



NUBEQA[®] (darolutamide)

Important Information for
Formulary Decision Makers



NUBEQA[®]
(darolutamide) 300 mg
tablets



Agenda

- // Prostate Cancer and Non-Metastatic Castration-Resistant Prostate Cancer
- // NUBEQA® (darolutamide)
- // Assisting Patients With Access to NUBEQA

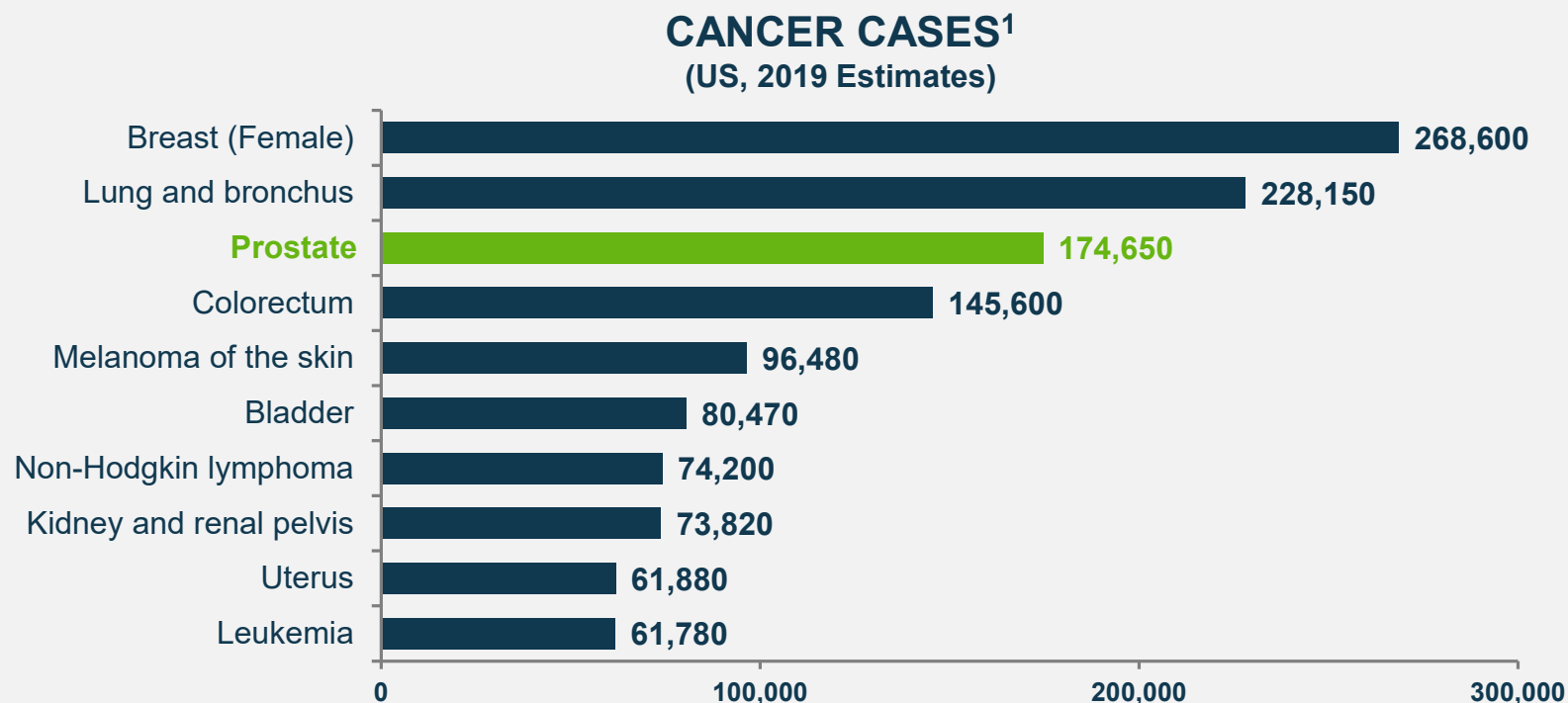


Prostate Cancer and Non-Metastatic Castration-Resistant Prostate Cancer

Landscape Overview



Prostate Cancer Is One of the Most Commonly Occurring Cancers Among Men in the United States

