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Xtandi Beats Casodex, Set to Top Zytiga

Medivation's prostate-cancer drug is generating strong data but the stock already reflects much of the potential



As expected, Medivation's Xtandi handily beat AstraZeneca's Casodex in the STRIVE prostate-cancer study, too.

Median progression-free survival (PFS) of 19.4 for Medivation's (ticker: MDVN) Xtandi versus 5.7 months for AstraZeneca's (AZN) Casodex in the STRIVE study, versus 15.7 versus 5.8 months (Xtandi versus Casodex) in the TERRAIN study. The longer PFS in STRIVE versus TERRAIN is expected, given that STRIVE included both M0 and M1 (both nonmetastatic and metastatic) patients (396 patients, all U.S.), while TERRAIN included only M1 (metastatic castration-resistant prostate cancer (CRPC)) patients (375 patients in North America and Europe).

Median time on treatment was 14.7 versus 8.4 months for Xtandi versus Casodex, respectively, and 11.7 versus 5.8 months in TERRAIN. Adverse events (AEs) were reported in 29.4% versus 28.3% (Xtandi versus Casodex) in STRIVE, and 31.1% versus 23.3% in TERRAIN. G3 or higher cardiac AEs were 5.1% versus 4.0% (Xtandi versus Casodex), in line with 5.5% versus 2.1% in TERRAIN. There was one seizure in the Xtandi arm versus none in the Casodex arm, versus two for Xtandi and none for Casodex. in TERRAIN.

The data are positive and very consistent with the TERRAIN data and confirm the drug's good activity and safety. Seizures are still there, but one in about 200 patients in STRIVE and two in about 200 in TERRAIN, but this looks like an acceptable risk/benefit and physicians have already been comfortable with it. We believe these data will help the drug get additional penetration in the pre-chemo setting, where we believe it will have the upper hand over [Johnson & Johnson's (JNJ)] Zytiga, mainly due to convenience. However, we believe that significant adoption in the earlier stages of the disease will require Phase 3 data, which will take many years to read out.

We believe Xtandi is a very active and well-tolerated agent that would have the upper hand in the pre-chemo setting given Zytiga's need for steroid use, so we project that Xtandi will eventually become the dominant player in these settings. However, given that Medivation shares this asset with Astellas Pharma [of Japan] (gets 50% of U.S. sales, low-teens to low-20s royalties outside the U.S.), and despite projecting very generous Xtandi sales (\$9 billion in 2026), we think Medivation shares already reflect the drug's potential and we would look for a better entry point into this story.

 $[\mbox{We rate Medivation at } \textbf{Sector Perform}.]$

-- Simos Simeonidis

companies being analyzed

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