

Therapeutic Class Overview: Newer Oral Anti Androgens – Expanding Role in The Treatment Paradigm of Prostate Cancer

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Abstracts

XTANDI (Enzalutamide) – Does it have potential to compete against ARN-509 in earlier setting? Zytiga (Abiraterone Acetate) – Ongoing Combination trials creates potential beyond Patent Expiry In recent past approval and launch of various newer treatment options like Xtandi (Enzalutamide, Astellas/Medivation), Zytiga (Abiraterone acetate, JNJ), Jevtana (Cabazitaxel, Sanofi), & Xofigo (radium Ra 223, Boehringer Ingelheim) has evolved the treatment paradigm of treating late stage prostate cancer. In coming years, we expect this to repeat in early stage prostate cancer treatment (nmCRPC, before Prostatectomy) due to launch of newer antiandrogens in this setting. Longer duration of therapy and high prevalence makes this earlier setting market more lucrative and bigger for newer options than late stage if they succeed. In coming years, we expect second generation antiandrogens (Androgen synthesis inhibitors/Androgen receptor inhibitors, Xtandi, ARN-509, ODM-021, Zytiga, TAK-700, TOK-001) to replace them and expand their use beyond current levels in nmCRPC (non metastatic Castrate resistance Prostate cancer) patients and also in pre-prostatectomy (Chart 3). These newer agents will expand these markets at least by \$10b (\$6b in pre prostatectomy, \$4b nmCRPC) if they get success. TAK-700 (Takeda), ARN-509 (JNJ) and Xtandi are strong candidates to get success in early stage prostate cancer and in next two years Phase III clinical data from EL-04, PROSPER and SPARTAN study, will decide who will lead this market. While TAK-700 has a first launch advantage it is important to see how ARN-509, compete to Xtandi in earlier setting and in terms of safety for penetrating in early prostate cancer market. Other than these Phase III studies, Xtandi Phase II data from neoadjuvant PC and ARN-509 data in preprostatectomy patients will decide their use in earlier setting. We estimate \$2.8b peak sales for Xtandi in mCRPC setting, while in earlier setting it has potential to generate at least ~\$2b if it gets success in PROSPER, STRIVE, TERRAIN and neoadjuvant study.

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