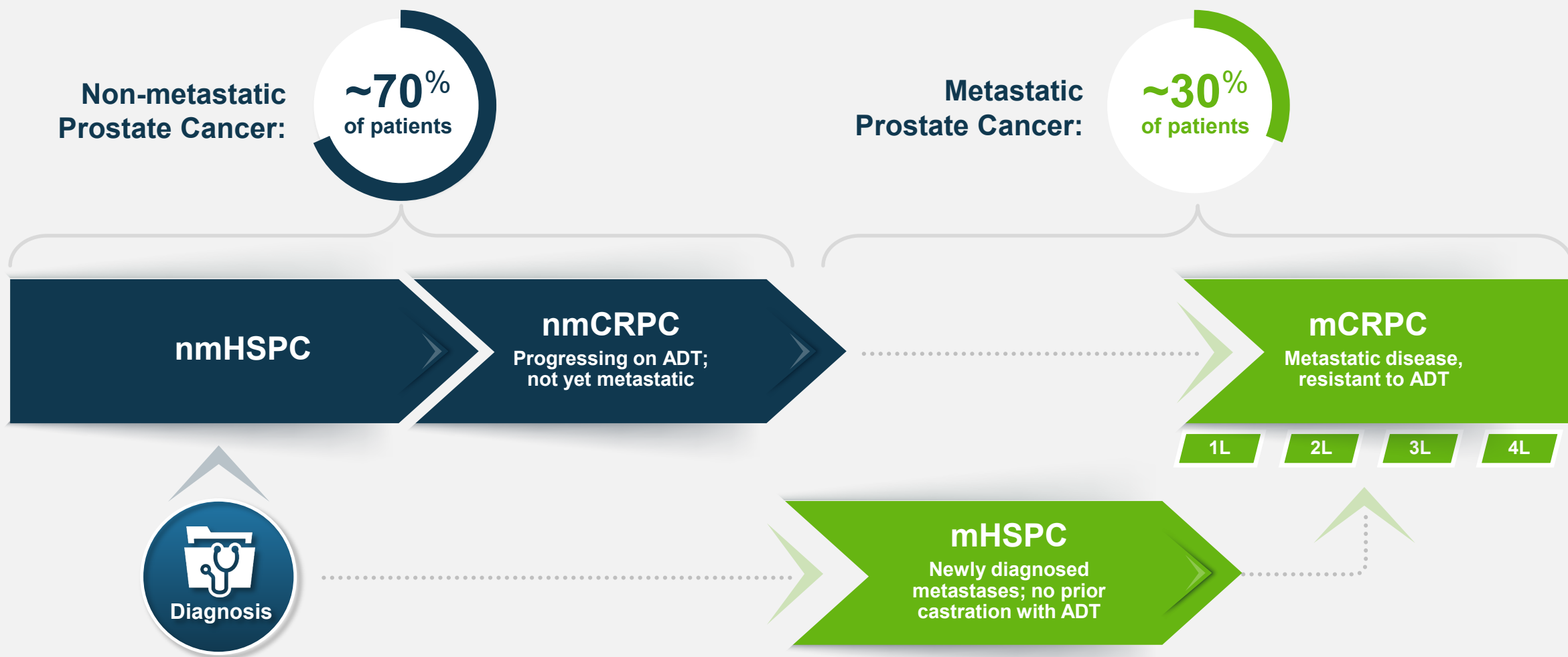


Prostate cancer is a leading cause of cancer-related mortality in men²

~31,620 prostate cancer-related deaths are projected for the US in 2019¹



Diagnosis Can Occur at Different Stages of the Disease and Progress Through Different Pathways^{1,2}



ADT=androgen deprivation therapy; mCRPC=metastatic castration-resistant prostate cancer; nmCRPC=non-metastatic castration-resistant prostate cancer; mHSPC=metastatic hormone-sensitive prostate cancer; nmHSPC=non-metastatic hormone-sensitive prostate cancer.

References: 1. National Cancer Institute. <https://www.ncbi.nlm.nih.gov/books/NBK66036>. Accessed July 3, 2019. 2. National Comprehensive Cancer Network website. http://www.nccn.org/professionals/physician_gls/f_guidelines.asp. Accessed July 3, 2019.



The Majority of Patients With Prostate Cancer Have Non-Metastatic Disease, Which May Lead to Progression

- The majority of patients have **non-metastatic**, earlier phase disease¹
- However, patients may become treatment resistant and progress from being **hormone-sensitive to castration-resistant** within **2–3 years** of ADT initiation²
- Patients with nmCRPC are at **risk of progression** with **33% to 46%** chance of developing bone metastasis at 2 years^{3,4}

➤ **Metastases** may lead to increased burden of illness for both patients and the healthcare system⁵

➤ **nmCRPC** offers a potential therapeutic window where the goal is delaying the development of distant metastases⁶

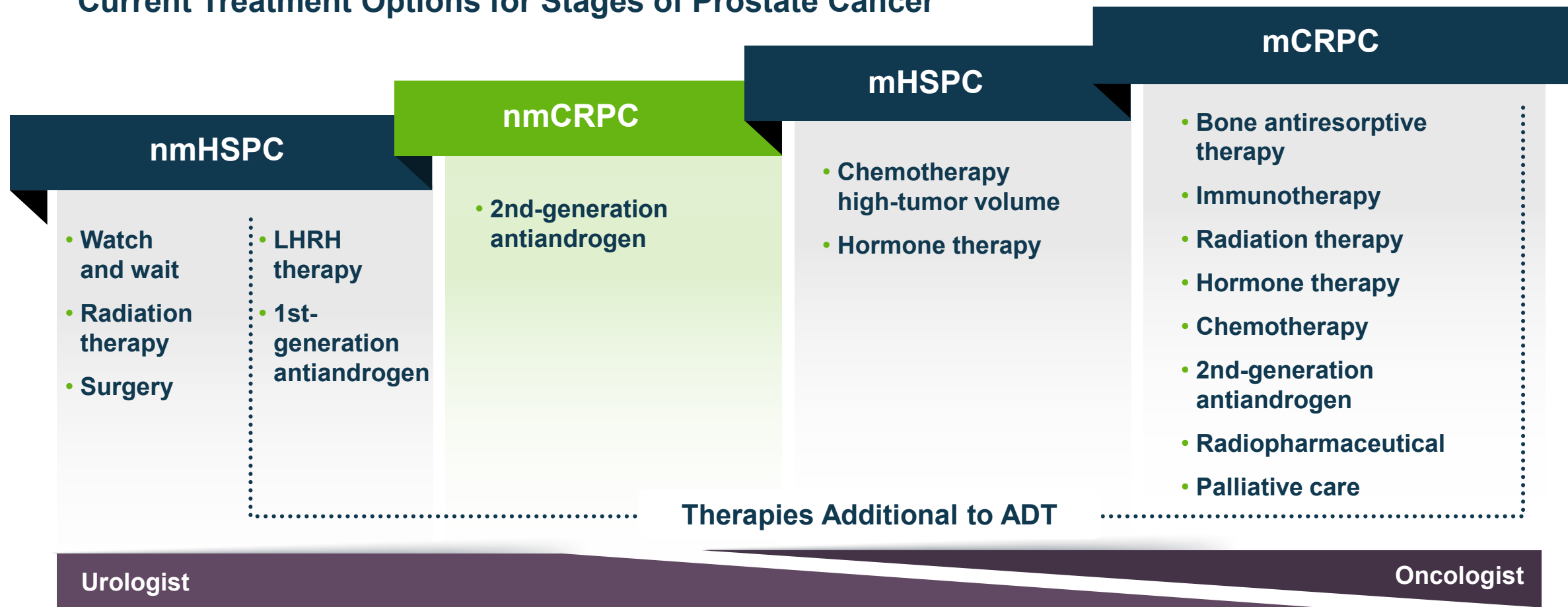
ADT=androgen deprivation therapy; nmCRPC=non-metastatic castration-resistant prostate cancer.

References: 1. Liede A et al. *ESMO Open*. 2016. doi:10.1136/esmoopen-2016-000047. 2. Chandrasekar T et al. *Transl Androl Urol*. 2015;4(3):365-380. 3. Smith MR et al. *Cancer*. 2011;117(10):2077-2085. 4. Tombal B. *Ann Oncol*. 2012;23(suppl 10):x251-x258. 5. Jayasekera J et al. *PharmacoEconomics*. 2014;32:173-191. 6. Fizazi K et al. *Expert Rev Anticancer Ther*. 2015;15(9):1007-1017.



