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NDA 218197 s-4
Capivasertib with Abiraterone and Prednisone for *PTEN*-deficient mHSPC

FDA Opening Remarks
Oncologic Drugs Advisory Committee Meeting

Elaine Chang, MD

Cross-Discipline Team Leader

Division of Oncology 1, Office of Oncologic Diseases

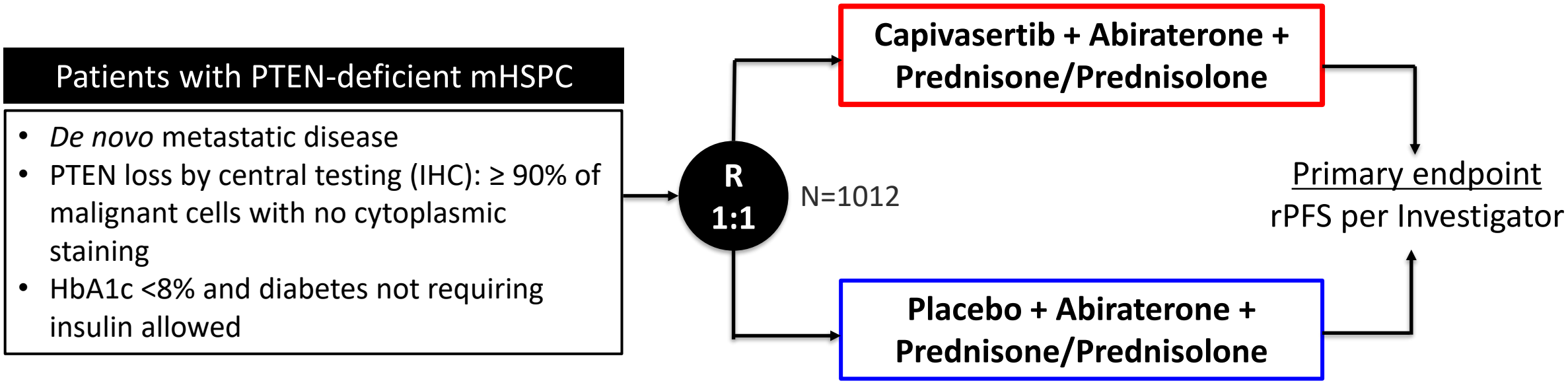
April 30, 2026

Proposed Indication

- **Indication: Capivasertib in combination with abiraterone**, is indicated for treatment of adult patients with metastatic hormone-sensitive prostate cancer **(mHSPC) that is PTEN-deficient**.

PTEN: Phosphatase and tensin homologue

CAPItello-281 Study Design



Stratification factors

- Volume of disease and presence of visceral metastases
- Geographic region

No crossover allowed

Imaging assessment every 16 weeks

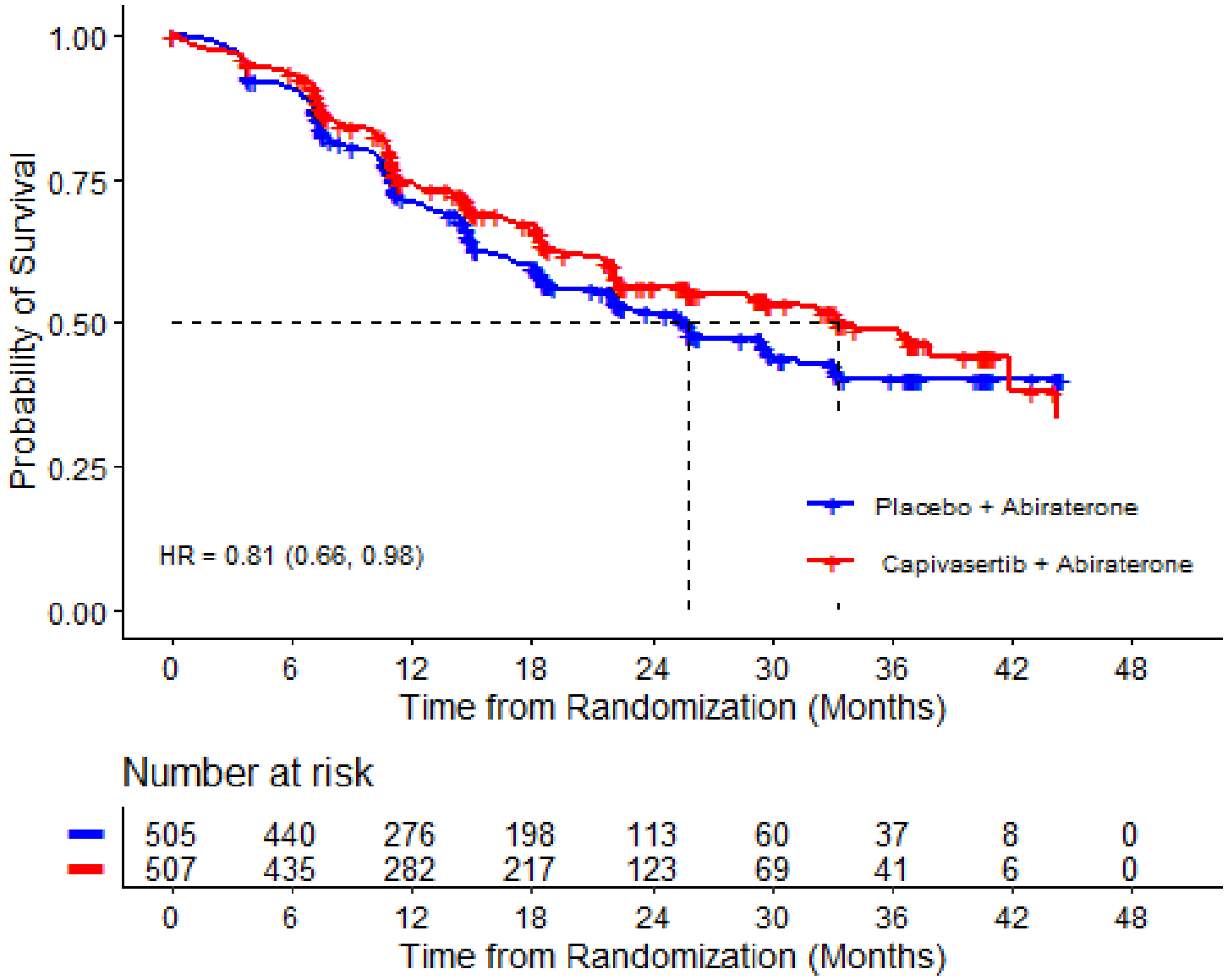
Capivasertib: 400 mg twice daily; 4 days on, 3 days off
Abiraterone: 1000 mg once daily
Prednisone (or prednisolone): 5 mg daily
Both arms also received androgen deprivation therapy

mHSPC: metastatic hormone-sensitive prostate cancer; PTEN: Phosphatase and tensin homologue; rPFS: radiographic progression-free survival

2020 FDA Feedback on Proposed Study Design

rPFS	OS
Acceptable primary endpoint, but • Clinical benefit of any improvement in rPFS will be assessed in terms of the magnitude of benefit and the consistency across endpoints. • Should be supported by consistency across secondary endpoints (including OS).	An improvement in OS or other clinically meaningful endpoints may be needed to demonstrate clinical benefit in the absence of a large magnitude of improvement in rPFS.

CAPItello-281 rPFS by Investigator



Statistically significant
rPFS HR 0.81 (95% CI: 0.66, 0.98).

Median rPFS: 33 (95% CI: 26, 44) vs. 26 (95% CI: 22, 30) months.

Medians occur where difference between KM curves appears largest.

