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Physician Views: Is Esperion's ETC-1002 a Viable Threat to the PCSK9 Inhibitors if Mid-Stage Data are Replicated in Phase III Studies?

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Abstracts

Last week saw Esperion Therapeutics release promising Phase IIb data for its oral hypercholesterolaemia treatment ETC-1002. When added to stable statin therapy, a 180mg dose of ETC-1002 demonstrated a 24 percent incremental reduction in LDL-cholesterol versus those patients treated only with a statin, while a lower 120mg dose demonstrated a 17 percent reduction in LDL-C.

Although some way below the approximately 60 percent LDL-C reductions demonstrated by the PCSK9 inhibitors (Amgen's Repatha and Regeneron Pharmaceuticals/Sanofi's Praluent), which are widely expected to reach the US market in the second half of 2015, the efficacy of ETC-1002 – if replicated in larger Phase III studies – could represent a threat to these injectable and (presumed) more costly treatments.

The PCSK9s are forecast to gain steady traction in certain patients, such as those with heterozygous familial hypercholesterolaemia (HeFH), but uptake in the broader statin population will be necessary if top-end forecasts are to be reached.

With payers having already called out the likely high price of the PCSK9 class, and with cardiologists recently polled by FirstWord noting that statin use remains sub-optimal, Esperion stands more than a glimmer of a chance to establish ETC-1002 in the treatment paradigm – potentially ahead of the PCSK9s – in patients who are completely intolerant to statins or intolerant to higher doses of statin therapy – if Phase III studies can produce comparable data to that generated in mid-stage studies.

Esperion CEO Tim Mayleben was in a bullish frame of mind as data for ETC-1002

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broke last week, proclaiming the drug to represent a "patient friendly, physician friendly and payer friendly approach" to expanding the treatment of hypercholesterolaemia beyond the statin class.

Much depends on clinical progression of the compound over the next few years, the role of regulators (in determining when – i.e. pre/post-launch – cardiovascular outcomes data will be required) and potential out-licensing of ETC-1002 to support these developments.

Nevertheless, even at this stage of development – and with the positioning of the PCSK9s still under much discussion – we are polling US and EU5 cardiologists to gauge their sentiment towards Phase IIb data for ETC-1002 and their potential usage should comparable data be produced in larger Phase III studies. Specifically we are asking them…

> If comparable efficacy data were demonstrated in Phase III studies – and ETC-1002 was priced on par with a branded statin – to what percentage of patients already receiving a statin would you also prescribe ETC-1002?
>
> If comparable efficacy data were demonstrated in Phase III studies, would you consider prescribing ETC-1002 ahead of a PCSK9 inhibitor to patients with uncontrolled LDL-C who are unable to tolerate higher statin doses?
>
> If comparable efficacy data were demonstrated in Phase III studies, would you consider prescribing ETC-1002 ahead of a PCSK9 inhibitor to patients who are unable to tolerate any statin therapy?
>
> If comparable data were demonstrated for ETC-1002 in Phase III studies, how significant a barrier to uptake would this product be in limiting/slowing use of the emerging PCSK9 inhibitor class?
>
> Based on the available data for ETC-1002 (and assuming comparable replication in Phase III) and LDL-C reduction demonstrated by the PCSK9 inhibitor class (approximately 60 percent), what impact would moderately positive cardiovascular outcomes data for the PCSK9 inhibitors have in limiting the use of ETC-1002?

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