

**Mapping Prostate Cancer :
A Comprehensive Analysis of Epidemiology
Diagnostic Advances, Therapeutic Approaches,
and Competitive Landscape**

By: Kumar Gaurav

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Objective:

- To evaluate current therapeutic approaches for prostate cancer
- To identify barriers to early detection and treatment adherence
- To explore market trends for prostate cancer drugs and diagnostics
- To assess the research and development pipelines of leading pharmaceutical companies in prostate cancer care

Methodology:

Study Design	Ethical Considerations
• A Quantitative approach is employed to provide a comprehensive analysis of prostate cancer • Quantitative data is sourced from national cancer registries, clinical trial databases, and market reports to examine epidemiological trends, diagnostic advancements, therapeutic approaches, and the competitive landscape	• Data Confidentiality: Confidentiality protocols is maintained when accessing and handling secondary data sources to safeguard privacy and sensitive information • Bias Mitigation: Vigilant in identifying and mitigating potential biases inherent in secondary data sources, ensuring fair and unbiased interpretation of results
Data Collection	Implications of Research
• Data collection involves extracting information from national cancer registries, and databases such as SEER for epidemiological analysis • For diagnostic advances, therapeutic approaches, and competitive landscape analysis, systematic review methodologies is employed to gather data from clinical trial databases, treatment registries, and market reports	• Clinical Practice: Provide insights into improving prostate cancer diagnosis, treatment selection, and patient management strategies, potentially leading to better outcomes and quality of care • Patient Education and Support: Empower patients and their families with evidence-based information about prostate cancer, its risk factors, treatment options, and support resources, enhancing shared decision-making and self-management

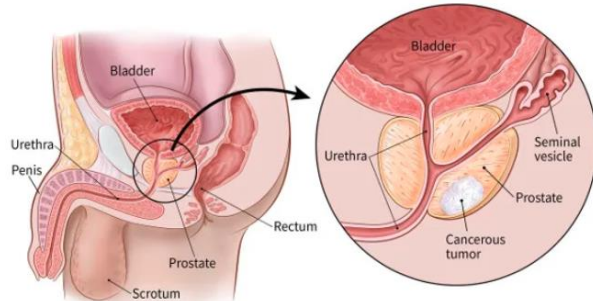
Understanding Prostate Cancer: An Overview

Overview

- The prostate is a small gland located below the bladder and in front of the rectum in men. Its primary role is to produce seminal fluid, a key component of semen that safeguards, nurtures, and aids in sperm movement.

Prostate Cancer

- Prostate cancer starts when normal cells in the prostate gland mutate and multiply excessively, creating a lump known as a tumor.
- Certain prostate cancers progress slowly and might remain asymptomatic for many years.
- Prostate cancer is the most frequently diagnosed cancer among men.



Risk Factors



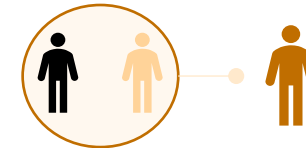
Around 1 out of every 8 men will be diagnosed with prostate cancer at some stage in their lifetime

Prostate Cancer is the most common cancer in men after skin cancer

Prostate cancer risk rises after age 50, with around 60% of cases diagnosed in those 65 and older

Family History

Prostate cancer that runs in a family, called familial prostate cancer, makes up about 20% of all prostate cancers



North American or Northern European location

Prostate cancer is common in North America and northern Europe, and rates are increasing among urbanized Asian populations in places like Hong Kong, Singapore, and Western cities

Diet

Eating lots of saturated fat and being overweight raise the chances of getting prostate cancer

Diagnosis for Prostate Cancer



Digital
rectal
examination



Trans
rectal
ultrasound
(TRUS)



