Baseline Characteristics of PSMA-PET Positive and Negative Patients with High-Risk Biochemical Recurrence (BCR) After Radical Prostatectomy (RP) in the Ongoing Phase 3 PRIMORDIUM Study

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Presented by B. Hadaschik at ASCO Genitourinary Cancers Symposium, January 25, 2024; San Francisco, California, USA

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KEY TAKEAWAY

Almost half of the patients with high-risk BCR without distant metastases on conventional imaging are positive for locoregional lesions ± distant metastases by PSMA-PET despite median PSA of 0.5 ng/mL.

BCR, biochemical recurrence; PSA, prostate-specific antigen; PSMA-PET, positron emission tomography of radiolabeled prostate-specific membrane antigen.

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CONCLUSIONS

- The PRIMORDIUM study is still recruiting participants; at the data cutoff date, 198 patients with high-risk BCR were enrolled
- 56% of patients had negative PSMA-PET documented at a median of 26 months after RP and a median PSA of 0.35 ng/mL
- 44% of patients had positive PSMA-PET documented at a median of 39 months after RP and a median PSA of 0.51 ng/mL; among these patients with locoregional lesion(s), 10% also had distant lesion(s) on PSMA-PET
- Limitation: baseline characteristics presented in this initial analysis may not reflect the full study population

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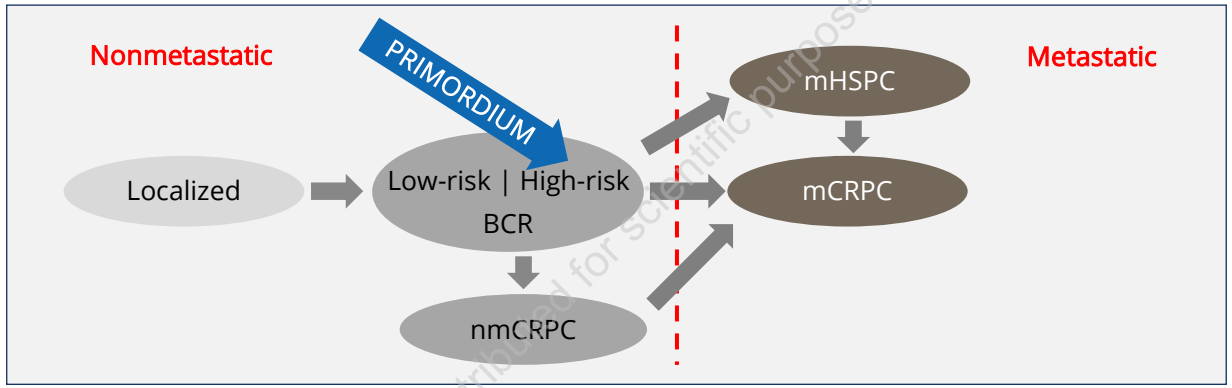
INTRODUCTION

- PSMA-PET is more sensitive and specific than conventional imaging for the detection of lesions in patients with BCR prostate cancer[1]
- The PRIMORDIUM study (NCT04557059) uses PSMA-PET to evaluate the intensification of LHRHa + radiotherapy with apalutamide for patients with high-risk BCR after RP

FIGURE 1: PRIMORDIUM location in prostate cancer pathway



BCR, biochemical recurrence; mHSPC, metastatic hormone-sensitive prostate cancer; mCRPC, metastatic castration-resistant prostate cancer; nmCRPC, nonmetastatic castration-resistant prostate cancer; PSMA-PET, positron emission tomography of radiolabeled prostate-specific membrane antigen; RP, radical prostatectomy.

1. Fanti S, Goffin K, Hadaschik BA, et al. Eur J Nucl Med Mol Imaging. 2021;48(2):469-476.

Presented by B. Hadaschik at ASCO Genitourinary Cancers Symposium, January 25, 2024; San Francisco, California, USA

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METHODS

- Full methods were presented previously at ESMO 2021[2]
- PRIMORDIUM includes two cohorts:
  - Interventional cohort (FIGURE 2): PSMA-PET positive patients (≥1 locoregional lesion ± metastasis); randomized, open-label treatment (data are presented as aggregated)
  - Observational cohort (FIGURE 3): PSMA-PET negative patients (no lesion); prospective follow-up, routine clinical practice
- All patients are nonmetastatic by conventional imaging at screening
- The data cutoff date for this analysis was 12 January 2023

PSMA-PET, positron emission tomography of radiolabeled prostate-specific membrane antigen.

