

Bristol Myers, Pfizer - FDA briefing document- Negative view on Xarelto approval in SPAF - BAYN stock price Overreacts

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Abstracts

On September 8, FDA advisory committee will meet to discuss approval of Xarelto in SPAF, while the briefing document released today recommends a complete response. The primary concerns being, in centers where INR control was better (ROCKET-AF trial), the risk reward profile of Xarelto is unfavorable. BAY stock price has come down 12% and we see this as an overreaction, as Xarelto potential in other indication remains intact. DVT treatment and Acute Coronary syndrome are other larger opportunities for Xarelto, where Pradaxa/Eliquis have failed to match Xarelto's clinical profile. And also not to forget that EU verdict is still open where AF prevalence is twice as compared to US. We expect cumulative sales of \$2.8b for Xarelto from VTE prevention/ DVT treatment/ Acute Coronary Syndrome. The data in ACS and DVT treatment is due by the end of this year and we expect a positive outcome from these studies.

Contents

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