However, KM curves suggest a modest treatment effect overall.

HR: hazard ratio; KM: Kaplan-Meier;
rPFS: radiographic progression-free survival

CAPItello-281 OS

Immature (51% information fraction).
OS HR 0.90 (0.71, 1.15).

CAPItello-281 not powered to detect an OS benefit.

Final OS predicted to occur 2027-2028.

Interim OS results do not appear to show detriment.

However, in the **absence of large rPFS improvement, considering added toxicity of capivasertib, a statistically significant OS** improvement may be needed to support favorable benefit:risk.

HR: hazard ratio; OS: overall survival; KM: Kaplan-Meier

Historical Context: mHSPC Approvals Based on rPFS

Studies that led to approval based on rPFS benefit showed large clinically meaningful rPFS effects.

Trial	Treatment Arm vs. Control Arm	Basis of Approval[1]
TITAN	Apalutamide + ADT vs. Placebo + ADT	**rPFS HR 0.48 (0.39, 0.60); OS HR 0.67 (0.51, 0.89)**
ARCHES	Enzalutamide + ADT vs. Placebo + ADT	**rPFS HR 0.39 (0.30, 0.50);** OS HR 0.81 (0.53, 1.25)[2]
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LATITUDE	Abiraterone + ADT vs. Placebo + ADT	OS HR 0.62 (0.51, 0.76)
ARASENS	Darolutamide + docetaxel + ADT vs. Placebo + docetaxel + ADT	OS HR 0.68 (0.57, 0.80)

[1]Efficacy data available at the time of initial approval of the indication.
[2]OS immature at time of approval. Final OS for ARCHES was 0.66 (95% CI: 0.53, 0.81).
[3]Not statistically significant
[4]Not formally tested

ADT: androgen deprivation therapy; HR: hazard ratio; rPFS: radiographic progression-free survival

Historical Context: mHSPC Approvals Based on OS

Studies that led to approval based on rPFS benefit showed large clinically meaningful rPFS effects.

Other studies led to approvals based on OS benefit

Trial	Treatment Arm vs. Control Arm	Basis of Approval
TITAN	Apalutamide + ADT vs. Placebo + ADT	**rPFS HR 0.48 (0.39, 0.60); OS HR 0.67 (0.51, 0.89)**
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ARASENS	Darolutamide + docetaxel + ADT vs. Placebo + docetaxel + ADT	OS HR 0.68 (0.57, 0.80)

Capivasertib with Abiraterone Safety Profile

- Compared to placebo with abiraterone, higher incidence of Grade ≥3 adverse reactions (ARs), serious ARs, and ARs leading to death.
- Increased incidence of high-grade skin reactions, diarrhea, infections, and hyperglycemia, leading to high rates of **drug discontinuation.**
  - Exposure to therapy in both arms: **~19 months**
- 44% of patients who received capivasertib with abiraterone required **initiation or change in anti-hyperglycemic regimen (17% initiated insulin).**

Patients treated with capivasertib experienced increased symptom and side effect burden, with higher healthcare utilization

Capivasertib with Abiraterone and Prednisone for PTEN-deficient mHSPC
Benefit/Risk Assessment Considerations

- CAPItello-281 demonstrated statistically significant improvement in **rPFS**
  - However, **benefit:risk assessment may not be favorable** in context

Early Metastatic Disease Setting	Effective Backbone
Median time to progression or death ~2 years.* Most patients had no/mild symptoms at baseline.	For a given patient, benefit from capivasertib cannot be assessed. **Potential for overtreatment is high for this regimen due to long duration of therapy.**

*Based on CAPItello-281 median rPFS in control arm

Capivasertib with Abiraterone and Prednisone for PTEN-deficient mHSPC
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- CAPItello-281 demonstrated statistically significant improvement in **rPFS**
  - However, **benefit:risk assessment may not be favorable** in context

Efficacy of **other available therapies**	**Toxicity**
Triplet (including docetaxel) may be preferred and more active	**Additive** with abiraterone and prednisone (hyperglycemia, with healthcare utilization), ↑deaths

mHSPC: metastatic hormone-sensitive prostate cancer; rPFS: radiographic progression-free survival

Question for ODAC

Based on the CAPItello-281 results, does the benefit of adding capivasertib to abiraterone and prednisone outweigh the risk for the proposed indication?

NDA 218197 s-4
Capivasertib with Abiraterone and Prednisone for *PTEN*-deficient mHSPC

FDA Presentation

Daniel Lee, MD, PhD

Clinical Reviewer

Division of Oncology 1, Office of Oncologic Diseases

April 30, 2026

FDA Review Team

- Angelo De Claro, Acting Director, Oncology Center of Excellence (OCE)
- Laleh Amiri-Kordestani, Director, Division of Oncology 1 (DO1)
- Daniel Suzman, Deputy Division Director, DO1
- Elaine Chang, Team Lead, DO1
- Daniel Lee, Clinical Reviewer, DO1
- Vishal Bhatnagar, Associate Director for Patient Outcomes, OCE
- Shenghui Tang, Division Director, Division of Biometrics V (DBV)
- Mallorie Fiero, Supervisory Mathematical Statistician, DBV
- Joyce Cheng, Statistical Team Lead, DBV
- Jianjin Xu, Statistical Reviewer, DBV
- Ilynn Bulatao, Safety Data Analyst, Office of Oncologic Diseases
- Xiaofeng Wang, Statistical Analyst, DAI
- Samina Jafri, Biologist, CDRH
- Shyam Kalavar, Supervisory Biologist CDRH

Voting Question

Based on the CAPItello-281 results, does the benefit of adding capivasertib to abiraterone and prednisone outweigh the risk for the proposed indication?

Outline

- FDA review issues
  - Magnitude of improvement in rPFS
  - Lack of supportive data
  - Increased toxicity with combination therapy
- Summary and question for ODAC

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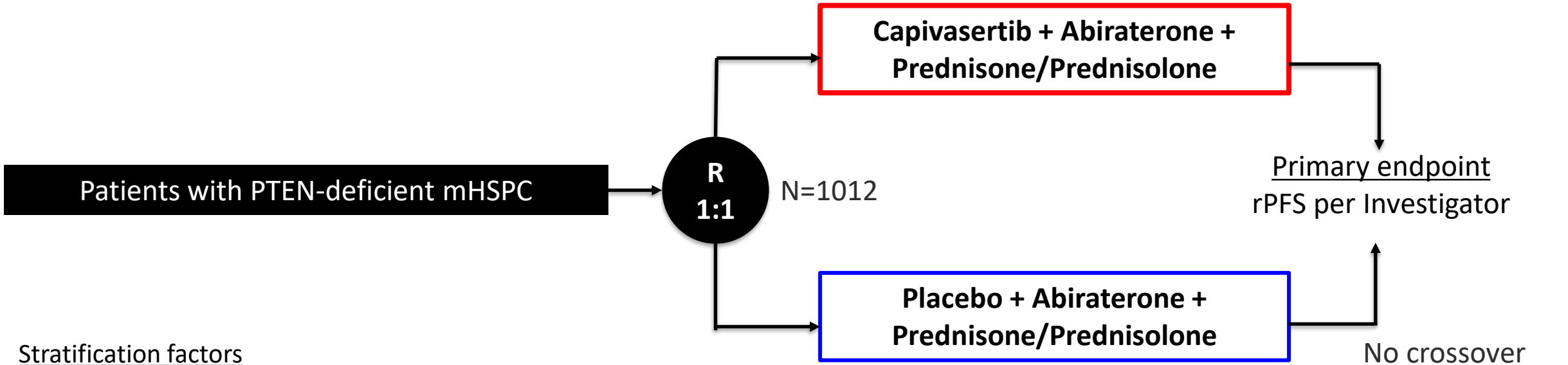
Primary Evidence of Efficacy: CAPItello-281