MRI
Fusion
biopsy



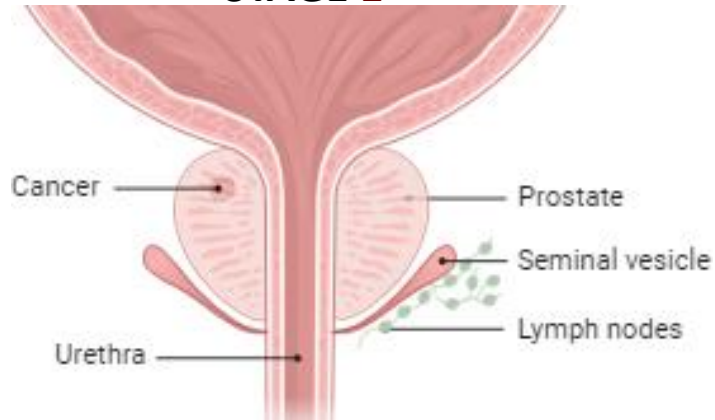
PCA3
(Prostate
CAncer
gene 3)



Prostate-specific
antigen
blood test (PSA)

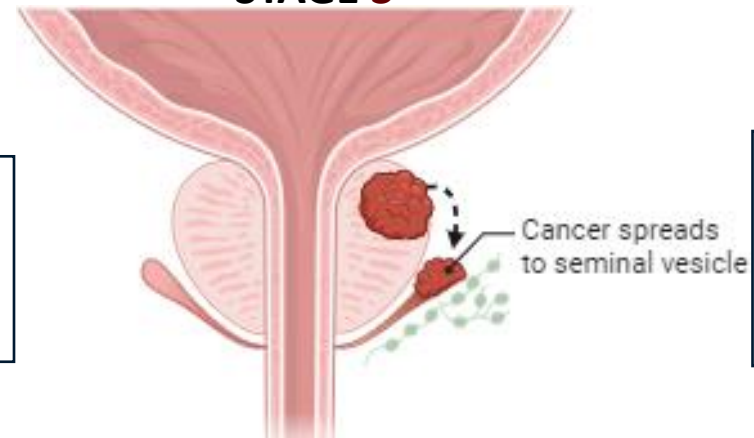
Mapping Prostate Cancer Progression: Understanding the Stages

STAGE 1



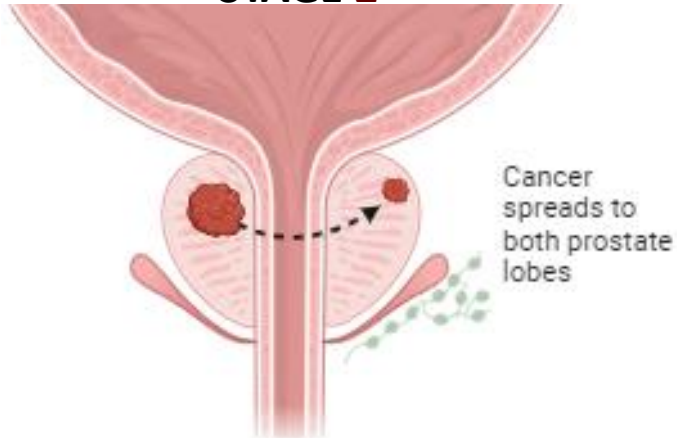
In its initial stages, cancer tends to grow slowly. PSA levels are minimal, and the cancer cells resemble healthy cells.

STAGE 3



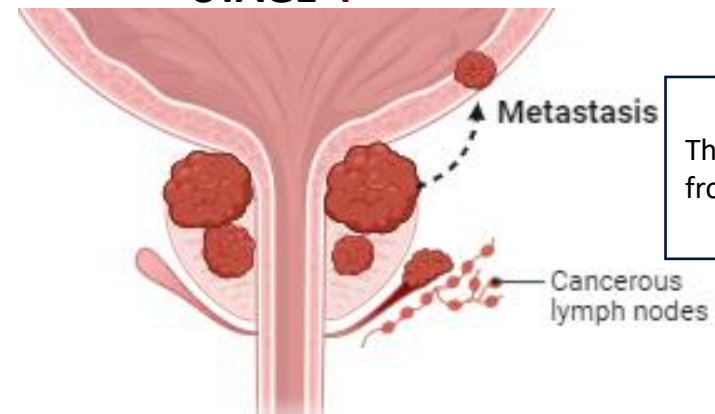
High levels of PSA, tumor is growing, it suggests an advanced stage of localized cancer with a high likelihood of further growth and spread.

STAGE 2



The tumor is confined to the prostate gland. PSA levels are moderate to low. It has the potential for growth and spread.