2. Hadaschik BA, Fanti S, Ost P, et al. Annals Oncol. 2021;32(Suppl5):S676-S677.

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METHODS

FIGURE 2: Interventional Cohort (~412 patients to achieve ~192 events)

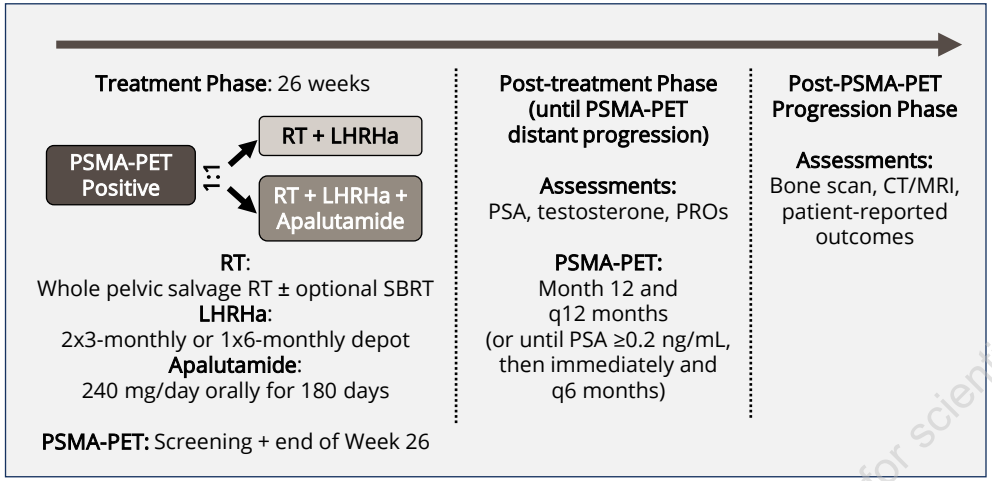
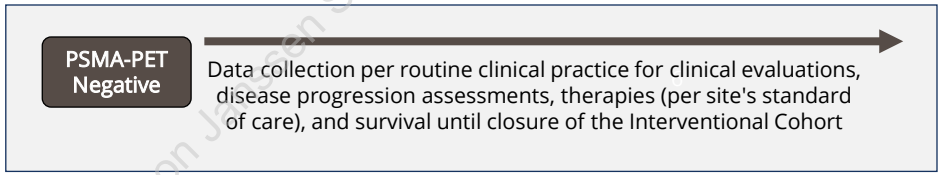


FIGURE 3: Observational cohort (~200 patients)



CT, computed tomography; LHRHa, luteinizing hormone-releasing hormone agonist; MRI, magnetic resonance imaging; PROs, patient-reported outcomes; PSA, prostate-specific antigen; PSMA-PET, positron emission tomography of radiolabeled prostate-specific membrane antigen; RT, radiotherapy; SBRT, stereotactic whole-body RT.

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RESULTS

- TABLE 1 summarizes baseline characteristics for the interventional cohort (as of 12 Jan 2023)
- TABLE 2 summarizes baseline characteristics for the observational cohort (as of 12 Jan 2023)
- TABLE 3 summarizes patients enrolled by country (as of 12 Jan 2023)
- FIGURE 4 shows countries with active sites (as of 31 Dec 2023)

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RESULTS

TABLE 1: Interventional Cohort

Characteristic	N=88
Age, years	69 [65; 74]
Race	
White	79 (89.8%)
Black/African American	1 (1.1%)
Native Hawaiian or other Pacific Islander	1 (1.1%)
Multiple or not reported	7 (8.0%)
Weight, kg	86.5 [79.0; 98.5]
Height, cm	175 [170; 181]
Months from RP to BCR	28.5 [14.7; 52.6]
Months from RP to PSMA-PET (N=87)	39.4 [21.5; 66.0]
PSA value closest to PSMA-PET, ng/mL	0.51 [0.30; 1.30]

