

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

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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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TAS-3681

ARV-330

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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
Panacela Labs
BHR pharma
DexTech Medical AB
ATLAB pharma
Madison Vaccines
Millennium pharmaceuticals
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