Stratification factors

- High-volume disease with visceral metastases *vs*. high-volume disease without visceral metastases *vs.* low-volume disease
- Geographic region

Key secondary endpoints included overall survival

Regulatory History: FDA Recommendations on Endpoints and Assessment of Benefit-Risk

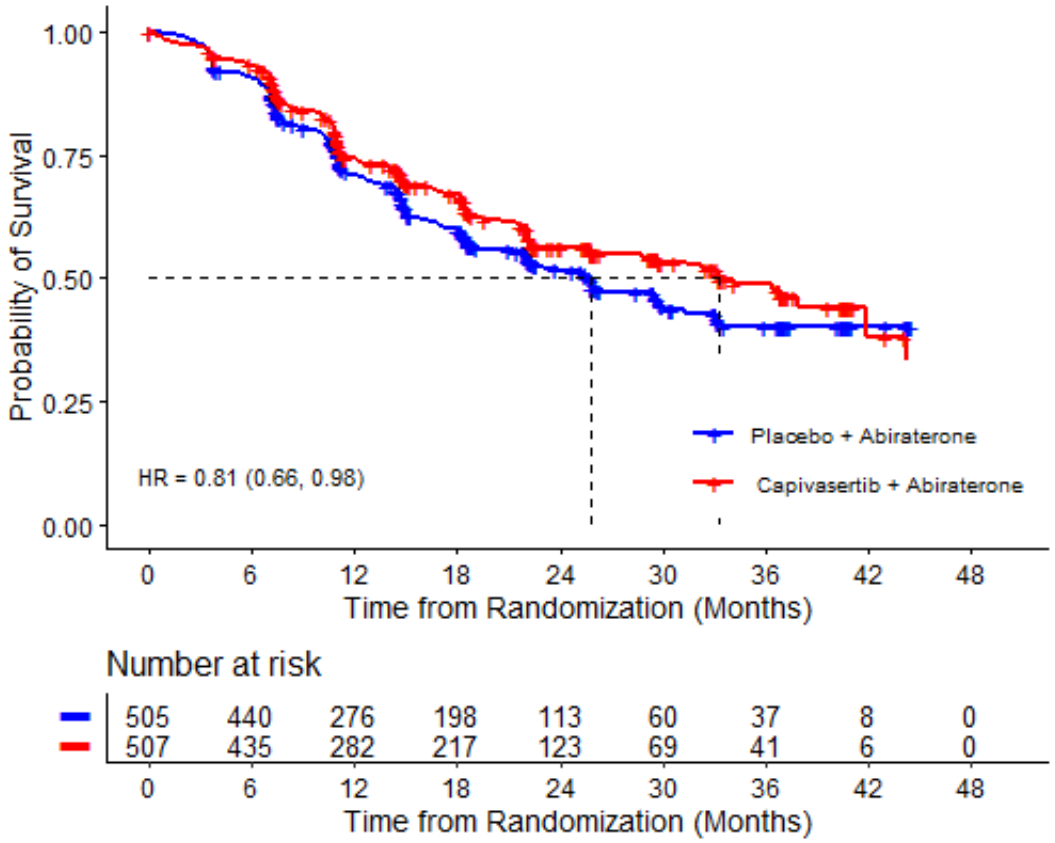
Date	Description
1/16/20	Meeting regarding the CAPItello-281 study design. FDA recommended, to **demonstrate favorable benefit:risk assessment**: • rPFS is an acceptable endpoint but should be supported by favorable OS. • In the **absence of a large magnitude of improvement in rPFS, an improvement in OS** or other clinically meaningful endpoints may be needed. Recommended including OS as a primary endpoint.
11/16/23	Capivasertib approved in combination with fulvestrant for advanced breast cancer with PIK3CA/AKT1/PTEN alteration.
1/24/25	FDA strongly advised against sNDA submission (rPFS magnitude of improvement insufficient).
8/18/25	NDA 218197 s-4 submitted

rPFS: radiographic progression-free survival; OS: overall survival

Primary Efficacy (rPFS by INV): CAPItello-281 Met its Primary Endpoint

	C+AAP N=507	P+AAP N=505
Number of events (%)	183 (36.1)	215 (42.6)
Median, months (95% CI)	33.2 (25.8, 44.2)	25.7 (22.0, 29.9)
Hazard Ratio (95% CI) [a]	**0.81 (0.66, 0.98)**	
p-value (2-sided) [b]	0.034	
rPFS at 6 months (%, 95% CI)	93 (91, 95)	91 (88, 93)
rPFS at 12 months (%, 95% CI)	74 (70, 78)	71 (67, 75)
rPFS at 18 months (%, 95% CI)	67 (62, 71)	60 (55, 64)
rPFS at 24 months (%, 95% CI)	56 (51, 61)	52 (46, 57)

[a], HR and CI based on stratified proportional hazards model.
[b], two-sided p-value based on a log-rank test stratified by volume of disease/visceral metastases, geographic location.



C+AAP: capivasertib + abiraterone + prednisone/prednisolone; INV: investigator;
P+AAP: placebo + abiraterone + prednisone/prednisolone; rPFS: radiographic progression-free survival

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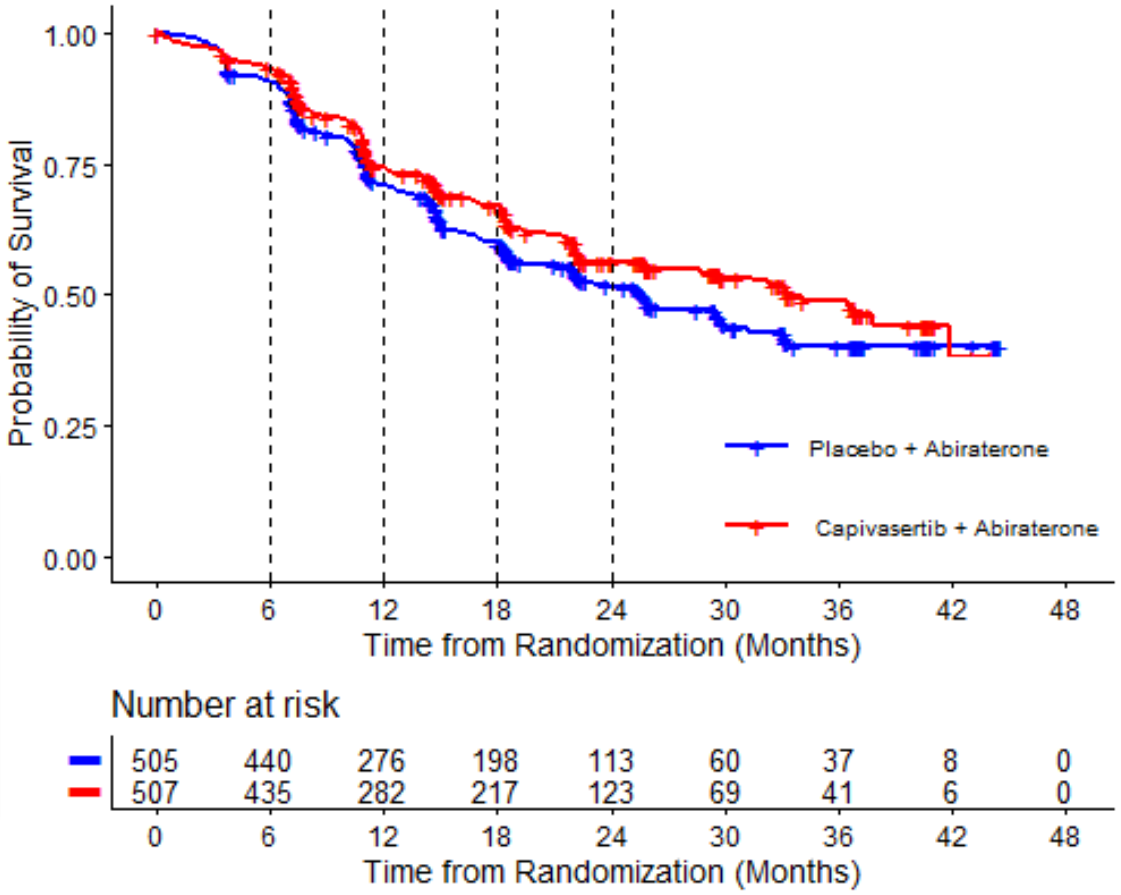

