

# Prostate Cancer - Newer Antiandrogens & Emerging Therapies Targeting a “Watchful Waiting” and Resistance Population

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## Abstracts

Xtandi – Replacing competitor from Zytiga to Casodex (Bicalutamide) for a bigger pie in Prostate cancer & Finding its niche in crowded BC market Xtandi + Zytiga vs. ARN-509 + Zytiga - Who will win the race? Rising star Anti Androgens – Third generation Antiandrogens- What left for AR-V7 mutants after TOK-001 failure?

Late Stage Prostate Cancer Pipeline drugs – AKT inhibitors or PARP inhibitors or a new MoA combination with Antiandrogen or IO combo - Competing to Xtandi/Zytiga or targeting Xtandi/Zytiga Resistance Population?

Increase in prevalence of Prostate cancer and availability of new treatment options (Zytiga, Xtandi, Cabazitaxel and Xofigo) in last few years has extended role of newer oral Antiandrogens to treat metastatic CRPC patient populations where the unmet need was high. This has expanded WW market size of Prostate cancer drugs to \$7b in 2016 from \$2.5b in 2011. Now nmCRPC, HSPC and Xtandi/Zytiga resistance population are the markets where in new pipeline drugs are under development.

Reported PhII clinical data of Xtandi, ARN-509 and ODM-201 in nmCRPC when indirectly compared demonstrate the bar is high for ARN-509 to compete against Xtandi in nmCRPC market and while ODM-201 is few years behind in clinical development. While in mHSPC reported clinical results of STAMPEDE study opens door for docetaxel combination approach as standard of care in first line setting.

Around 8 plus drugs are in PhIII development for Prostate cancer treatment and 26 plus drugs are in PhII development (21 small molecules) - success of a few (ARN-509, ODM-201, AZD 5363, GX301) in coming years will expand nmCRPC (\$3.5be), mHSPC

market (\$1be) and Xtandi/Zytiga resistant population (\$1be) market by 2023. Longer duration of therapy and high prevalence makes earlier setting market more attractive and bigger for newer options than the late stage if they succeed.

For drugs targeting through androgen pathway - Now trials and clinical development is underway for second and third generation androgen receptor inhibitors (ARN-509, ODM-201, ODM-204, EPI-506, VT-464, TAS-3681 and DR103). While androgen synthesis inhibitors still needs a proof of concept in clinic due to failure of TAK-700 & TOK-001. Expected data from VT-464 (Apr 2017) & ASN-001 will be important to watch to taste the success for this class. Androgen receptor degrader is another MoA in development from a decade and success of in clinic compound GTX-758 (Data expected anytime from now as study completed in March 2016- less likely to succeed) will decide the proof of concept.

Other than pipeline drugs targeting androgen pathway, NCE targeting AKT pathway (AZD5363, Ipatasertib) appears to be more promising to succeed in late stage, while drugs acting through PARP inhibition (Olaparib, Niraparib) still needs a taste of success. Other interesting pipeline asset is LHRH agonist LMIS 50 mg, which is designed to overcome the drawbacks of the commercial depot products containing GnRH agonists by using a proprietary delivery system.

Also 6 therapeutic vaccines are in clinical development to treat prostate cancer. Recently launched PD-L1 IO therapy has increased hope of treating cancer in much safer way. Current ongoing studies of late stage IO mab are in Ph I/II clinical development and would be able to answer of PTEN hypothesis for role of PD-1, PD-L1 inhibitor to treat prostate cancer in coming years.

Resistant development is another challenge with long term use of Xtandi/Zytiga and needs to be addressed by pipeline second/third generation Antiandrogens/ combination approach with IO/PARP/AKT inhibitors to treat mCRPC. Increase in pricing pressure in developed market again put inference on Combination approach unless the advantage is significant and improve the QoL in earlier setting. Due to that, drugs targeting adjuvant setting has high bar to deliver (Atezolizumab, GX301, Mipsagargin and Olaparib) in the clinical development to add significant value.

This report details current unmet need, changing regulatory requirement, reimbursement challenges & market dynamics of Prostate Cancer drugs. Report mention pipeline Antiandrogens, late stage prostate cancer pipeline drugs/new Mechanism of action & major companies developing Prostate cancer drugs. It also

provides insight on clinical development strategy of combination pipeline/ marketed drugs & therapeutic competitive landscape to find treatment paradigm fit & market potential of new drugs for treatment of Prostate Cancer

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SHR3680

GT0918 (Proxalutamide)

ONC1-13B

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DR103

AZD3514

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BMS-641988

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VT-464

ASN001

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GTX-758

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OGX-011

TAS-3681

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Pembrolizumab

Durvalumab with or without Tremelimumab

Atezolizumab (Tecentriq)

Nivolumab

## 8. NEW PIPELINE DRUGS

AZD 5363  
ADXS31-142 (ADX-PSA)  
[68Ga]RM2 or Ga-bombesin  
Recombinant adenovirus (Ad5-SGE-REIC/Dkk3)  
SM-88  
Mobilan (M-VM3)  
Dendritic cells DCVAC  
LMIS 50 mg  
NBTXR3  
Niraparib  
GX301  
ODX (Osteodex)  
BHR-200 (transdermal estradiol gel)  
Mipsagargin (G-202)  
PROSTVAC-V/F  
ProstAtakÂ  
99mTc-MIP-1404 injection  
PectaSol –C Modified Citrus Pectin  
ATL-101  
MVI-816  
Olaparib (Lynparza)  
TAK-385 (Relugolix)  
Ipatasertib (GDC-0068, RG7440)  
LY3023414  
PSMA ADC  
Zoptrex (Zoptarelin doxorubicin)

## COMPANIES MENTIONED:

Pfizer  
Medivation  
Astellas  
Valeant pharmaceuticals  
Turing pharmaceuticals  
Abbott  
Johnson & Johnson

Tokai pharmaceuticals  
Bayer pharmaceuticals  
AstraZeneca  
Teva pharmaceuticals  
Mylan  
Bind therapeutics  
NanoString Technologies  
Zenith Technologies  
Actavis  
Apotex  
Par pharmaceuticals  
Citron pharma  
Dr. Reddy's Laboratories  
Sun pharma  
Wockhardt  
Amneal pharmaceuticals  
West-ward pharmaceuticals (Hikma pharmaceuticals)  
Hetero Labs.  
BTG International Ltd.  
Janssen pharmaceuticals  
Amerigen pharmaceuticals  
Aragon pharmaceuticals  
Sanofi  
Arno Therapeutics  
Invivis pharmaceuticals  
Orion pharmaceuticals  
Endo pharma  
ESSA pharma  
Jiangsu Hengrui Medicine Co.  
Suzhou Kintor pharmaceuticals Inc.  
Allchem pharma  
Harbor Bioscience  
Bristol-Myers Squibb pharma  
Takeda pharma  
Viamet pharmaceuticals  
Innocrin pharmaceuticals  
Asana Bioscience  
GTx pharma  
OncoGenex pharmaceuticals



Taiho Oncology  
Arvinas pharmaceuticals  
Roche pharmaceuticals  
Merck pharmaceuticals  
Sotio pharma  
Foresee pharmaceuticals  
Advantagene  
Progenics pharmaceuticals  
Econugenics  
Bavarian Nordic  
Mediolanum S.p.A  
Piramal Imaging S.A  
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Inspyr Therapeutics  
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