Potential Market Expansion for Prostate Cancer Drug
The U.S. prostate cancer market is expected to grow to $3.7 billion by 2023 from about $1.6 billion in 2013. The leading treatments are two blockbusters, Zytiga and Xtandi, both with global sales of more than $2 billion.

Zytiga is currently approved to treat men with metastatic castration-resistant prostate cancer (mCRPC), who have disease progression despite initial treatment with androgen-deprivation therapy (ADT) with either chemical/medical (hormone treatment) or physical castration. MCRPC is an advanced form of prostate cancer that has spread to other parts of the body and resists other forms of testosterone-lowering treatments.

Zytiga is administered in conjunction with prednisone. However, when treatment with Zytiga and prednisone is added to an ADT such as Lupron (leuprolide) among “hormone-naïve” patients — those who have not yet been treated — it can delay cancer progression by an average of 33 months, 18 months more than the placebo group. The regimen also reduced risk of death by 38 percent compared with a control group who were given ADT alone. The results of the LATITUDE clinical trial were recently published in the New England Journal of Medicine.

We expect the manufacturer may present this data to the U.S. Food and Drug Administration (FDA) to get approval for Zytiga as a first-line treatment for men with mCRPC.

An oral prostate cancer medication used primarily for patients with castration-resistant metastatic cancer, after initial treatment, may soon become a first-line treatment for high-risk patients, greatly expanding its potential market.
Prevalence and Potential Market Size

About 119.8 per 100,000 men are diagnosed with prostate cancer each year and 60 percent of cases are in men 65 and older. Approximately 11.6 percent of men are diagnosed with prostate cancer at some point during their lifetime. Although the overall five-year survival rate for prostate cancer is high — 98.6 percent — survival rates for men with metastatic cancer are much lower at 29.8 percent. This makes the reduction in death rate reported in the LATITUDE trial significant. Prostate cancer is expected to result in an estimated 26,730 deaths in 2017.

Based on the number of new diagnoses each year and the percentage of those that are at risk of metastatic cancer, if approved as a first-line treatment, Zytiga would be prescribed to just over 8,000 additional patients each year. The average wholesale price for Zytiga is $11,275. If all eligible patients are prescribed the drug as first-line therapy that could generate impact of more than $1 billion annually.*

Looking into the Future

While the primary patent expired at the end of 2016, Zytiga has other active protections until 2027, which could delay the entry of generics. Xtandi, the other leading drug to treat metastatic cancer post-castration is also in trials as a first-line treatment for patients with mCRPC. However, we anticipate it may be several years before the drug is approved for that use.* The prostate cancer pipeline is robust with two drugs in the near-term pipeline, at least one of which, apalutamide (stage 3 trials), is also expected to be a top blockbuster drug. Unlike Zytiga and Xtandi, apalutamide is being studied for use in non-metastatic prostate cancer patients so it is unlikely to compete with the existing therapies.

Ongoing monitoring of the drug pipeline can help payors anticipate and plan for the impact of new drugs or expanded indications.

It is estimated that in 2017 there will be:

- 161,360 new cases of prostate cancer
- 26,730 deaths from prostate cancer
- which is about 4.4% of all cancer deaths

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Appropriate utilization management strategies, including specialty guideline management, can help ensure that the right patients are being prescribed the drug based on their clinical profile, and help payors manage the trend impact.
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