STAGE 4



The cancer has metastasized from the prostate.

Prostate Cancer : Incidence (2024)

Incidence of Patients by Stage			
Stage	Stage Overview	% Contribution	Patients
Localized	The tumor cells have not spread beyond the prostate	70%	209,307
Regional	The tumor has spread outside the prostate to nearby structures or lymph nodes	13%	38,871
Distant	The tumor has spread beyond the prostate to other parts of the body	8%	23,920
Unstaged	Results from insufficient information available to determine stage of disease at diagnosis	9%	26,910
			Total = 299,010

299,010

men are expected to be diagnosed with prostate cancer

35,250

men are expected to die from prostate cancer

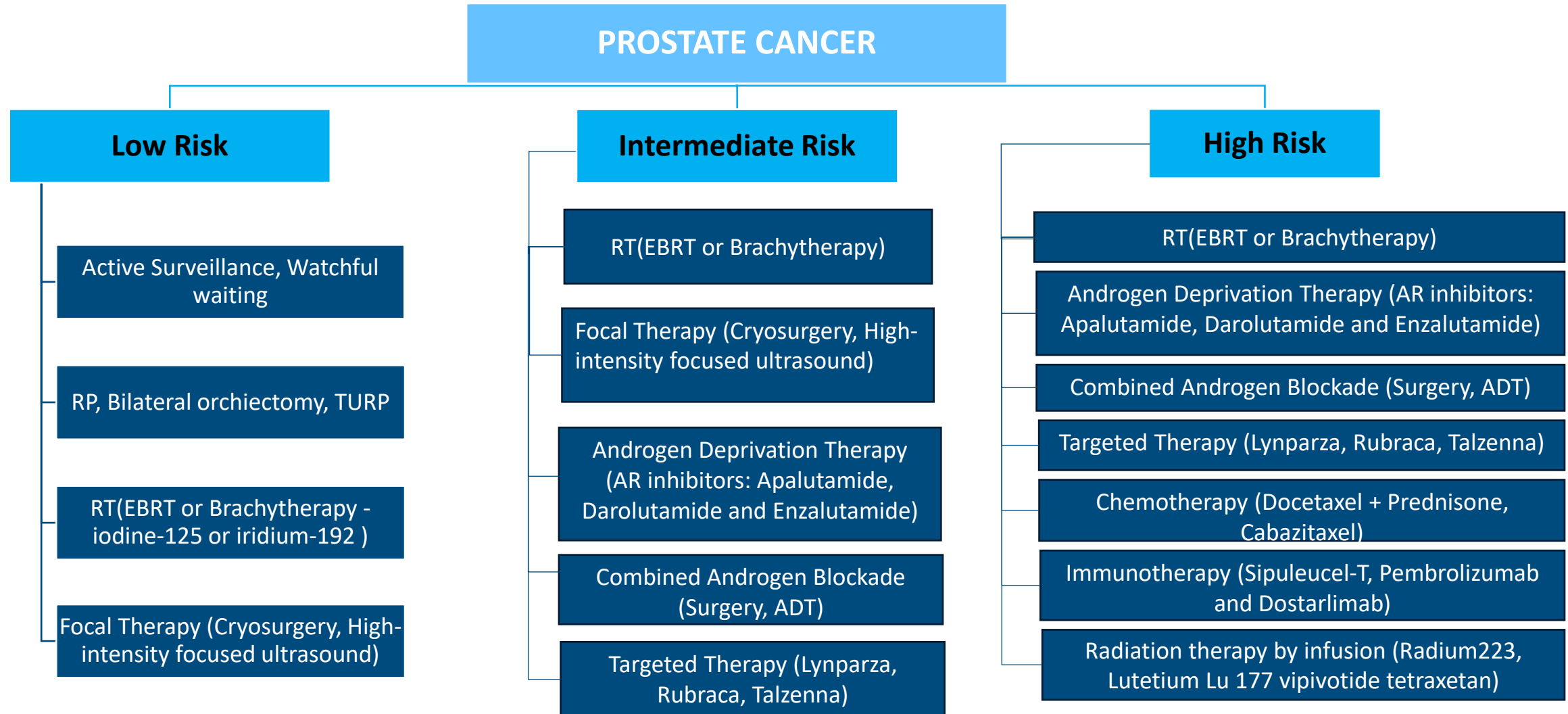
14.9%

% of all New Cancer cases

5.8%

% of all Cancer deaths

Empowering Patients: Understanding Prostate Cancer Treatment Choices



Source: [Cancer.net](https://www.cancer.net)

