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Physician Views: What Impact Will New Kyprolis Data Have on MM Treatment Paradigm?

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Abstracts

Amgen has been under fire ever since announcing plans to acquire Onyx for $10.4 billion as the Street has consistently questioned whether the US drugmaker will be able to achieve the type of growth with multiple myeloma (MM) drug Kyprolis (carfilzomib) – the crown jewel of the acquisition – necessary to make the deal work, particularly in light of looming competition from (soon-to-be) cheaper and/or more convenient agents.

At this point, it is not hard to understand why investors have been critical of Amgen's decision to buy Onyx, as the company reported only $331 million in 2014 sales of Kyprolis, which has been relegated largely to later line. Indeed, barring a significant acceleration of the drug's current trajectory, which would involve achieving far greater penetration into earlier stage MM patients, it is hard to imagine Amgen achieving the type of revenues needed to consider the deal a success.

This week thus has the potential to be an important watershed moment for the company thanks to results from the Phase III ENDEAVOR trial as Kyprolis appears to have emerged as the clear winner in a head-to-head matchup against its biggest competitor, Velcade (bortezomib) from Johnson & Johnson and Takeda. The study, which enrolled 929 patients whose MM had relapsed after at least one (but not more than three) prior therapies, showed Kyprolis achieved progression-free survival of 18.7 months, which was almost twice the 9.4 months observed for Velcade.

Analysts were quick to note that the results may give Kyprolis an important leg up on Velcade in the marketplace – and none too soon for Amgen as the company will now be in a race to win over as much of the market in second-line (ie, relapsed/refractory) MM as it can before Velcade goes generic in 2017.

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What's more, Amgen will soon be looking at the possibility of facing additional competition from several oral proteasome inhibitors, which will have an obvious advantage in convenience over Kyprolis, an intravenously infused proteasome inhibitor. The most advanced of the oral agents appears to be Takeda's ixazomib, which could come to market as soon as 2016.

In addition to how much market share Kyprolis can win from Velcade, another open question is how much headway Amgen can make in pushing the drug into earlier stage patients, and how much – if any – impact this might have on use of Celgene's Revlimid, which currently dominates the setting.

The consensus among analysts has been that Kyprolis will achieve 2020 sales of roughly $1.6 billion, which may rise in the coming weeks given the new data. Porges is taking more optimistic view of Amgen's prospects and thinks Kyprolis sales could reach as high as $1.5 billion to $2 billion by 2022. (See ViewPoints: With generic Velcade on the horizon, Amgen delivers a timely boost to Kyprolis profile.)

To gain further insight into just how much of an impact the ENDEAVOR results are likely to have with physicians, and whether it could serve as the breakthrough Amgen needs to invigorate Kyprolis sales, FirstWord is polling US- and EU5-based oncologists and asking them…

> Interim results from the Phase III ENDEAVOR study show Kyprolis achieved significantly better progression-free survival than Velcade (18.7 months vs 9.4 months) in second-line multiple myeloma, meaning relapsed and refractory patients. How will these data affect your use of Kyprolis in this setting?
>
> IWhat future disclosures from the ongoing ENDEAVOR study will be most important for supporting increased use of Kyprolis?
>
> IBased on the success of Kyprolis plus Revlimid in relapsed MM (third-line) from the ASPIRE trial, and now Kyprolis' efficacy in relapsed MM (second-line) in ENDEAVOR, how frequently – if at all – might you combine Kyprolis with Revlimid in newly diagnosed MM patients?
>
> IOverall, how will the new Kyprolis data affect your use of Revlimid?
>
> IGiven the impending emergence of oral proteasome inhibitors (Takeda's ixazomib could be approved in 2016), how at-risk is Kyprolis of losing market

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