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ASTELLAS - Enzalutamide Filed in the US - A ‘Priority Review’ is Likely!

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Abstracts

Following our recent meeting with Astellas, we form an opinion that Enzalutamide is likely to get priority review status from the FDA – if granted, FDA will take an approval decision in a 6-month timeframe (vs. ~10 months). The decision of granting a priority review will be due within 60 days from the filing date, i.e. May 23rd. Enzalutamide is the first in class androgen receptor signaling inhibitor, and has been filed for the treatment of post chemo castration resistant prostate cancer (CRPC). It is one of the most advanced onco candidates in the Astellas pipeline. However, there has been no head to head trial with competitor Zytiga wherein enzalutamide may have shown superior data, but it offers two distinct advantages: 1) Zytiga is typically prescribed with a steroid while enzalutamide administration is steroid free. 2) Overall survival (OS) data is better for enzalutamide - 4.8 months vs. 3.9 months for Zytiga. Despite enzalutamide’s solid data, we find a limited bottom line impact on Astellas due to its commercialization agreement with Medivation that leaves little for Astellas’s investors

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