Notes : ADT: Androgen deprivation therapy, EBRT: Electron beam radiotherapy, RP: Radical prostatectomy, RT: Radiotherapy, TURP: Transurethral resection of the prostate

Androgen Receptors: Contrasting the First and Second Generations

Aspects	First Generation Androgen Receptor Inhibitor (FGARI)	Second Generation Androgen Receptor Inhibitor (SGARI)
MOA	It blocks testosterone and dihydrotestosterone from binding to the androgen receptor, halting the cellular pathway that fuels prostate cancer growth	It blocks androgen binding to receptors by impeding nuclear translocation of activated receptors and their connection to DNA
ROA	Oral	Oral
Target	Androgen receptor	Androgen receptor
Application	Metastatic prostate cancer	Metastatic & Non-Metastatic CRPC, CSPC
Side Effects	Fatigue, Nausea, Diarrhea	Fatigue, Nausea, Hypertension
Drugs	Bicalutamide (Casodex), Flutamide (available as generic drug), and Nilutamide (Nilandron)	Apalutamide (Erleada), Darolutamide (Nubeqa), and Enzalutamide (Xtandi)

Source: [Cancer.net](https://www.cancer.net), [Frontiers in Oncology](https://www.frontiersin.org)

Notes: CRPC; Castration-resistant prostate cancer, CSPC; Castration-sensitive prostate cancer



Nubeqa vs Other SGARI products



Attributes	Subtype	Nubeqa	Erleada	Xtandi	Zytiga
Indication level approval	nmHSPC	NA	NA	Nov 16, 2023	NA
	nmCRPC	July 30, 2019	Feb 14, 2018	Jul 13, 2018	NA
	mHSPC	Aug 5, 2022	Sep 17, 2019	Dec 16, 2019	Feb 8, 2018
	mCRPC	NA	NA	Aug 31, 2012	Apr 28, 2011
ROA		Oral	Oral	Oral	Oral
Company		Bayer	Janssen	Astellas	Janssen

Possible Threats : Competitors pose a challenge to Nubeqa's market share

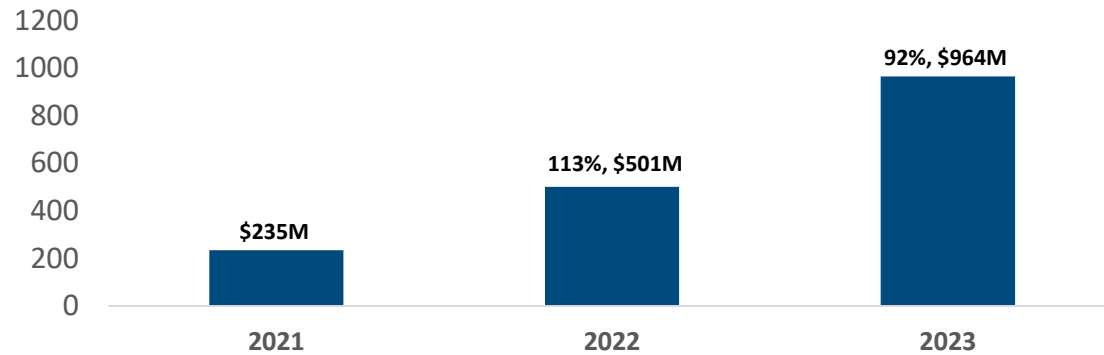
- Nubeqa’s fewer approved indications than Xtandi, might limit patient choices and sway doctors toward other options
- Generic versions of Zytiga could threaten Nubeqa's sales
- Nubeqa's requirement for twice-daily dosing compared to Erleada's once-daily format, may affect patient adherence and preference

Source: [Bayer Annual Report](#), [Johnson & Johnson Annual Report](#), [Astellas Annual Report](#), [Drugs.com](#)

