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Physician Views: Will PEGASUS Data Make AstraZeneca's Brilinta Fly?

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Abstracts

Despite the publication of full data from AstraZeneca's PEGASUS-TIMI 54 study this weekend, their remains mixed views as to whether trial results will drive a significant increase in the use of the platelet aggregation inhibitor Brilinta.

The PEGASUS study has been designed to evaluate whether the continued treatment of acute coronary syndrome (ACS) patients with the combination of Brilinta and aspirin reduces the risk of subsequent heart attacks. It is standard practice to treat ACS patients with a combination of aspirin and an adenosine diphosphate (ADP) receptor inhibitor such as Brilinta, Sanofi's Plavix or Eli Lilly's Effient for a 12-month period, while PEGASUS is assessing whether extension of this treatment over subsequent years is effective. AstraZeneca has suggested a positive result could effectively double the commercial opportunity of Brilinta versus its current label.

As announced in January, top-line data from PEGASUS demonstrated a statistically significant reduction in major cardiovascular events (a composite primary endpoint comprising cardiovascular death, myocardial infarction or stroke). Full data released this weekend demonstrated that versus placebo, the combination of Brilinta and aspirin delivered a relative risk reduction of 15 percent to 16 percent (depending on Brilinta dose), or an absolute level of reduction of 1.2 percent.

The primary safety endpoint of PEGASUS was major bleeding and unsurprisingly the presence of two antiplatelet agents in the Brilinta arm resulted in a higher rate versus placebo (2.5 percent versus 1.0 percent). The rate of intracranial/fatal bleeding was consistent across both arms.

While some analysts remain bullish that full data from PEGASUS is supportive of

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AstraZeneca's peak revenue forecasts ($3.5 billion versus 2014 sales of $476 million), others are sceptical that the new results will have any significant impact on increased uptake of Brilinta. One potential barrier to uptake is design of the PEGASUS study, and specifically the choice to compare Brilinta against placebo rather than Sanofi's Plavix.

A sub-analysis of the 2007 CHARISMA study (which influenced the design of PEGASUS) demonstrated that the combination of Plavix and aspirin delivered similar results to the extended use of Brilinta and aspirin. As a result, analysts at Bernstein estimate that around 20 percent of eligible Brilinta patients in the US are already treated with this combination, with Plavix now available generically at a significantly lower cost. Is it plausible that positive data from PEGASUS could actually stimulate further penetration of this much cheaper combination (on an off-label basis) at the expense of Brilinta market share gain?

Another factor to consider, as noted in an editorial published in the NEJM alongside publication of the PEGASUS study, is whether the balance of higher efficacy, but increased bleeding, is "close to an even proposition." Noting that treating 10 000 patients with low-dose Brilinta over the course of one year "would prevent approximately 42 primary endpoint events and produce approximately 31 major bleeding events," the editorial argues that PEGASUS results may "prompt speculation as to whether dual platelet inhibition with high-potency agents is approaching the point of diminishing returns."

Speaking on a conference call held by AstraZeneca on Monday, Marc Sebatine – lead investigator of the PEGASUS study - noted that Plavix use in this setting is evidence that physicians need something more effective than aspirin monotherapy, and Brilinta can fill this gap (as the only drug which has data to support this indication). Sebatine also argued that major bleeding events are reversible, thus he disagrees with the issue of "diminishing returns" raised in the NEJM editorial.

To better understand the impact of the PEGASUS data, FirstWord is this week polling US and EU5-based cardiologists. Specifically we are asking them…

How impressive do they think the PEGASUS data are?

Whether they think the PEGASUS data will have an indirectly positive impact on usage of generic clopidogrel in this indication?

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Whether they agree with statements made in the NEJM editorial (the net clinical benefit is "close to an even proposition" and that data could prompt speculation as to whether "dual platelet inhibition with high-potency agents is approaching the point of diminishing returns")?

How they expect their usage of Brilinta to evolve in this indication based on the PEGASUS data?

Whether they think that Brilinta will only be used in this indication in highly selected patients with lower risk of bleeding complications and particularly high cardiovascular risk, rather than the broader ACS population?

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