C+AAP: capivasertib + abiraterone + prednisone/prednisolone; INV: investigator;
P+AAP: placebo + abiraterone + prednisone/prednisolone; rPFS: radiographic progression-free survival

Sensitivity Analyses Show Consistent and Modest rPFS Effect

		HR (95% CI)
Primary analysis	rPFS not censored for receiving a new anti-cancer therapy[1]	0.81 (0.66, 0.98)
rPFS by BICR	Same with above	0.86 (0.69, 1.07)
Stratification factors	Stratified analysis based on case report form stratification factor data	0.82 (0.68, 1.01)
	Unstratified analysis	0.84 (0.69, 1.02)
New anti-cancer therapy	rPFS censored for receiving a new anti-cancer therapy[1]	0.77 (0.62, 0.95)
	rPFS event for receiving a new anti-cancer therapy[2]	0.89 (0.74, 1.08)

[1], rPFS censored for progression or death after missing 2 or more consecutive tumor assessments
[2], rPFS not censored for progression or death after missing 2 or more consecutive tumor assessments

The clinical meaningfulness of the results remains uncertain.

Historical Context: mHSPC Approvals Based on rPFS

Studies that led to approval based on rPFS benefit showed large clinically meaningful rPFS effects.

Trial	Treatment Arm vs. Control Arm	Basis of Approval[1]
TITAN	Apalutamide + ADT vs. Placebo + ADT	**rPFS HR 0.48 (0.39, 0.60); OS HR 0.67 (0.51, 0.89)**
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[1]Efficacy data available at the time of initial approval of the indication.
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[3]Not statistically significant
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ADT: androgen deprivation therapy

Historical Context: mHSPC Approvals Based on OS

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Other studies led to approvals based on OS benefit

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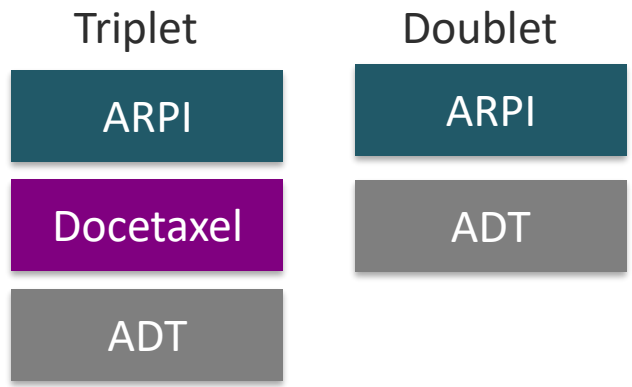
Clinical Context: Control Arm Therapy and Patient Population

- Control arm therapy: acceptable but may **not** reflect the most **active or preferred** therapy for the enrolled population.
- Guidelines and expert consensus encourage triplet for patients who are chemotherapy-fit and have synchronous high-volume* (SHV) mHSPC.[1,2] **74%** of patients enrolled in CAPItello-281 had SHV disease.

Standard of care options for mHSPC



*High-volume defined as presence of either visceral metastases or ≥ 4 bone metastases with ≥ 1 beyond the vertebral bodies and pelvis.
ADT: androgen deprivation therapy
ARPI: androgen receptor pathway inhibitor
SHV: synchronous (*de novo* metastatic) high-volume
[1]Gillessen S et al. Eur J Cancer. 2023;185:178-215.
[2]NCCN. Version 5.2026; MS 46-47.

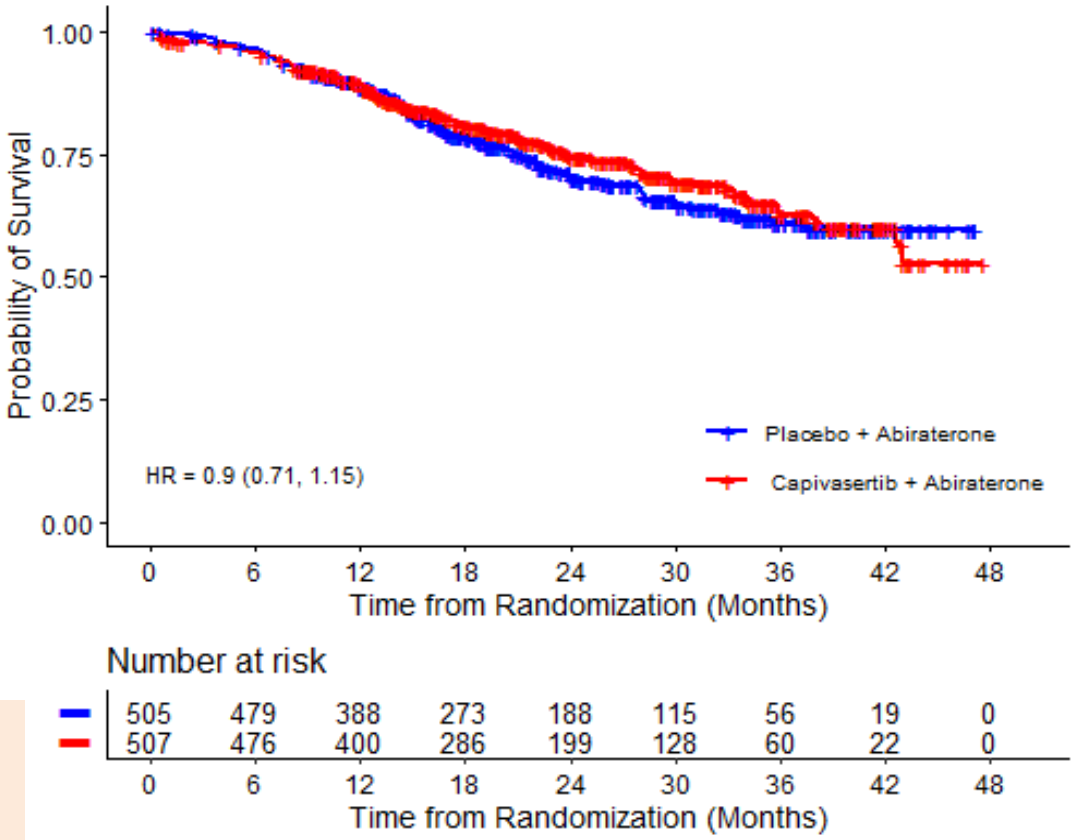
Outline

- FDA review issues
  - Magnitude of improvement in rPFS
  - Lack of supportive data
  - Increased toxicity with combination therapy
- Summary and question for ODAC

Lack of Supportive Data: Overall Survival

	C+AAP N=507	P+AAP N=505
Number of events (%)	129 (25.4)	138 (27.3)
Median, months (95% CI)	NE (43, NE)	NE (NE, NE)
Hazard Ratio (95% CI)[a]	**0.90 (0.71, 1.15)**	
p-value (2-sided)[b]	0.401	

C+AAP: capivasertib + abiraterone + prednisone/prednisolone; P+AAP: placebo + abiraterone + prednisone/prednisolone



No OS benefit at interim analysis (51% information fraction).

