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Physician Views: How Have Recent Data, Study Design Events Shaped Doctors' Thinking on Lead NASH Agents

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Abstracts

Biotech is a notoriously volatile sector, and pure-play nonalcoholic steatohepatitis (NASH) drug developers have for the past couple years occupied one of the more volatile neighbourhoods within it thanks to growing appreciation for the how big the multi-billion dollar market could be and, in turn, more interest from investors attempting to predict how the race to the regulatory finish line – and the subsequent battle for scripts – will play out.

Genfit and Intercept, which along with Gilead are two of the three most advanced companies in the space, recently made important announcements regarding their respective NASH development programmes.

The more binary of the two events was a Phase II readout from Genfit, which put on a brave face while reporting in late March that its GFT505 missed the study's primary endpoint by failing to achieve a significant impact on fibrosis after one year. The company said the inclusion of less severe NASH patients confounded the results, thus masking the true effect of the compound, and that it would plough ahead into Phase III testing based on the findings. (See ViewPoints: Genfit ploughs on with GFT505, but Phase II data far from GOLDEN.)

With Gilead still in the midst of Phase II testing, Genfit's stumble left Intercept as the undisputed leader in the race to market based on the success of its obeticholic acid (OCA), which was the first programme to draw the attention of generalist investors when in January 2014 it produced unexpectedly strong results in the Phase II FLINT study. The company's shares tripled on the day of the announcement.

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In the months since, Intercept has gone on to provide a number of updates on the study, some good (eg, achieving a significant impact on fibrosis) and others not so good (eg, concern about its cardiovascular safety profile based on elevations of cholesterol levels), many of which have resulted in massive swings in the company's market cap.

The most recent update came last month when Intercept announced it had received approval from the FDA and EMA on the design of the Phase III REGENERATE trial that will get underway next quarter and is intended to support registration of OCA inside and outside the US. Analysts seemed to like the study but investors appeared to be taken off guard, both by its size (2500 patients) and the robustness of the co-primary endpoints, which included liver fibrosis improvement with no worsening of NASH and NASH resolution with no worsening of liver fibrosis. Indeed, Intercept shares have slumped more than 20 percent since the detailed plans were disclosed. (See Spotlight On: Full steam ahead – regulators onside as late-stage studies for key pipeline drugs are approved, but Intercept investors not convinced.)

How damaging was GFT505's Phase II readout? Are doctors concerned about OCA's efficacy or safety profile? To gain better understanding about how the recent announcements from Intercept and Genfit are into physician's evolving views on the various NASH agents, FirstWord PLUS is polling US- and/or EU5-based gastroenterologists and asking them…

> How confident are you that OCA will meet its co-primary endpoints?
>
> Intercept has suggested a cardiovascular outcomes trial (CVOT) will not be required prior to approval. Assuming efficacy endpoints are reached (and cholesterol increases are on par with Phase II data) how concerned will you be about the safety profile of OCA in the absence of CVOT data?
>
> How concerned would you be about using concomitant statin therapy to manage OCA's impact on LDL cholesterol?
>
> OCA could be launched to treat primary biliary cirrhosis as soon as early 2016. Assuming this happens and no untoward surprises are observed in other studies, how often might you consider prescribing the product to NASH patients (in the intervening years prior to when OCA is potentially approved for NASH in the 2019 timeframe)?

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Genfit’s GFT505 recently failed to hit its primary endpoint in a Phase IIb study, which was blamed on the inclusion of less severe NASH patients. Based on your experience with less severe NASH patients, would you agree that this could logically have confounded an otherwise good result?

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