Patients With nmCRPC Need Treatment Options That Delay Progression to Metastatic Disease

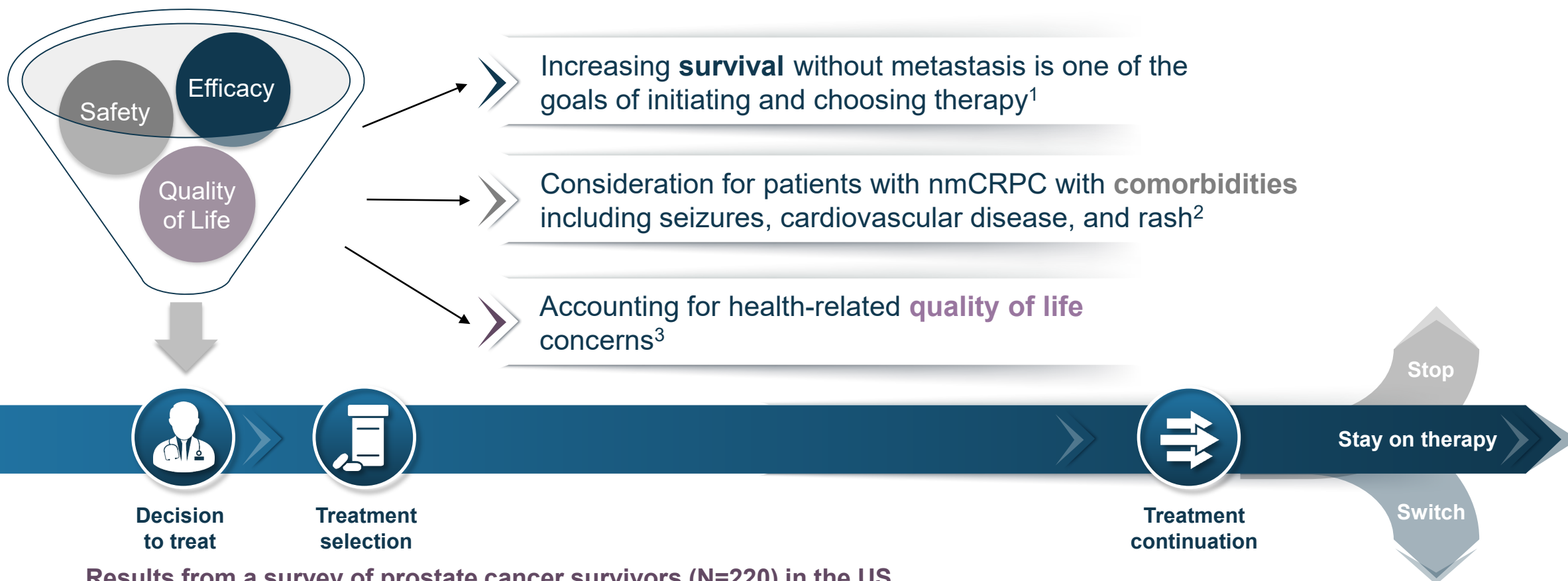
Current Treatment Options for Stages of Prostate Cancer



ADT=androgen deprivation therapy; LHRH=luteinizing hormone-releasing hormone; mCRPC=metastatic castration-resistant prostate cancer; mHSPC=metastatic hormone-sensitive prostate cancer; nmCRPC=non-metastatic castration-resistant prostate cancer; nmHSPC=non-metastatic hormone-sensitive prostate cancer.

Reference: National Comprehensive Cancer Network website. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 3, 2019.

Efficacy, Safety and Quality of Life Are Important Factors in Treatment Decision-Making for Patients¹



Results from a survey of prostate cancer survivors (N=220) in the US.

Patients cite disease progression (80%), disease recurrence (76%), quality of life (70%), and side effects of treatment (62%) as concerns about their disease experience^{1*}

nmCRPC=non-metastatic castration-resistant prostate cancer.

References: 1. Cancer Support Community website. https://www.cancersupportcommunity.org/sites/default/files/uploads/our-research/2017_Report/the_prostate_specialty_report_7-10.pdf. Accessed July 3, 2019. 2. Alpajaro SIR et al. *Prostate Cancer Prostatic Dis.* 2019;22(1):16-23. 3. Foucher Y et al. *Health and Quality of Life Outcomes.* 2018;16:40. doi:10.1086/s12955-018-0870-6.