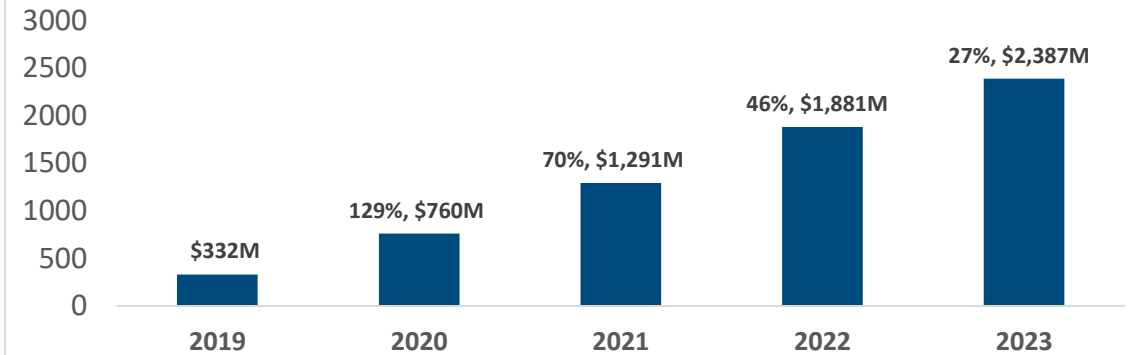
Notes: mCRPC; Metastatic Castration-resistant prostate cancer, mHSPC; Metastatic Hormone-sensitive prostate cancer, nmCRPC; Non-Metastatic Castration-resistant prostate cancer, nmHSPC; Non-Metastatic Hormone-sensitive prostate cancer

SGARI Sales & YoY Growth

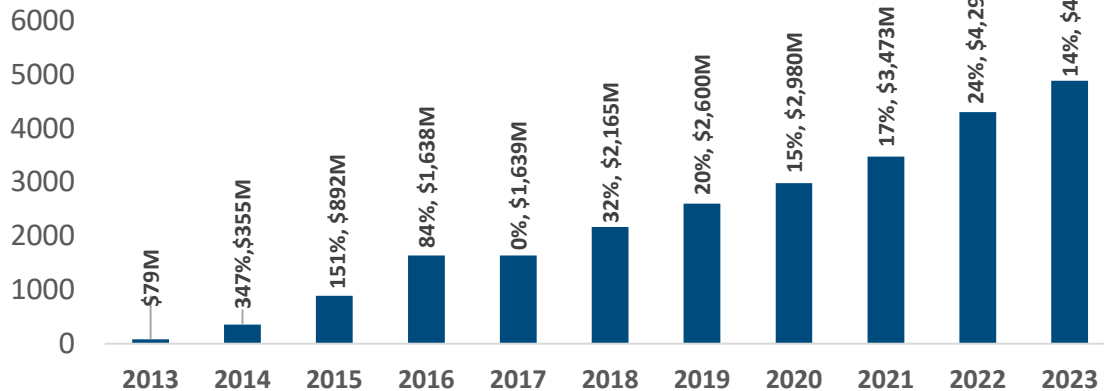
Nubeqa



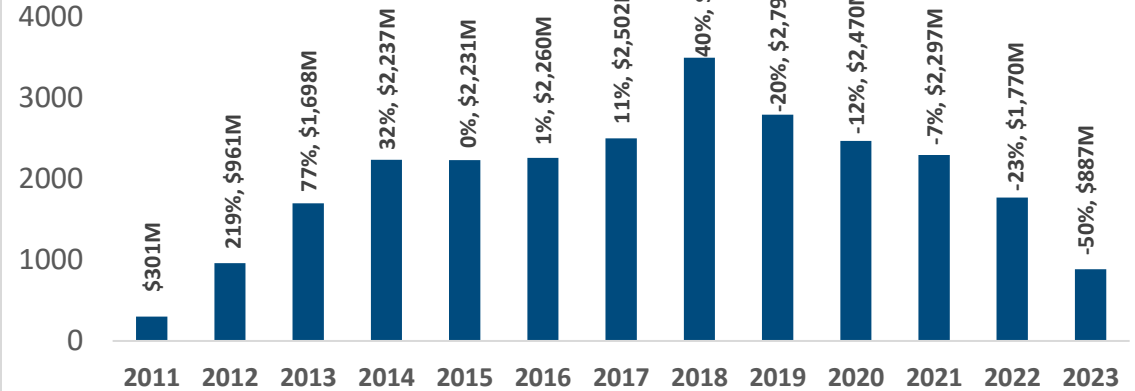
Erleada



Xtandi



Zytiga



Source: [Bayer Annual Report](#), [Johnson & Johnson Annual Report](#), [Astellas Annual Report](#)

