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Physician Views: Celgene's mongersen continues to impress in Crohn's – is it too good to be true?

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Abstracts

There are a handful of reasons why sceptics are incredulous about Celgene's mongersen, this despite – or perhaps even because of – recently unveiled Phase II results that analysts say show the oral antisense agent could replace biologics as front-line therapy for Crohn's disease thanks to the trifecta of higher efficacy, better safety and more convenient administration.

There is no denying that the data thus far are impressive, and the fact that Celgene, which has shown a good eye for picking winners, was willing to pay $710 million up front to license the programme suggests there is likely to be some fire beneath the smoke.

Results from a 166-patient Phase II trial presented at the United European Gastroenterology Week meeting on October 21 showed mongersen, also known as GED-0301, achieved a 65 percent remission rate after four weeks (at the highest dose). This number drew some 'oohs' and 'ahhs' from the Street as it matches up favourably against four-week remission rates of between 15 percent and 48 percent produced by blockbuster biologics like AbbVie's Humira and Johnson & Johnson's Remicade in pivotal studies.

ISI's Mark Schoenebaum was among several analysts to highlight the clear dose response, with the three escalating doses of mongersen achieving better efficacy, which he says further validates that the activity seen was in fact real. See ViewPoints: Expectations heightened for Celgene's Crohn's disease gamble.

While there is some theoretical risk mongersen could cause fibrosis by raising TGF-beta levels (via SMAD7 inhibition), the compound's safety profile thus far has proven to be

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relatively benign, and its oral bioavailability would offer an obvious advantage versus the injectable biologics.

Deutsche Bank and UBS analysts agreed that mongersen's profile would seem to make it a clear new standard-of-care should Celgene's planned Phase III trial, which will start this year and run for 52 weeks, successfully reproduce what's been seen so far.

But is it too good to be true?

Among the reasons being seized upon for suspicion have been mongersen's outdated technology, unvalidated target, mechanistic uncertainty, little-known originator and perceived flaws in the design of the Phase II trial.

Poll Questions

To gain further insight into how the medical community is thinking about both the impressive potential and unanswered questions associated with mongersen, FirstWord is polling gastroenterologists in the US and EU5 asking them...

> The percentage of patients with moderate to severe Crohn's disease they typically prescribe a biologic drug (eg, TNF inhibitors)?
>
> How do Phase II data presented last week and showing mongersen achieved a 65-percent remission rate, which – given caveats with making cross-study comparisons – looks impressive versus remission rates of between 15 percent and 48 percent produced in studies of marketed biologics, change their perception of mongersen?
>
> How confident are they that the efficacy and safety shown by mongersen in the Phase II trial can be reproduced in a Phase III setting?
>
> Which of the potential issues that have been raised about the study/programme are they most concerned about?
>
> If Celgene does reproduce the Phase II data in Phase III, to what percentage of front-line patients would they expect to prescribe mongersen within 12 months of launch?

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