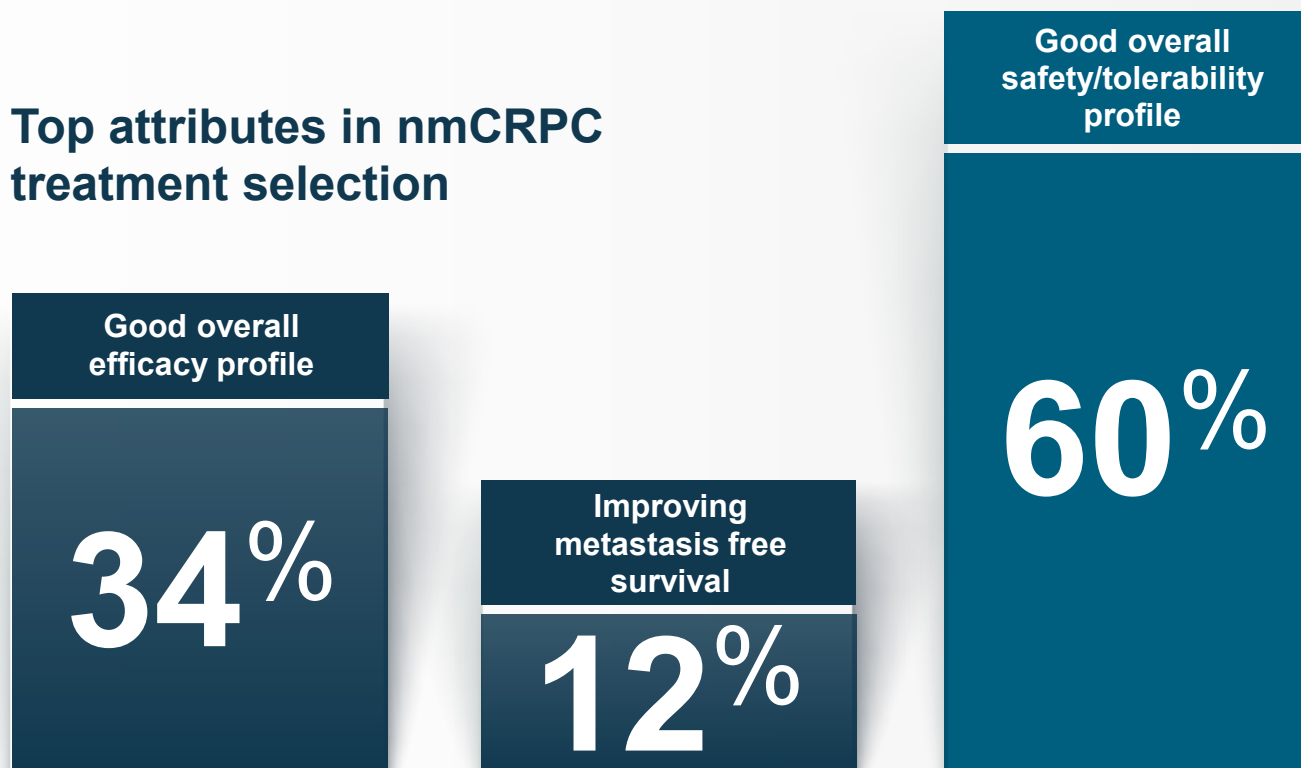


Oncologists and Urologists Indicate the Significance of Safety and Tolerability in Treatment Choice

Bayer Global Survey Result

Through unaided mentions by oncologists and urologists (n=216)

Top attributes in nmCRPC treatment selection



nmCRPC=non-metastatic castration-resistant prostate cancer.

Reference: Data on File, Bayer HealthCare, 2018.

NUBEQA[®] (darolutamide)

An androgen receptor inhibitor for the treatment of non-metastatic castration-resistant prostate cancer



NUBEQA® (darolutamide): Approved by the FDA on 7/30/2019¹



- **NUBEQA® (darolutamide):** an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer²
- NUBEQA will be distributed through an **extensive specialty pharmacy network**
- NUBEQA is available in bottles of **120 tablets each**, with a per-tablet dose of 300 mg. The NDC is 50419-395-01²

FDA=US Food and Drug Administration; NDC=national drug code

References: 1. Bayer website. <https://www.bayer.us/en/newsroom/press-releases/article/?id=123336>. Accessed July 31, 2019. 2. NUBEQA [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019.

Please see the Important Safety Information throughout and full Prescribing Information for NUBEQA available at this presentation.


NUBEQA®
(darolutamide) 300 mg
tablets

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NUBEQA® (darolutamide) Important Safety Information



IMPORTANT SAFETY INFORMATION

Embryo-Fetal Toxicity: Safety and efficacy of NUBEQA have not been established in females. NUBEQA can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception during treatment with NUBEQA and for 1 week after the last dose.

Adverse Reactions:

Serious adverse reactions occurred in 25% of patients receiving NUBEQA and in 20% of patients receiving placebo. Serious adverse reactions in $\geq 1\%$ of patients who received NUBEQA were urinary retention, pneumonia, and hematuria. Overall, 3.9% of patients receiving NUBEQA and 3.2% of patients receiving placebo died from adverse reactions, which included death (0.4%), cardiac failure (0.3%), cardiac arrest (0.2%), general physical health deterioration (0.2%), and pulmonary embolism (0.2%) for NUBEQA.

Adverse reactions occurring more frequently in the NUBEQA arm ($\geq 2\%$ over placebo) were fatigue (16% vs. 11%), pain in extremity (6% vs. 3%) and rash (3% vs. 1%).

Clinically significant adverse reactions occurring in $\geq 2\%$ of patients treated with NUBEQA included ischemic heart disease (4.0% vs. 3.4% on placebo) and heart failure (2.1% vs. 0.9% on placebo).

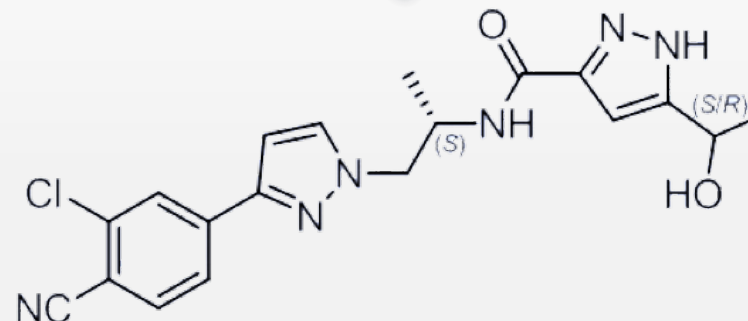


NUBEQA® (darolutamide) Mechanism of Action



- NUBEQA is an AR inhibitor
- NUBEQA competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription
- A major metabolite, keto-darolutamide, exhibited similar in vitro activity to NUBEQA. In addition, NUBEQA functioned as a PR antagonist in vitro (approximately 1% activity compared to AR)
- NUBEQA decreased prostate cancer cell proliferation in vitro and tumor volume in mouse xenograft models of prostate cancer

NUBEQA
Structural
Formula



The chemical name of NUBEQA is N-[(2S)-1-[3-(3-chloro-4-cyanophenyl)-1H-pyrazol-1-yl]propan-2-yl]-5-[(1S)-1-hydroxyethyl]-1H-pyrazole-3-carboxamide, with a molecular weight of 398.85 and a molecular formula of $C_{19}H_{19}ClN_6O_2$.

AR=androgen receptor; PR=progesterone receptor.

Reference: NUBEQA [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019.