Characteristic	N=88
Total Gleason score after RP	
<7	6 (6.8%)
7	49 (55.7%)
3+4	26 (53.1%)[a]
4+3	23 (46.9%)[a]
>7	32 (36.4%)
Unknown	1 (1.1%)
Extended lymph node dissection (N=87)	58 (66.7%)
ECOG performance status	
0	84 (95.5%)
1	4 (4.5%)
PSA doubling time	
≤6 months	43 (48.9%)
>6-12 months	39 (44.3%)
>12 months (includes values ≤0)	6 (6.8%)
PSMA-PET findings	
Any locoregional lesion	88 (100.0%)
Any distant metastasis	9 (10.2%)

Data are shown as n (%) or median [interquartile range].
PSA, prostate-specific antigen; PSMA-PET, positron emission tomography of radiolabeled prostate-specific membrane antigen; RP, radical prostatectomy.
[a]% of patients with Gleason score=7

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TABLE 2: Observational Cohort

Characteristic	N=110
Age, years	66.5 [61; 72]
Race	
White	108 (98.2%)
Not reported	2 (1.8%)
Weight, kg	86.0 [78.0, 95.4]
Height, cm	174 [170; 180]
Months from RP to BCR	17.9 [10.5; 36.8]
Months from RP to PSMA-PET	26.0 [16.7; 45.6]
PSA closest to PSMA-PET, ng/mL (N=109)	0.35 [0.24; 0.60]

Characteristic	N=110
Total Gleason score after RP	
<7	9 (8.2%)
7	59 (53.6%)
3+4	36 (60.0%)[a]
4+3	24 (40.0%)[a]
>7	41 (37.3%)
Unknown	1 (0.9%)
Extended lymph node dissection	64 (58.2%)
ECOG performance status	
0	96 (87.3%)
1	14 (12.7%)
PSA doubling time (N=109)	
≤6 months	51 (46.8%)
>6-12 months	44 (40.4%)
>12 months (includes values ≤0)	14 (12.8%)

Data are shown as n (%) or median [interquartile range].
PSA, prostate-specific antigen; PSMA-PET, positron emission tomography of radiolabeled prostate-specific membrane antigen; RP, radical prostatectomy.
[a]% of patients with Gleason score=7

This study is not designed to compare results across interventional and observational cohorts.

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TABLE 3: Number of patients enrolled by 12 January 2023, by country

Country	Interventional Cohort	Observational Cohort
Australia	3	7
Austria	1	2
Belgium	1	3
Brazil	1	1
Czech Republic	5	3
Denmark	16	9
Hungary	0	2
Italy	6	7
Lebanon	3	0
Poland	9	26
Portugal	3	6
Russian Federation	9	5
Slovakia	4	6
Spain	14	18
Sweden	3	2
Turkey	10	13

