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Bristol-Myers Squibb - Eliquis: FDA Decision Date Extended by Three Months

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Abstracts

Owing to submission of additional clinical data by BMY, the USFDA has extended the review period for Eliquis by 3 months (new PDUFA June 28th). At this stage, the USFDA has not announced any advisory committee to discuss Eliquis approval, but one may not rule out the possibility owing to increasing concerns over safety of Dabigatran. This delay in Eliquis approval, will obviously give some additional time for Xarelto and Pradaxa to strengthen their position in SPAF space. Our discussion with physicians suggests that patients adequately controlled on warfarin will not switch owing to the burden of twice daily dosing as the associated risk of compliance can worsen the bleeding concerns. The frequent INR monitoring associated with warfarin has to be weighed against the inconvenience of twice daily dosing.

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