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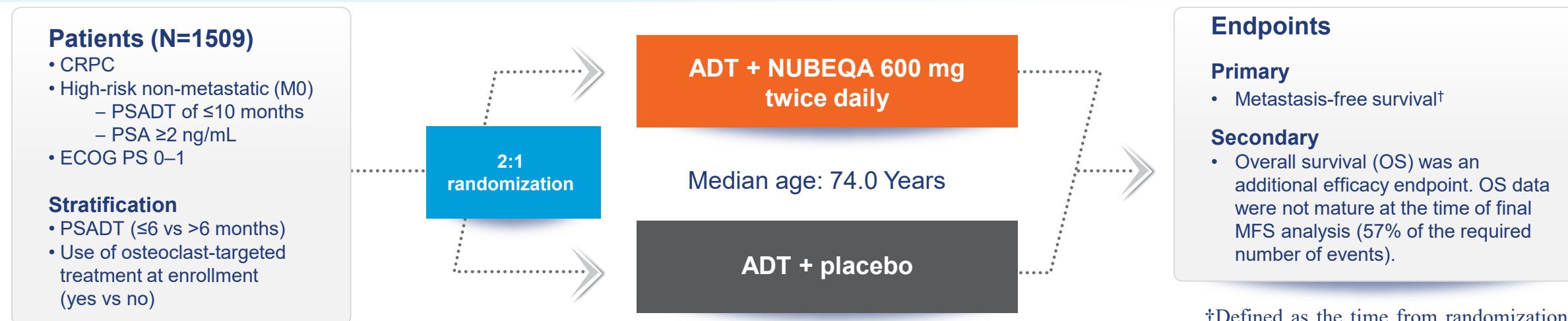
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ARAMIS Phase 3 Trial^{1,2}



ARAMIS (Androgen Receptor inhibiting Agent for Metastatic-free Survival, NCT02200614) is a global,* randomized, double-blind, placebo-controlled phase 3 trial investigating the safety and efficacy of NUBEQA[®] (darolutamide) in men with nmCRPC at high risk for metastasis



Treatment continued until radiographic disease progression as assessed by CT, MRI, 99mTc bone scan by BICR, unacceptable toxicity or withdrawal. All patients received a GnRH analog concurrently or had a bilateral orchiectomy.

[†]Defined as the time from randomization to the time of first evidence of BICR-confirmed distant metastasis or death from any cause within 33 weeks after the last evaluable scan, whichever occurred first.

ADT=androgen deprivation therapy; BICR=blinded independent central review; bid=twice a day; CRPC=castration-resistant prostate cancer; CT=computed tomography; ECOG GnRH=gonadotropin-releasing hormone; PS=Eastern Cooperative Oncology Group Performance Status; MRI=magnetic resonance imaging; nmCRPC=non-metastatic castration-resistant prostate cancer; OS=overall survival; PSA=prostate-specific antigen; PSADT=prostate-specific antigen doubling time; SSE=symptomatic skeletal event.

*400 centers in North and South America, Europe, Africa, the Middle East, and Asia-Pacific regions.

[†]In the phase 3 ARAMIS trial with NUBEQA, radiographic evidence of metastasis is by CT/MRI and bone scan. Pelvic lymph nodes < 2 cm in the short axis below the aortic bifurcation are not considered evidence of metastasis.

References: 1. ClinicalTrials.gov website. <https://clinicaltrials.gov/ct2/show/NCT02200614>. Accessed July 3, 2019. 2. Fizazi K et al. *N Engl J Med*. 2019;380(13):1235-1246.

Please see the Important Safety Information throughout and full Prescribing Information for NUBEQA available at this presentation.

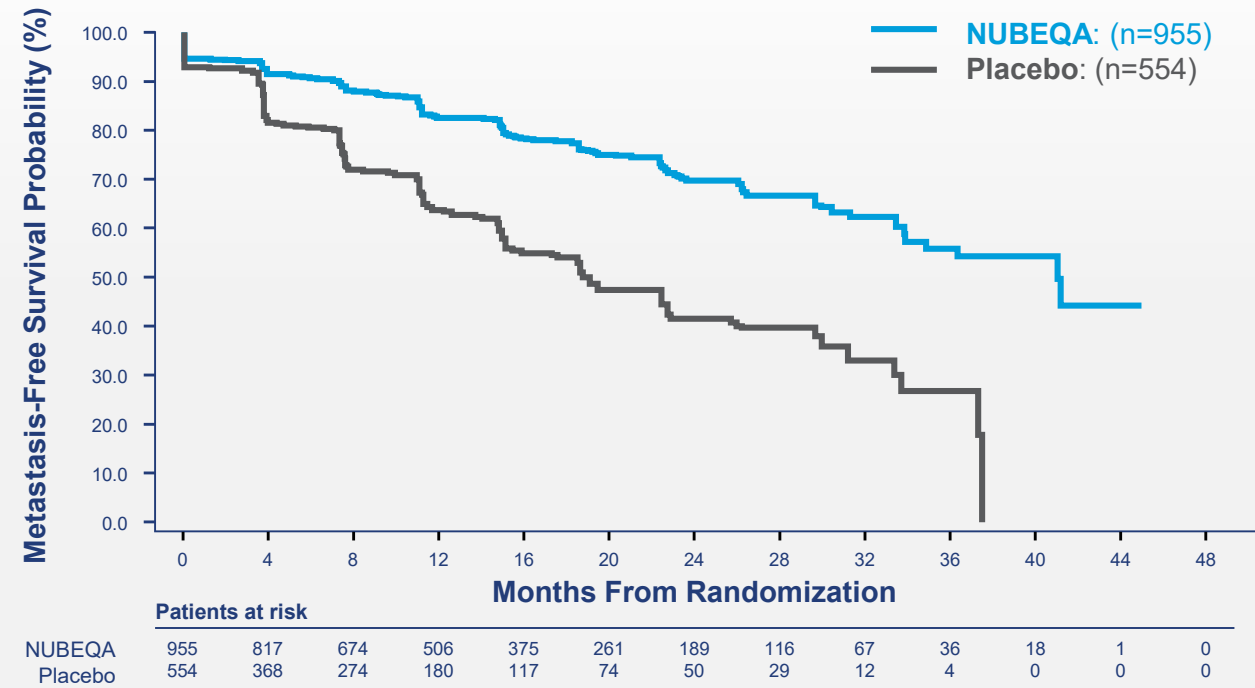
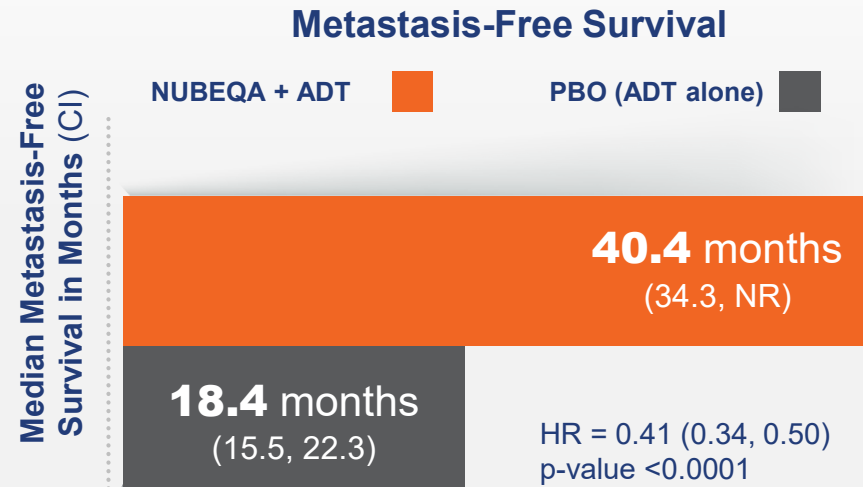