Notes : Product sales are as available from Investor Relations report, hence some products do not have data since launch



Xofigo vs Other IV Radiation Therapy

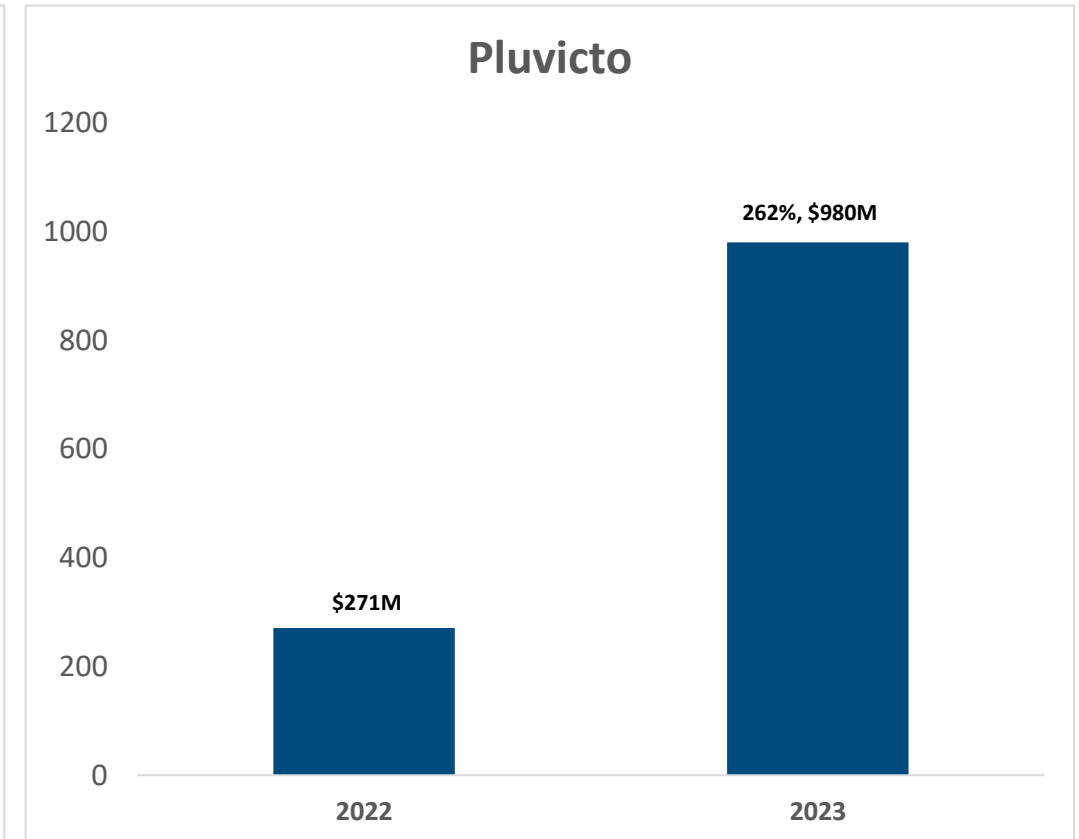
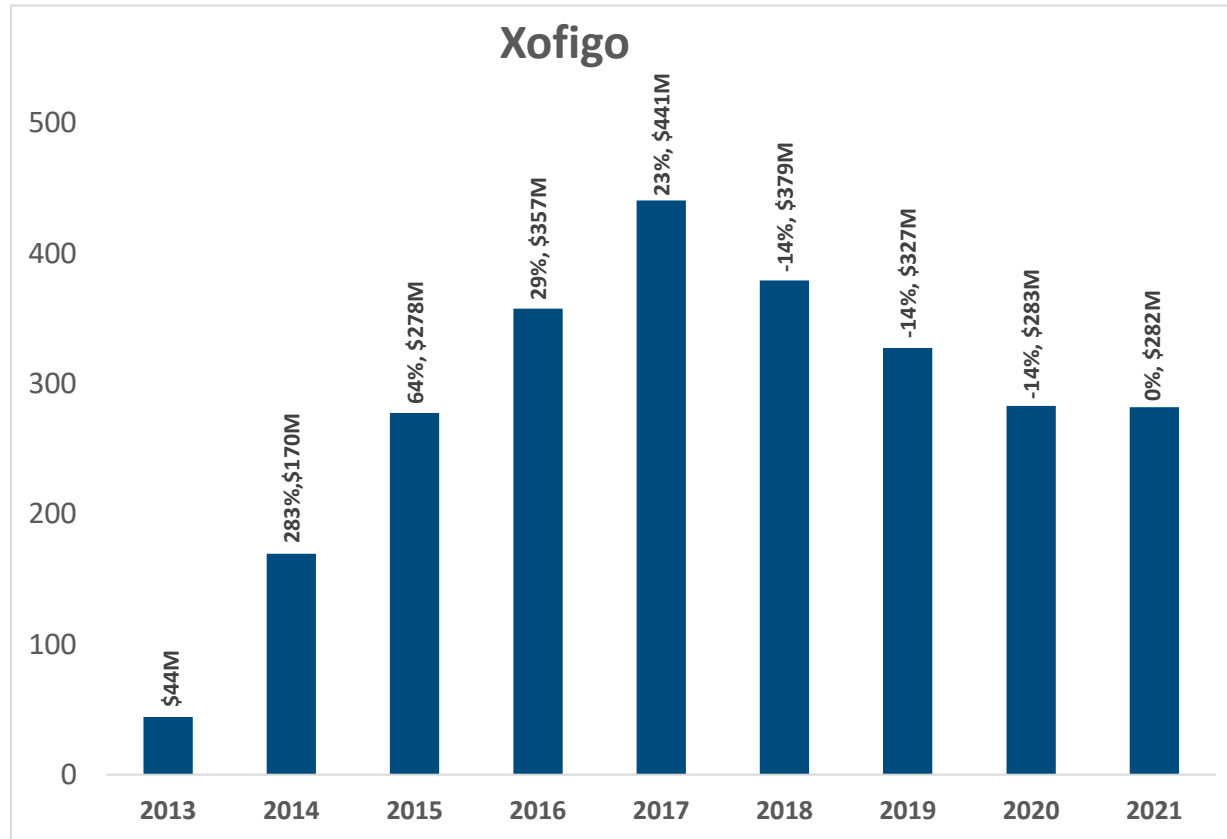


