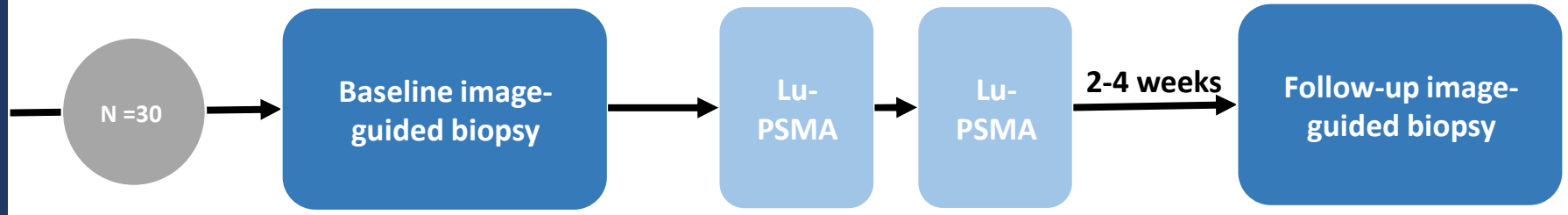
UCLA

Guided Biopsies to Identify Mechanisms of Resistance

NCT 05398302

Phase 1, single arm

- Eligible for 177Lu-PSMA-617 under expanded access protocol or as part of an approved trial
- Based on PET/CT evidence of lymph node or soft tissue metastatic disease amenable to image-guided biopsy
- No alterations on coagulation



Endpoints

Primary: Proportion of metastatic castration resistant prostate cancer (mCRPC) patients with molecular and cellular alterations in tumor, immune and stromal cells after radioligand therapy

mCRPC

UCLA

CaRe prostate

Phase 1/2a, open-label, dose escalation, and expansion

NCT 06056791

- Asymptomatic mCRPC
- Disease progression on abiraterone (PSA or radiological progression)
- ECOG 0-2
- Documented castrate level of serum testosterone (<50 ng/dl)
- Screening PSA must be ≥ 1.0 ng/Ml
- No prior treatment with enzalutamide, apalutamide, darolutamide, or other investigational AR targeted

N =30

Initial planned dose 1 x 10^8 INKmune on days 1, 8 and 15	Initial planned dose 1 x 10^8 INKmune on days 1, 8 and 15	Initial planned dose 1 x 10^8 INKmune on days 1, 8 and 15
Initial planned dose 3 x 10^8 INKmune on days 1, 8 and 15	Initial planned dose 3 x 10^8 INKmune on days 1, 8 and 15	Initial planned dose 3 x 10^8 INKmune on days 1, 8 and 15
Initial planned dose 3 x 10^8 INKmune on days 1, 8 and 15	Initial planned dose 3 x 10^8 INKmune on days 1, 8 and 15	Initial planned dose 3 x 10^8 INKmune on days 1, 8 and 15

MOA:

- **INKmune**: biologic delivery system and method for cancer treatment using in vivo priming and activation of natural killer cells

Endpoints

Primary: optimal concentration of INKmune therapy to be used in patients with mCRPC, safety

Apalutamide With Carotuximab

NCT 05534646

Phase 2, randomized control trial, permitted cross-over

- **mCRPC with rising PSA (prostate-specific antigen) on a contemporary ARSI (abiraterone, enzalutamide, darolutamide)**
- **Must have had 1 and can have up to 2 prior AR-targeted therapy with the exception of apalutamide**
- **Must decline or be ineligible for taxane therapy in the opinion of the treating physician**

N =90

Apalutamide 240 mg QD

Apalutamide 240 mg QD + Carotuximab

MOA:

- **Carotuximab**: mAb potently inhibits CD105 (co-receptor for the transforming growth factor-beta)-mediated signaling

Endpoints

Primary: rPFS
Secondary: AEs, ORR, biochemical PFS