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NUBEQA® (darolutamide) Demonstrated Statistically Significant Metastasis-Free Survival Compared to Placebo



Primary Endpoint



OS data were not mature at the time of final MFS analysis (57% of the required number of events)

ADT=androgen deprivation therapy; CI=confidence interval; HR=hazard ratio; NR=not reached; PBO=placebo.

Reference: NUBEQA [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019.

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PRESPECIFIED SECONDARY EFFICACY END POINTS (INTENTION-TO-TREAT POPULATION)



Data on Secondary Endpoints From the *New England Journal of Medicine* Publication of the ARAMIS Trial

End Point	Darolutamide (n=955)		Placebo (n=554)	
	Median Duration (months)	# of Events	Median Duration (months)	# of Events
Secondary end points				
Overall survival	NR	78	NR	58
Time to pain progression	40.3	251	25.4	178

Overall survival (OS) and time to pain progression were additional efficacy endpoints. OS data were not mature at the time of final MFS analysis (57% of the required number of events). The MFS result was supported by a delay in time to pain progression, defined as at least a 2-point worsening from baseline of the pain score on Brief Pain Inventory-Short Form or initiation of opioids, in patients treated with NUBEQA as compared to placebo. Pain progression was reported in 28% of all patients on study. A final analysis for overall survival and other secondary endpoints is planned for when the predetermined number of overall survival events have occurred.

Secondary endpoints were evaluated in a hierarchical order, with a significance level of 0.05 split between the primary analysis and final analysis (planned to occur after 240 deaths from any cause) of secondary endpoints. The endpoint of overall survival was used to determine the alpha spend and significance threshold for each of the secondary endpoints. This prevented the significance criteria from being met in all secondary endpoints at the interim analysis.

Reference: Fizazi K et al. *N Engl J Med*. 2019;380(13):1235-1246.

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NUBEQA® (darolutamide) Safety Data From ARAMIS Trial



Data on Adverse Events of Any Grade From the *New England Journal of Medicine* Publication of the ARAMIS Trial

Adverse Events*	NUBEQA (n=954)		Placebo (n=554)	
	Any Grade	Grade 3 or 4	Any Grade	Grade 3 or 4
	Number of patients (percent)			
Any adverse events	794 (83.2)	236 (24.7)	426 (76.9)	108 (19.5)
Serious adverse events	237 (24.8)	151 (15.8)	111 (20.0)	70 (12.6)
Grade 5 adverse events	37 (3.9)	—	18 (3.2)	—
Adverse event leading to discontinuation of the trial regimen	85 (8.9)	32 (3.4)	48 (8.7)	24 (4.3)
Adverse events that occurred in ≥5% of patients in either group				
Fatigue	115 (12.1)	4 (0.4)	48 (8.7)	5 (0.9)
Back pain	84 (8.8)	4 (0.4)	50 (9.0)	1 (0.2)
Arthralgia	77 (8.1)	3 (0.3)	51 (9.2)	2 (0.4)
Diarrhea	66 (6.9)	0	31 (5.6)	1 (0.2)
Hypertension	63 (6.6)	30 (3.1)	29 (5.2)	12 (2.2)
Constipation	60 (6.3)	0	34 (6.1)	0
Pain in an extremity	55 (5.8)	0	18 (3.2)	1 (0.2)
Anemia	53 (5.6)	8 (0.8)	25 (4.5)	2 (0.4)
Hot flush	50 (5.2)	0	23 (4.2)	0
Nausea	48 (5.0)	2 (0.2)	32 (5.8)	0
Urinary tract infection	47 (4.9)	6 (0.6)	28 (5.1)	3 (0.5)
Urinary retention	33 (3.5)	15 (1.6)	36 (6.5)	11 (2.0)
Fatigue or asthenic conditions†	151 (15.8)	6 (0.6)	63 (11.4)	6 (1.1)
Bone fracture‡	40 (4.2)	9 (0.9)	20 (3.6)	5 (0.9)

*This category combines the following Medical Dictionary for Regulatory Activities, version 20.0 (MedDRA) terms: Asthenic conditions, disturbances in consciousness, decreased strength and energy, malaise, lethargy, asthenia, and fatigue.

†This category combines the following MedDRA terms: Any fractures and dislocations, limb fractures and dislocations, skull fractures, facial bone fractures and dislocations, spinal fractures and dislocations, and thoracic cage fractures and dislocations.

Reference: Fizazi K et al. *N Engl J Med*. 2019;380(13):1235-1246.



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NUBEQA® (darolutamide) Safety Data From ARAMIS Trial (continued)



Data on Adverse Events of Any Grade From the *New England Journal of Medicine* Publication of the ARAMIS Trial

Adverse Events*	NUBEQA (n=954)		Placebo (n=554)	
	Any Grade	Grade 3 or 4	Any Grade	Grade 3 or 4
	Number of patients (percent)			
Adverse events of interest				
Falls, including accident [§]	40 (4.2)	8 (0.8)	26 (4.7)	4 (0.7)
Seizure, any event	2 (0.2)	0	1 (0.2)	0
Rash [¶]	28 (2.9)	1 (0.1)	5 (0.9)	0
Weight decrease, any event	34 (3.6)	0	12 (2.2)	0
Dizziness, including vertigo	43 (4.5)	2 (0.2)	22 (4.0)	1 (0.2)
Cognitive disorder	4 (0.4)	0	1 (0.2)	0
Memory impairment	5 (0.5)	0	7 (1.3)	0
Change in mental status	0	0	1 (0.2)	0
Hypothyroidism	2 (0.2)	0	0	0
Cerebral ischemia	13 (1.4)	7 (0.7)	8 (1.4)	4 (0.7)
Coronary-artery disorder ^{**}	31 (3.2)	16 (1.7)	14 (2.5)	2 (0.4)
Heart failure ^{††}	18 (1.9)	5 (0.5)	5 (0.9)	0