No formal power calculation for OS.

Final OS analysis projected to be in Q4 2027 – Q2 2028.

Lack of Supportive Data: Secondary and Exploratory Endpoints

Secondary Endpoint	C+AAP vs P+AAP	
	# of events (%)	HR (95% CI)
Time to first subsequent therapy	192 (37.9) vs 206 (40.8)	**0.91** (0.75, 1.11)
○ Most common subsequent therapy is chemotherapy. ○ Clinical interpretation of delay of subsequent therapy as an efficacy measure is challenging.		
Symptomatic skeletal event-free survival	150 (29.6) vs 176 (34.9)	**0.82** (0.66, 1.02)
○ Results not consistent with a clinically meaningful effect given pain progression results below.		
Time to pain progression	46 (9.1) vs 41 (8.1)	**1.14** (0.75, 1.75)
○ Difficult to interpret due to small number of events.		

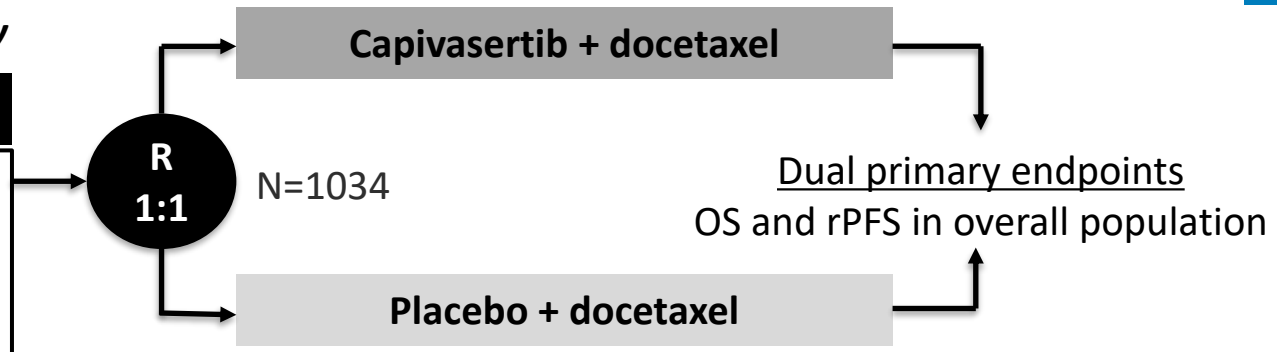
- All secondary endpoint results are considered exploratory only.
- Other exploratory endpoints:
  - Clinical relevance of **Time to PSA progression**, **Time to Castration Resistance** is unclear.
  - **Time to First Subsequent Chemotherapy** is not suitable for evaluating clinical benefit.
- The results of secondary and exploratory endpoints **do not overcome concerns with the uncertain clinical meaningfulness of rPFS results.**

Lack of Supportive Data: Capivasertib in mCRPC (CAPItello-280)

Rationale: docetaxel activates the AKT pathway

Patients with mCRPC

- Received prior ARPI
- No prior chemo
- PTEN status (all-comers)
  - PTEN-proficient: >10% IHC+
  - PTEN-deficient: ≥90% IHC-negative
  - Others=PTEN-unknown



Futility analysis

	Medians: Capivasertib vs Placebo (months)	Hazard ratio (95% CI)
rPFS	8.3 vs 8.3	0.98 (0.84, 1.15); p=0.844
OS	16.7 vs 19.4	1.22 (1.00, 1.49); p=0.055

Source: CAPItello-280 CSR

Trial terminated in April 2025 following IDMC recommendation for both futility and increased deaths.

Lack of Supportive Data: Ipatasertib and Abiraterone in mCRPC

Phase 2 (ASTON MARTIN)	• PTEN-deficient subgroup (≤90% IHC): rPFS HR=0.39 (90% CI: 0.22, 0.70) • Hypothesis-generating given small sample size (n=46) and from a post-hoc subgroup

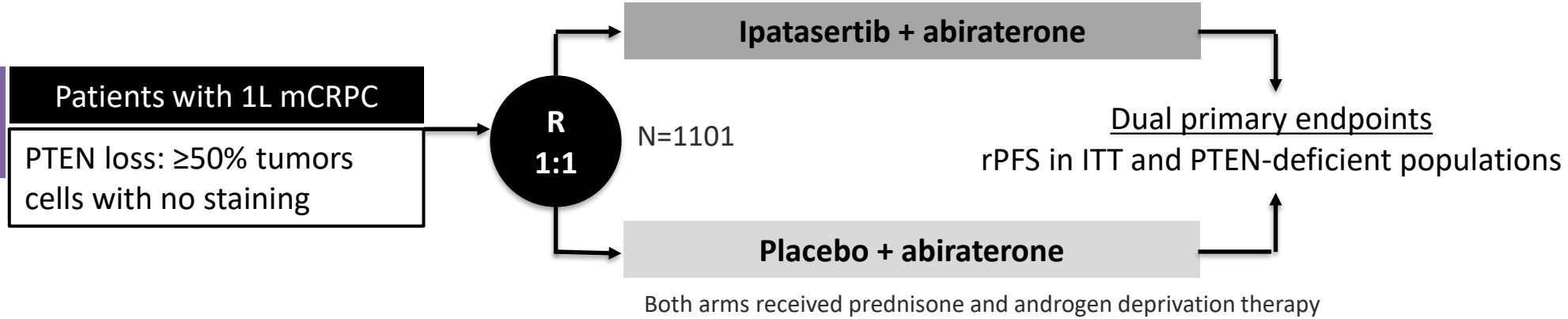
1L: first-line; CI: confidence interval; IHC: immunohistochemistry: radiographic progression-free survival

Lack of Supportive Data: Ipatasertib and Abiraterone in mCRPC

Phase 2 (ASTON MARTIN)

- PTEN-deficient subgroup (≤90% IHC): rPFS HR=0.39 (90% CI: 0.22, 0.70)
- Hypothesis-generating given small sample size (n=46) and from a post-hoc subgroup

Phase 3 IPATential150



Sweeney et al. Lancet 2021; 398(10295):131-142.

1L: first-line; ITT: intent-to-treat; mCRPC: metastatic castration resistant prostate cancer; rPFS: radiographic progression-free survival

Lack of Supportive Data: Ipatasertib and Abiraterone in mCRPC

Phase 2 (ASTON MARTIN)

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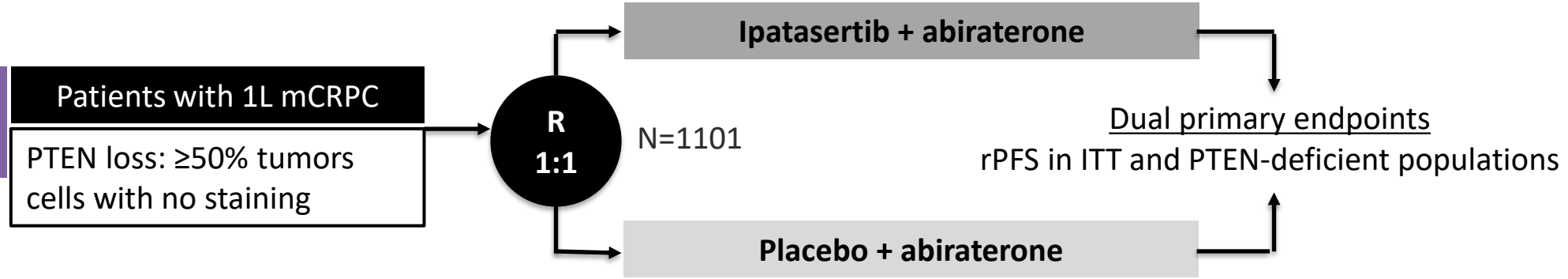


Results (PTEN-Deficient Population [N=521])

Endpoint	Median (months) Ipatasertib vs Placebo	Hazard Ratio (95% CI)
rPFS by Investigator	18.5 vs 16.5	0.77 (0.61, 0.98); p=0.034[1]
OS (final)	36.8 vs 35.8	0.94 (0.76, 1.17); p=0.57

IPATential150 results support FDA's concern about the **clinical meaningfulness** of the added rPFS treatment with addition of **AKT** pathway inhibitor in prostate cancer.

