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Physician Views: Can Portola's reversal agent act as growth catalyst for novel anticoagulants?

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Abstracts

Initial Phase III data released by Portola Pharmaceuticals last week appears to have nudged its recombinant Factor Xa antidote andexanet alfa closer to market. The product is designed to be used in patients who have received therapy with a Factor Xa inhibitor, but whom subsequently need the anticoagulant action to be reversed due to bleeding or the requirement for surgery.

Portola's assertion that andexanet alfa will meet demand for a significant unmet need is shared by the FDA, which has granted the drug Breakthrough Therapy status. The regulator is also allowing Portola to submit the compound for approval on the basis of a smaller Phase III study, followed by a larger post-approval confirmatory trial. Analysts expect the compound to reach the market in 2016.

Although the market for Factor Xa inhibitors – comprising Bayer/Johnson & Johnson's Xarelto, Daiichi Sankyo's Edoxaban and Bristol-Myers Squibb/Pfizer's Eliquis – has rapidly achieved multi-billion dollar status, the rate at which this novel anticoagulant class has gained share at the expense of generic warfarin has been slower than many analysts had expected.

Emergence of an antidote product is seen as a potential catalyst that could increase usage of the Factor Xa class, with Portola successfully leveraging this dynamic to secure co-funding for its clinical studies from some of the larger pharmaceutical manufacturers who compete in this segment. Portola's recently unveiled Phase III data demonstrates the ability of andexanet alfa to reverse the effect of Eliquis, but studies are also under way with Xarelto, for example (ViewPoints: Portola leverages support from future competitors into successful data for Factor Xa antidote).

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With these factors in mind, FirstWord is polling US and EU5-based cardiologists to ascertain whether and how the availability of andexanet alfa would impact their usage of Factor Xa inhibitors. Specifically, we are asking them.

How aware they are of the andexanet alfa development programme?

What percentage of eligible patients they currently treat with a Factor Xa inhibitor?

What percentage of eligible patients they choose NOT to treat with a Factor Xa anticoagulant due to bleeding risk?

By what percentage they would expect treatment of eligible patients with a Factor Xa inhibitor to increase if an effective 'reversal agent' was available?

Theoretically, whether the availability of a reversal agent has a positive impact on your use of a specific Factor Xa inhibitor in favour of others (bearing in mind their slightly different clinical profiles)?

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