* Exposure-adjusted incidences of adverse events in the NUBEQA group and the placebo group were as follows: fatigue or asthenic conditions (11.3 patients per 100 years of exposure and 11.1 patients per 100 years of exposure, respectively), back pain (6.3 and 8.8), arthralgia (5.8 and 9.0), diarrhea (4.9 and 5.5), hypertension (4.7 and 5.1), constipation (4.5 and 6.0), pain in extremity (4.1 and 3.2), anemia (4.0 and 4.4), hot flush (3.7 and 4.1), nausea (3.6 and 5.6), weight loss (2.5 and 2.1), falls (2.7 and 4.1), bone fracture (3.0 and 3.5), memory impairment (0.4 and 1.2), cognitive disorder (0.3 and 0.2), and seizure (0.2 and 0.2); *Exposure-adjusted incidences of adverse events in the NUBEQA group and the placebo group were as follows: fatigue or asthenic conditions (11.3 patients per 100 years of exposure and 11.1 patients per 100 years of exposure, respectively), back pain (6.3 and 8.8), arthralgia (5.8 and 9.0), diarrhea (4.9 and 5.5), hypertension (4.7 and 5.1), constipation (4.5 and 6.0), pain in extremity (4.1 and 3.2), anemia (4.0 and 4.4), hot flush (3.7 and 4.1), nausea (3.6 and 5.6), weight loss (2.5 and 2.1), falls (2.7 and 4.1), bone fracture (3.0 and 3.5), memory impairment (0.4 and 1.2), cognitive disorder (0.3 and 0.2), and seizure (0.2 and 0.2).

§All events that had been recorded under the MedDRA term "accident" were determined to have been accidental falls and are included in this category.

¶This category combines the following MedDRA terms: Dermatitis, erythema, rash, macular rash, maculopapular rash, papular rash, and pustular rash.

||This category combines the following MedDRA terms: Cerebral infarction, cerebral ischemia, cerebrovascular accident, ischemic stroke, and transient ischemic attack. Grade 5 events occurred in one patient receiving NUBEQA and three patients receiving placebo.

**This MedDRA High Level Group Term includes coronary-artery disorders not elsewhere classified, coronary-artery arteriosclerosis, coronary artery disease, coronary-artery occlusion, and coronary-artery stenosis. Grade 5 events occurred in three patients receiving NUBEQA and one patient receiving placebo.

††This MedDRA High Level Group Term includes heart failure not elsewhere classified, cardiac failure, acute cardiac failure, chronic cardiac failure, congestive cardiac failure, and cardiogenic shock. Grade 5 events occurred in four patients receiving NUBEQA and three patients receiving placebo.

Reference: Fizazi K et al. *N Engl J Med*. 2019;380(13):1235-1246.

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NUBEQA® (darolutamide) Prescribing Information – Safety¹



Adverse reactions in the NUBEQA arm with a $\geq 2\%$ absolute increase in frequency compared to placebo

Adverse Reaction	NUBEQA (n=954) ^{2,*}		Placebo (n=554)	
	All Grades %	Grades ≥ 3 %	All Grades %	Grades ≥ 3 %
Fatigue [†]	16	0.6	11	1.1
Pain in extremity	6	0	3	0.2
Rash	3	0.1	1	0

Overall, serious adverse reactions occurred in 25% of patients receiving NUBEQA and in 20% of patients receiving placebo. Serious adverse reactions in $\geq 1\%$ of patients who received NUBEQA included urinary retention, pneumonia and hematuria. Additionally, clinically significant adverse reactions occurring in 2% or more of patients treated with NUBEQA included ischemic heart disease (4.0% versus 3.4% on placebo) and heart failure (2.1% versus 0.9% on placebo).

*In the ARAMIS clinical trial, 1 patient in the NUBEQA group did not start treatment.

[†]Includes fatigue and asthenia.

References: 1. NUBEQA [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019. 2. Fizazi K et al. *N Engl J Med*. 2019;380(13):1235-1246.

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NUBEQA® (darolutamide) Prescribing Information – Dosing Adjustments due to Adverse Reactions¹



Permanent discontinuation rates due to adverse reactions were comparable across both study arms

Permanent discontinuation due to adverse reactions occurred in 9% of patients receiving NUBEQA or placebo

The most frequent adverse reactions requiring permanent discontinuation in patients who received NUBEQA included cardiac failure (0.4%), and death (0.4%).

Dosage reductions due to adverse reactions occurred in 6% of patients treated with NUBEQA

The most frequent adverse reactions requiring dosage interruption in patients who received NUBEQA included hypertension (0.6%), diarrhea (0.5%), and pneumonia (0.5%).

Dosage interruptions due to adverse reactions occurred in 13% of patients treated with NUBEQA

The most frequent adverse reactions requiring dosage reduction in patients treated with NUBEQA included fatigue (0.7%), hypertension (0.3%), and nausea (0.3%).

References: 1. NUBEQA [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019. 2. Fizazi K et al. *N Engl J Med*. 2019;380(13):1235-1246

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NUBEQA® (darolutamide) Drug-Drug Interactions^{1,2}



➤ Effect of NUBEQA on Other Drugs

Drug Class	Drug Interactions
BCRP Substrates	<ul style="list-style-type: none">• NUBEQA is an inhibitor of BCRP transporter. Concomitant use of NUBEQA increases the AUC and C_{max} of BCRP substrates, which may increase the risk of BCRP substrate-related toxicities• Avoid concomitant use with drugs that are BCRP substrates where possible. If used together, monitor patients more frequently for adverse reactions, and consider dose reduction of the BCRP substrate drug. Consult the approved product labeling of the BCRP substrate when used concomitantly with NUBEQA

➤ Effect of Other Drugs on NUBEQA

Drug Class	Drug Interactions
Combined P-gp and Strong or Moderate CYP3A4 Inducer	<ul style="list-style-type: none">• Concomitant use of NUBEQA with a combined P-gp and strong or moderate CYP3A4 inducer decreases darolutamide exposure, which may decrease NUBEQA activity• Avoid concomitant use of NUBEQA with combined P-gp and strong or moderate CYP3A4 inducers
Combined P-gp and Strong CYP3A4 Inhibitors	<ul style="list-style-type: none">• Concomitant use of NUBEQA with a combined P-gp and strong CYP3A4 inhibitor increases darolutamide exposure, which may increase the risk of NUBEQA adverse reactions• Monitor patients more frequently for NUBEQA adverse reactions and modify NUBEQA dosage as needed

BCRP=breast cancer resistance protein; CYP=cytochrome P-450 system; P-gp=P-glycoprotein.