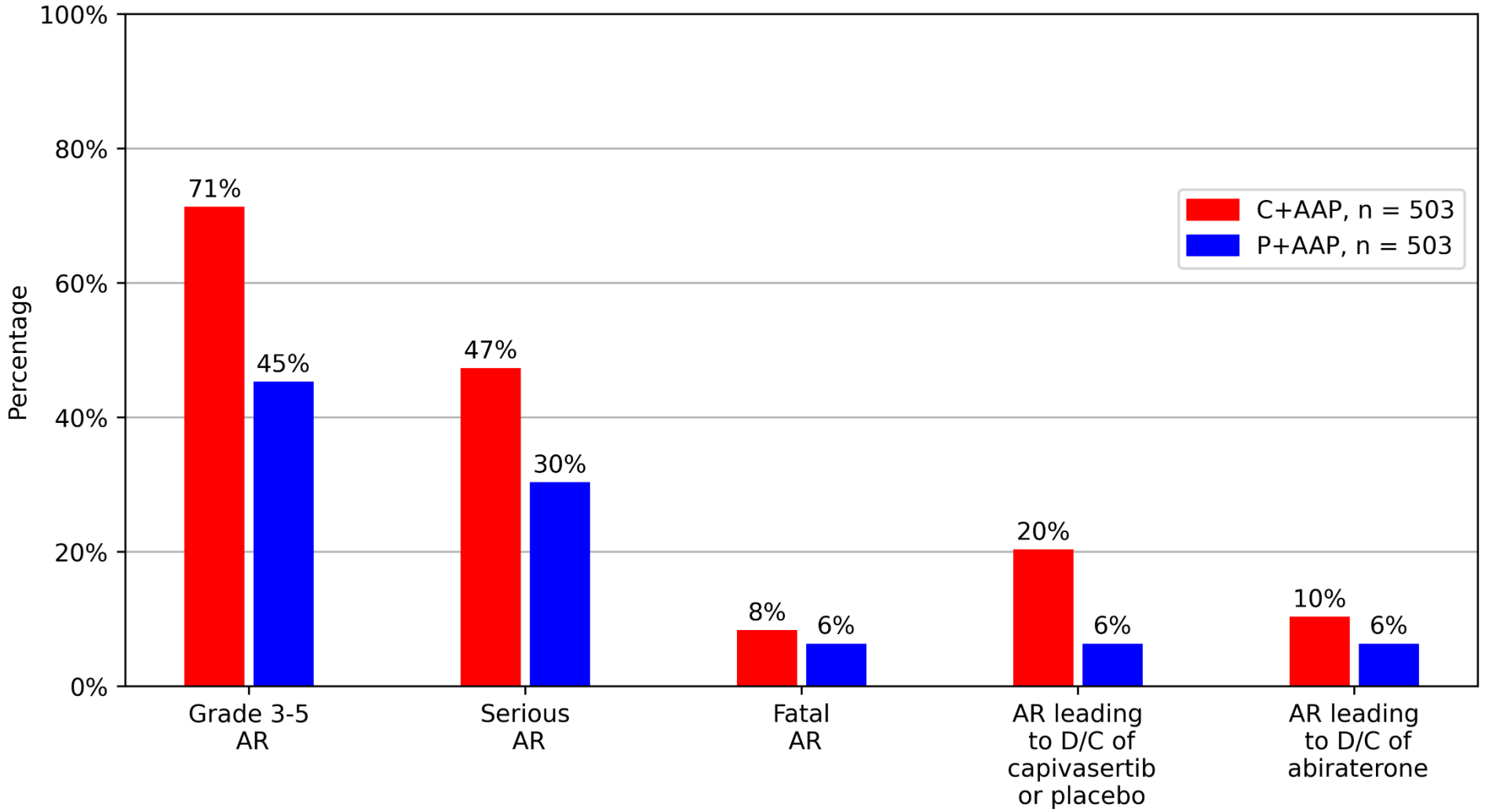
[1], significant at alpha=0.04

Sweeney et al. Lancet 2021; 398(10295):131-142.
deBono et al. Eur Urol 2025; 87(6):672-68.

Outline

- Overview of CAPItello-281 results
- FDA review issues
  - Magnitude of improvement in rPFS
  - Lack of supportive data
  - Increased toxicity with combination therapy
- Summary and question for ODAC

Capivasertib + Abiraterone is Substantially More Toxic Than Placebo + Abiraterone



AR: adverse reaction

More Fatal Adverse Reactions Among Patients Treated with Capivasertib + Abiraterone Than Placebo + Abiraterone

Adverse Reaction (AR) Category	C+AAP N=503	P+AAP N=503
Fatal ARs*	**8%**	6%
Fatal AR with onset in first 3 months of therapy	**2.8%**	1.2%

*Fatal ARs reported in ≥2 patients were sepsis (1.2%), ischemic cerebro-/cardiovascular event (1%), hemorrhage (0.6%), and pneumonia (0.4%). These ARs were also increased in the capivasertib arm in the Grade 3-4 AR analysis.

Early deaths in
- Disease setting where median overall survival is several years; minimal symptoms at baseline
- Trial participants who met strict eligibility criteria at baseline to mitigate risks

AR: adverse reaction; C+AAP: capivasertib + abiraterone + prednisone/prednisolone; P+AAP: placebo + abiraterone + prednisone/prednisolone

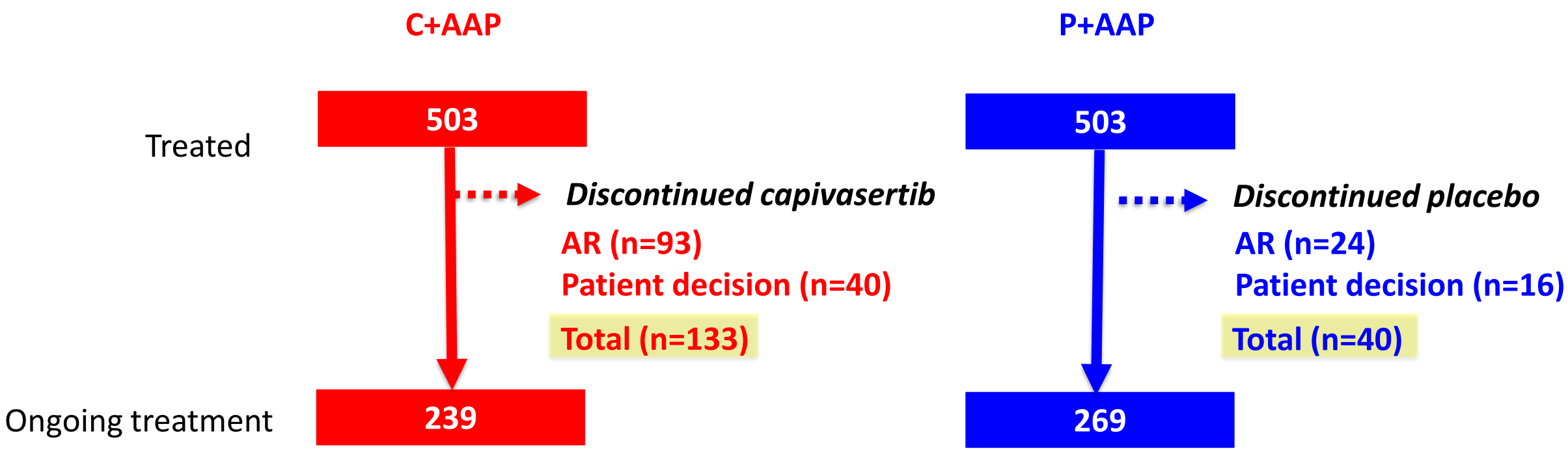
Patient Impact: Early Treatment-Related Deaths