Attributes	Type	Sub Type	Xofigo	Pluvicto
Indication	mCRPC	Pre-Chemo	May 15, 2013	Oct 23, 2023 (ESMO Data Read Out)
		Post-Chemo		Mar 23, 2022
ROA			IV	IV
Company			Bayer	Novartis

- Possible Threat :
- Xofigo's patent expiration in 2022 poses a significant threat to its market position and revenue sustainability in prostate cancer treatment
- The entry of Pluvicto as a new alternative presents a potential challenge to Xofigo, as it could swiftly gain traction in the market
- Pluvicto's novelty in approval may attract prescribers seeking the latest treatment options, further impacting Xofigo's market presence

Source: [Bayer Annual Report](#), [Novartis Annual Report](#), [Novartis Press Release](#) [Drugs.com](#)

IV Radiation Therapy Sales & YoY Growth



Source: [Bayer Annual Report](#), [Novartis Annual Report](#)

Notes : Product sales are as available from Investor Relations report, hence some products do not have data since launch

Barriers to Early Detection and Treatment Adherence:



Lack of Awareness



Insufficient Healthcare Workforce



Cultural Belief & Myth



Fear of Recurrence



Financial Constraints



Fear of Diagnosis

Key Clinical Trials:

Trial Name	Indication	Interventions	Phase	PCD	Completion Date	Additional Comments
ARAMIS	nmCRPC	Darolutamide	Phase 3	09/03/2018	06/14/2021	Study evaluates the safety and efficacy of BAY1841788 in nmCRPC patients
ARASENS	mHSPC	Darolutamide, ADT, Docetaxel	Phase 3	10/25/2021	04/11/2023	Study aims to evaluate the efficacy and safety of darolutamide combined with standard ADT and docetaxel in mHSPC patients
ARANOTE	Prostatic Neoplasms	Darolutamide, Placebo, ADT	Phase 3	06/07/2024	09/26/2025	Study aims to evaluate darolutamide's efficacy and safety alongside standard ADT in mHSPC patients
ARASEC	mHSPC	Darolutamide, ADT	Phase 2	12/15/2024	06/22/2026	Study aims to determine if adding darolutamide to ADT improves progression-free survival in mHSPC compared to ADT alone
ARAMON	Biochemically Recurrent Prostate Cancer	Darolutamide, Enzalutamide	Phase 2	08/19/2025	05/28/2026	Study investigates the impact of darolutamide versus enzalutamide on testosterone levels in hormone-naïve prostate cancer patients
ARASTEP	Biochemically Recurrent Prostate Cancer	Darolutamide, Placebo matching darolutamide, ADT	Phase 3	01/29/2027	02/28/2029	Study compares the efficacy of darolutamide plus ADT versus ADT alone in men with HSPC experiencing PSA elevation post-local therapies

Key Clinical Trials Contd.

Trial Name	Indication	Interventions	Phase	PCD	Completion Date	Additional Comments
ALSYMPCA	HRPC, Bone Metastases	Radium-223 dichloride, BSoC	Phase 3	07-2011	02-2014	Study assessing the efficacy and safety of Radium-223 dichloride in HRPC patients with skeletal metastases
ERA 223	Prostatic Neoplasms	Radium-223 dichloride, Abiraterone, Prednisone/Prednisolone	Phase 3	02/15/2018	02/08/2024	Study aims to assess whether adding radium-223 dichloride to standard treatment extends overall survival and delays bone-related events in metastatic prostate cancer
RaRe	Prostate Cancer Metastatic to Bone	Radium-223 chloride, Rhenium-188-HEDP	Phase 3	05/16/2022	05/16/2024	Study aims to determine if rhenium-188-HEDP treatment improves overall survival compared to radium-223 chloride in CRPC metastatic to bone
IMbassador 250	CRPC	Atezolizumab, Enzalutamide	Phase 3	12/20/2022	12/20/2022	Study assesses the safety and efficacy of atezolizumab combined with enzalutamide compared to enzalutamide alone in mCRPC patients following failure of an androgen synthesis inhibitor and taxane regimen

Findings:



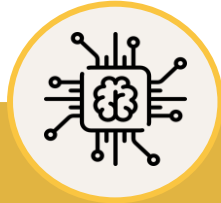
Current Treatment Landscape

- Traditional therapies like surgery and radiation remain mainstays
- New options include immunotherapy and targeted therapies, showing promise
- Personalized medicine is on the rise, focusing on tailoring treatment to individual patients



Early Detection Barrier

- Challenges include lack of access, socioeconomic differences, and patient compliance
- Solutions involve targeted public health interventions and patient education programs
- Patient-centered care, multidisciplinary support networks are crucial



Technological Advancements in Diagnosis

- Advanced diagnostic procedures, such as MRI-ultrasound fusion for biopsies and PSMA PET imaging, significantly aid in early diagnosis and relapse assessment
- Programs funded by institutions like NCI and PCF support the translation of research into practice, improving diagnostic and treatment options



Innovations in Treatment Option

- New drugs like Nubeqa and Pluvicto, along with enhancements in radiation therapy and surgical techniques, have improved the quality of care while reducing the impact of prostate cancer
- Ongoing clinical trials, such as PEACE III and ARANOTE, are exploring novel methods and drug combinations



Personalized Medicine and Patient-Centered Care

- Personalized medicine, focusing on patient-specific treatment plans, is a key area of development
- Patient-centered care practices emphasize the importance of integrated biopsychosocial models that address both the physical and psychological aspects of cancer care



THANK YOU