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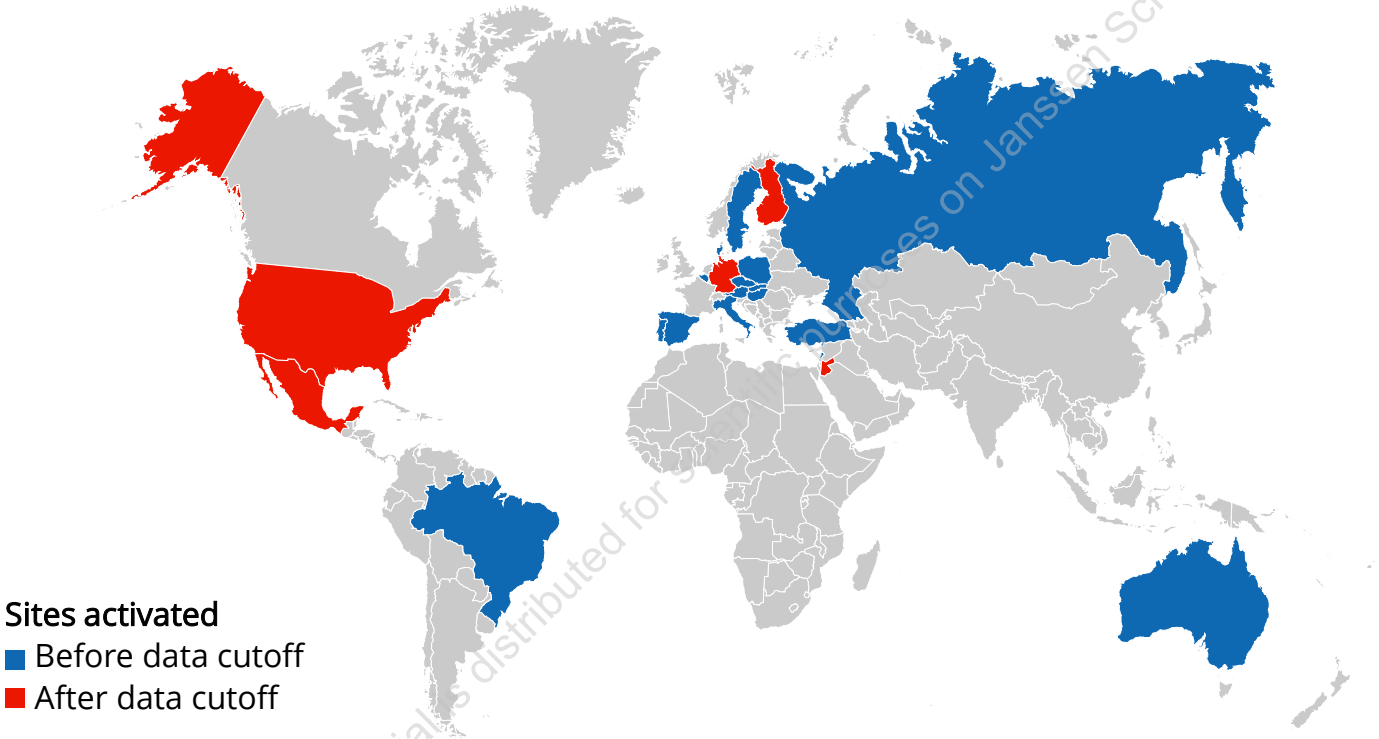
FIGURE 4: Countries with active sites as of 31 December 2023



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DISCLOSURES:

Hadaschik: advisory board (Janssen, Bayer, ABX, Lightpoint, Amgen, MSD, Pfizer, Novartis), invited speaker (Astellas, Janssen R&D), institutional royalties (Uromed), institutional funding (AAA/Novartis, Bristol-Myers Squibb, German Research Foundation), advisory role (German Cancer Aid), leadership role/speaker (DKG AUO). Mottet: advisory board (Astellas, Bayer, Sanofi), invited speaker (Astellas, Janssen, Bayer, IPSEN, Sanofi, Astra Zeneca, Riley's lab), lectures (ISMAR health care), leadership role/prostate cancer guideline chair (EAU). Ost: consultancy (Ferring, Janssen, Bayer), research grant (MSD, Varian, Ferring). de Nunzio: consultancy (Ferring, IBSA, Janssen, PierreFabre, Sanofi, Omegapharm). Tunariu: advisory board (Janssen), invited speaker (Janssen). Zaucha: invited speaker (Bristol-Myers Squibb, Novartis, Ipsen), principal investigator (Bristol-Myers Squibb, Astra Zeneca, Ipsen, Roche, Janssen). Brasso: research (Janssen). Osman-Garcia: advisory board (Janssen, Bayer), invited speaker (Astellas, Janssen, Ipsen, Bayer); research (Janssen). Tural: research (Janssen). Lukac: consultancy (Janssen). Stitou: Janssen employee and shareholder. Pissart: Janssen employee and shareholder. Efficace: Janssen employee and shareholder. Fanti: consultancy (AAA, Astellas, Janssen, Sanofi, GE, Bayer, Amgen, IBA, Novartis, Telix)

ACKNOWLEDGMENTS:

The authors acknowledge the dedicated efforts of the investigational sites contributing to the study and the patients who are allowing collection of their data. The authors also acknowledge Belen Liebana, Henrieke de Bruin, Lada Mitchell, Tan Dinh, and Laurent Antoni (Janssen employees) and their respective teams responsible in study implementation, data management, statistics & programming, regulatory affairs, and medical affairs. This work was funded by Janssen Pharmaceutica NV. Jonathan Latham, PharmaScribe, LLC, provided editorial assistance.

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