After 10 days of therapy and no diabetes mellitus history:

- 74M developed septic shock from urinary tract infection, **glucose > 1000 mg/dL,** and multi-organ failure. **Death on Day 11.**

- 77M developed drug **rash, glucose 789 mg/dL**, and fever. **Death on Day 23.**

Greater Proportion of Treatment Discontinuations Were Due to Adverse Reaction in Capivasertib Arm



AR: adverse reaction; C+AAP: capivasertib + abiraterone + prednisone/prednisolone; P+AAP: placebo + abiraterone + prednisone/prednisolone

Most Common Adverse Reactions: Increases in Infections, Skin Reactions, Diarrhea, and Hyperglycemia

Event	C+AAP N=503 %	P+AAP N=503 %
Infections	57	44
Skin reactions	53	17
Diarrhea	53	9
Hyperglycemia	51	16
Musculoskeletal pain	27	30
Fatigue	26	18
Anemia	25	14

C+AAP: capivasertib + abiraterone + prednisone/prednisolone;
P+AAP: placebo + abiraterone + prednisone/prednisolone

High-Grade Toxicity Substantially Increased with Addition of Capivasertib

Parameter	C+AAP N=503 %	P+AAP N=503 %
Any Grade 3-4 Adverse Reaction	63	38
Infections	18	6
Skin reactions	17	0.4
Hyperglycemia	15	1
Hypokalemia	10	5
Hypertension	7	9
Diarrhea	7	0.4

Capivasertib: Increased Hyperglycemia Risks in Combination with Abiraterone and Prednisone in mHSPC

Parameter	C+AAP N=503 %	P+AAP N=503 %	CAPItello-291 Capivasertib + Fulvestrant (mBC)
Grade 3-4 hyperglycemia	15%	1%	3%
Diabetic ketoacidosis (DKA)	1.2%	0	0.3%
Required initiation or change in antihyperglycemic medications	44%	14%	12%
Initiated insulin	17%	3%	5%

C+AAP: capivasertib + abiraterone + prednisone/prednisolone;
mBC: metastatic breast cancer; P+AAP: placebo + abiraterone + prednisone/prednisolone

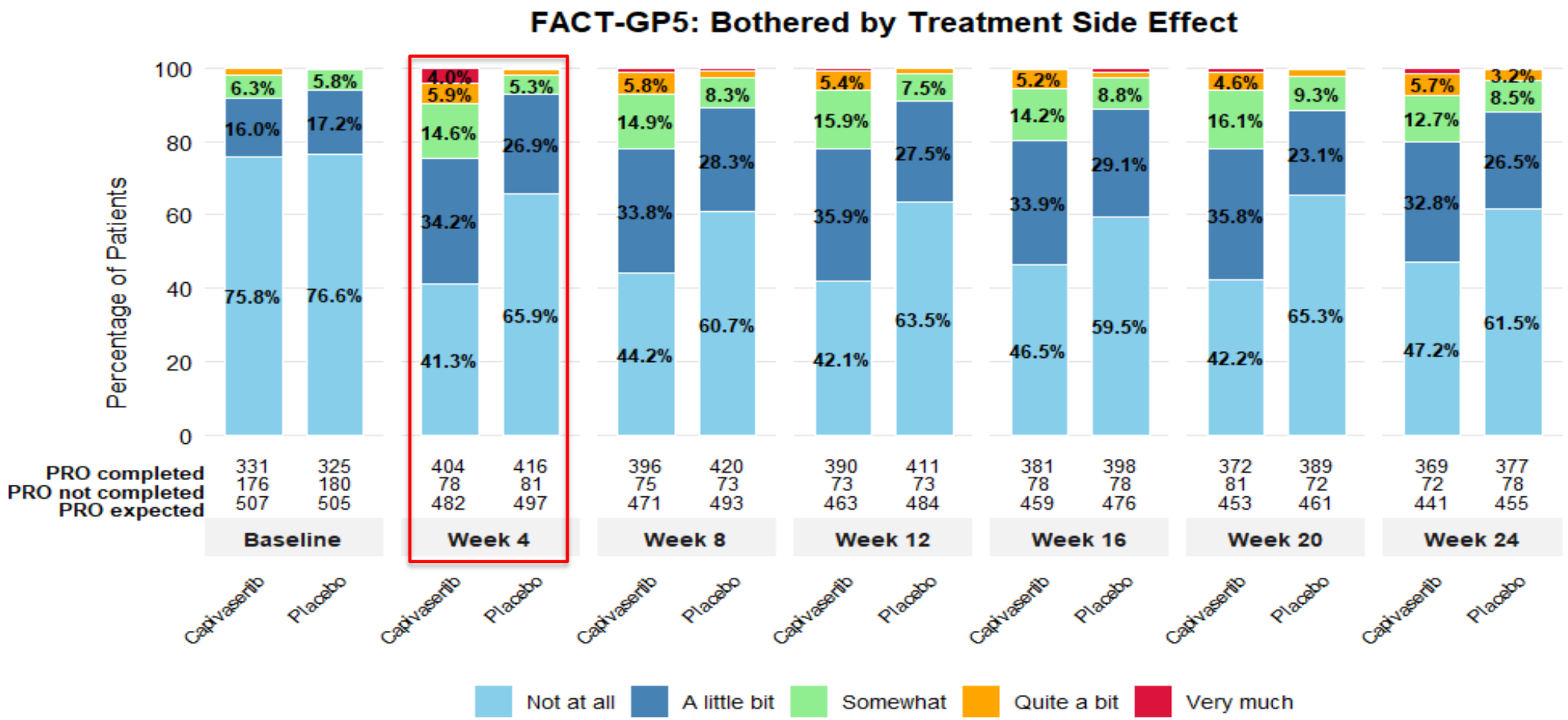
CAPItello-281: Patient-Reported Outcomes (PROs)

- Clinician reported ARs, including grade 3 or higher ARs, were more frequently observed in the capivasertib arm.
- Patient-reported symptoms and overall side-effect bother were assessed using PRO-CTCAE and FACT-GP5, respectively.
- Patients reported worse patient-reported diarrhea and skin symptoms in the capivasertib arm:
  - Example: In the last 7 days, how often did you have loose or watery stools?

    At Week 8: 38% in the capivasertib and 75% in the placebo arm reported “never.”
  - Higher rates of overall side-effect bother throughout treatment.
- PRO results support the clinician-reported adverse reaction findings.

Functional Assessment of Cancer Therapy (FACT) - Item GP5: FACT-GP5
Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events: PRO-CTCAE

CAPItello-281: Patients Treated with Capivasertib Report Greater Side-Effect Bother Throughout Treatment



Summary: Safety and Tolerability Concerns Challenge Favorable Benefit-Risk Assessment

Clinician-Reported Toxicity

- **High** rates of **serious, life-threatening** toxicities
- Severe complications (diabetic ketoacidosis, sepsis)

Patient-Reported Outcomes

- PROs (diarrhea, skin symptoms, overall side effect bother) support clinician-reported ARs and further demonstrate tolerability concerns with capivasertib.