References: 1. NUBEQA (darolutamide) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019. 2. US Food and Drug Administration website. <https://www.fda.gov/drugs/drug-interactions-labeling/drug-development-and-drug-interactions-table-substrates-inhibitors-and-inducers#classSub>. Accessed July 29, 2019.

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NUBEQA® (darolutamide) Demonstrated Efficacy and Safety in an Important Stage of Prostate Cancer Treatment



NUBEQA: an androgen receptor inhibitor (ARI) indicated for the treatment of nmCRPC¹



nmCRPC represents a subset of patients with prostate cancer who have progressive disease without evidence of metastases. For men with nmCRPC, NUBEQA offers an option that focuses on both efficacy and tolerability



NUBEQA is available in bottles of 120 tablets each, with a per-tablet dose of 300 mg. The NDC is 50419-395-01¹

NDC=national drug code; nmCRPC=non-metastatic castration-resistant prostate cancer.

References: 1. NUBEQA [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019. 2. Fizazi K et al. *N Engl J Med*. 2019;380(13):1235-1246.

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Assisting Patients With Access to NUBEQA® (darolutamide)



Support From DUDE Access Services™



For more information,
visit **NUBEQAhcp.com**

- Administers NUBEQA Free Trial Program*
- Administers \$0 Co-pay Program for commercially insured patients†
- Identifies and refers appropriate patients to independent cost assistance foundations or the Bayer US Patient Assistance Foundation
- Performs benefits verification to identify patient's insurance coverage and out-of-pocket expenses
- Assists with prior authorizations and appeals, as well as provision of payer policy information
- Identify and triage prescription to specialty pharmacy covered by patient's health plan

*The NUBEQA Free Trial Program provides 2 months' supply of NUBEQA at no cost to patients who meet the program eligibility requirements and agree to the terms and conditions. For full terms and conditions, please call DUDE Access Services at 1-833-337-DUDE (1-833-337-3833) or visit NUBEQAhcp.com to download the Patient Service Request Form with full terms and conditions.

†Restrictions may apply. For full terms and conditions, please call DUDE Access Services at 1-833-337-DUDE (1-833-337-3833) or visit NUBEQAhcp.com to download the Patient Service Request Form with full terms and conditions. Patients who are enrolled in any type of government insurance or reimbursement programs are not eligible. As a condition precedent of the co-payment support provided under this program, eg, co-pay refunds, participating patients and pharmacies are obligated to inform insurance companies and third-party payers of any benefits they receive and the value of this program, as required by contract or otherwise. Void where prohibited by law, taxed, or restricted. Eligibility and participation are subject to review and may be modified or discontinued at any time.

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NUBEQA Free Trial Program



Overview, Terms, and Eligibility

Program

- Offers **2 months of free drug** to all eligible patients
- Begins at **launch** and runs **through year-end, 2020**

Eligible Patients

- **All new patients are eligible** for participation in the FTP (regardless of insurance coverage)
- Patients **already taking** NUBEQA® (darolutamide) are **not eligible** for the FTP

Program Logistics

- **Centrally managed by enrollment in DUDE Access Services™**
- **Single specialty pharmacy** (Theracom) outside of the closed specialty pharmacy distribution network will dispense all FTP-related drug

Program Profile

- **2 months of free drug**
- Offers physicians and patients the opportunity to **try NUBEQA for free to assess safety and PSA response**

FTP=free trial program; PSA=prostate-specific antigen.

Please see the Important Safety Information throughout and full Prescribing Information for NUBEQA available at this presentation.


NUBEQA®
(darolutamide) 300 mg tablets

NOT FOR DISTRIBUTION

NUBEQA® (darolutamide) Distribution Is Supported by a Robust Pharmacy Network



AcariaHealth™	Avella™ Specialty Pharmacy	Diplomat® Specialty Pharmacy
Accredo® Specialty Pharmacy	Biologics by McKesson	Humana Specialty Pharmacy
Aetna® Specialty Pharmacy	Optum Specialty Pharmacy (BrivoRx®)	Onco360 Oncology Pharmacy Solutions
AllianceRx Walgreens Prime	CVS® Caremark Specialty Pharmacy	US Bioservices

➤ Bayer collaborates with in-office dispensing pharmacies and IDN outpatient pharmacies to bring a higher level of comprehensive, coordinated care to patients

NUBEQA® (darolutamide) Important Safety Information (cont'd)



Drug Interactions:

Effect of Other Drugs on NUBEQA – Concomitant use of NUBEQA with a combined P-gp and strong or moderate CYP3A4 inducer decreases darolutamide exposure, which may decrease NUBEQA activity. Avoid concomitant use of NUBEQA with combined P-gp and strong or moderate CYP3A4 inducers.

Concomitant use of NUBEQA with a combined P-gp and strong CYP3A4 inhibitor increases darolutamide exposure, which may increase the risk of NUBEQA adverse reactions. Monitor patients more frequently for NUBEQA adverse reactions and modify NUBEQA dosage as needed.

Effects of NUBEQA on Other Drugs – NUBEQA is an inhibitor of breast cancer resistance protein (BCRP) transporter. Concomitant use of NUBEQA increases the exposure (AUC) and maximal concentration of BCRP substrates, which may increase the risk of BCRP substrate-related toxicities. Avoid concomitant use with drugs that are BCRP substrates where possible. If used together, monitor patients more frequently for adverse reactions, and consider dose reduction of the BCRP substrate drug. Consult the approved product labeling of the BCRP substrate when used concomitantly with NUBEQA.



Thank You



NUBEQA[®]
(darolutamide) 300 mg tablets

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