Clinical Context

- mHSPC **unique** from breast cancer context
- Drug **discontinuation** before PD → are the efficacy results **clinically meaningful**?
- Other available therapy: **shorter duration** and qualitatively distinct ARs

ARs: adverse reactions; mHSPC: metastatic hormone-sensitive prostate cancer; PD: progression of disease; PROs: patient-reported outcomes; rPFS: radiographic progression-free survival

Outline

- Overview of CAPItello-281 results
- FDA review issues
  - Magnitude of improvement in rPFS
  - Lack of supportive data
  - Increased toxicity with combination therapy
- Summary and question for ODAC

Summary: Capivasertib with Abiraterone and Prednisone Benefit:Risk May be Unfavorable

Efficacy	Increased Toxicity	Clinical Context
• Statistically significant rPFS is modest with **unclear clinical meaningfulness**	• **Higher rates** of serious and life-threatening toxicities, and healthcare utilization in the capivasertib arm	• Effective backbone: even patients not benefiting from capivasertib may be exposed to it for a long time • **Early**, PTEN-deficient, metastatic disease setting

The modest rPFS benefit does not appear to outweigh the substantial toxicity.

OS: overall survival; rPFS: radiographic progression-free survival

Question for ODAC

Based on the CAPItello-281 results, does the benefit of adding capivasertib to abiraterone and prednisone outweigh the risk for the proposed indication?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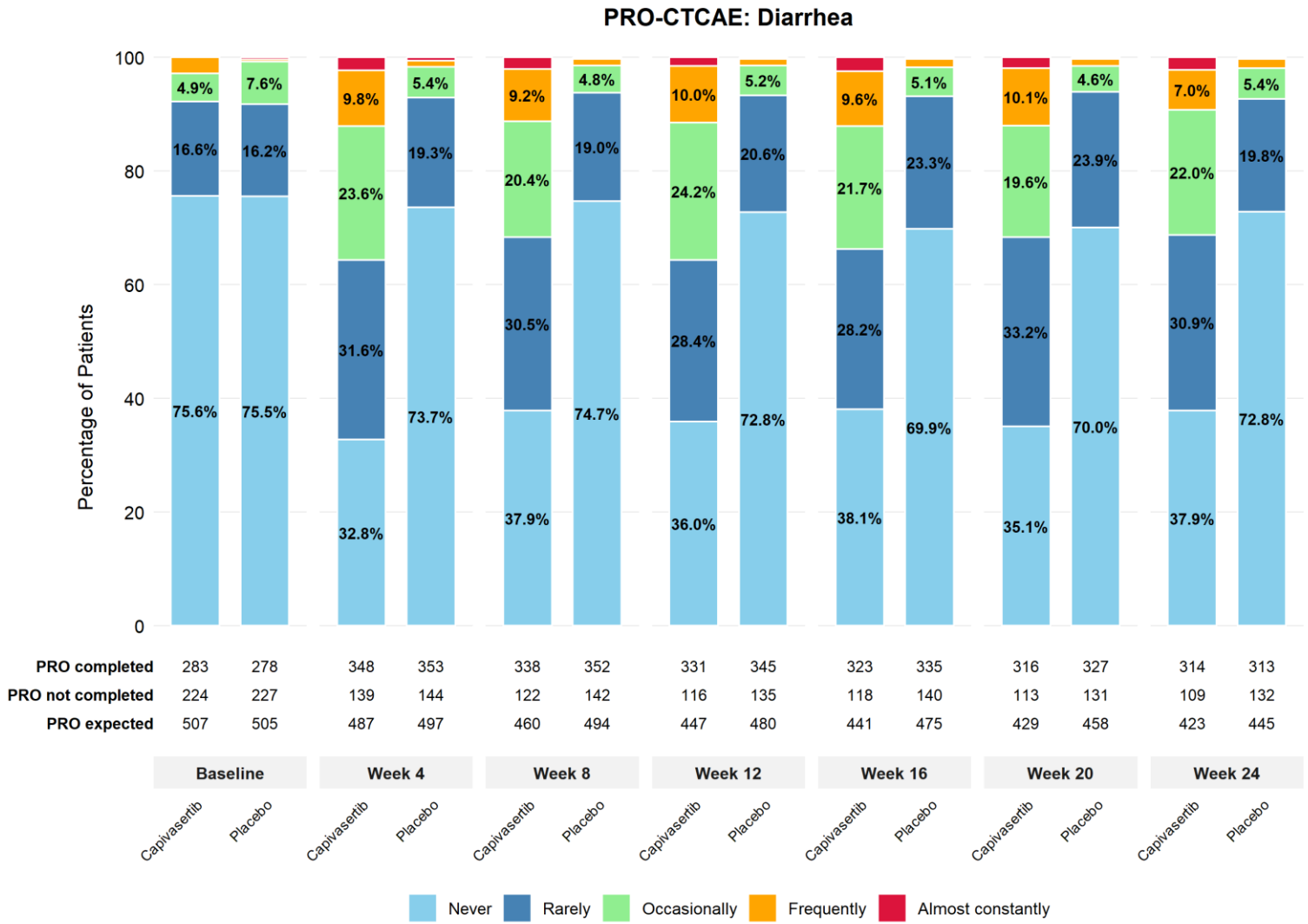
ADMINISTRATION

BACKUP SLIDES SHOWN

PTEN score cutoff

Endpoint	rPFS by INV		OS	
PTEN loss >=90 (ITT)	N=1012		N=1012	
Median	33 vs 26		NE vs NE	
HR	0.81 (0.66, 0.98)		0.9 (0.71, 1.15)	
PTEN loss >=95	Yes (n=814, 80%)	No (n=198, 20%)	Yes	No
median	33 vs 23	38 vs NE	NE	43 vs NE
HR	0.77 (0.62, 0.95)	1.25 (0.77, 2.05)	0.8 (0.62, 1.05)	1.72 (0.93, 3.30)
PTEN loss=100	Yes (n=331, 33%)	No (n=681,67%)	Yes	No
median	34 vs 22	33 vs 29	NE	NE
HR	0.70 (0.49, 0.98)	0.92 (0.72, 1.17)	0.76 (0.51, 1.13)	1 (0.74, 1.36)

These findings are hypothesis generating only


PRO-CTCAE: Diarrhea
Percentage of Patients
100
80
60
40
20
0
4.9%
16.6%
75.6%
7.6%
16.2%
75.5%
9.8%
23.6%
31.6%
32.8%
5.4%
19.3%
73.7%
9.2%
20.4%
30.5%
37.9%
4.8%
19.0%
74.7%
10.0%
24.2%
28.4%
36.0%
5.2%
20.6%
72.8%
9.6%
21.7%
28.2%
38.1%
5.1%
23.3%
69.9%
10.1%
19.6%
33.2%
35.1%
4.6%
23.9%
70.0%
7.0%
22.0%
30.9%
37.9%
5.4%
19.8%
72.8%
PRO completed 283 278 348 353 338 352 331 345 323 335 316 327 314 313
PRO not completed 224 227 139 144 122 142 116 135 118 140 113 131 109 132
PRO expected 507 505 487 497 460 494 447 480 441 475 429 458 423 445
Baseline
Week 4
Week 8
Week 12
Week 16
Week 20
Week 24
Capivasertib
Placebo
Never
Rarely
Occasionally
Frequently
Almost constantly