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Esperion shifts to show not tell

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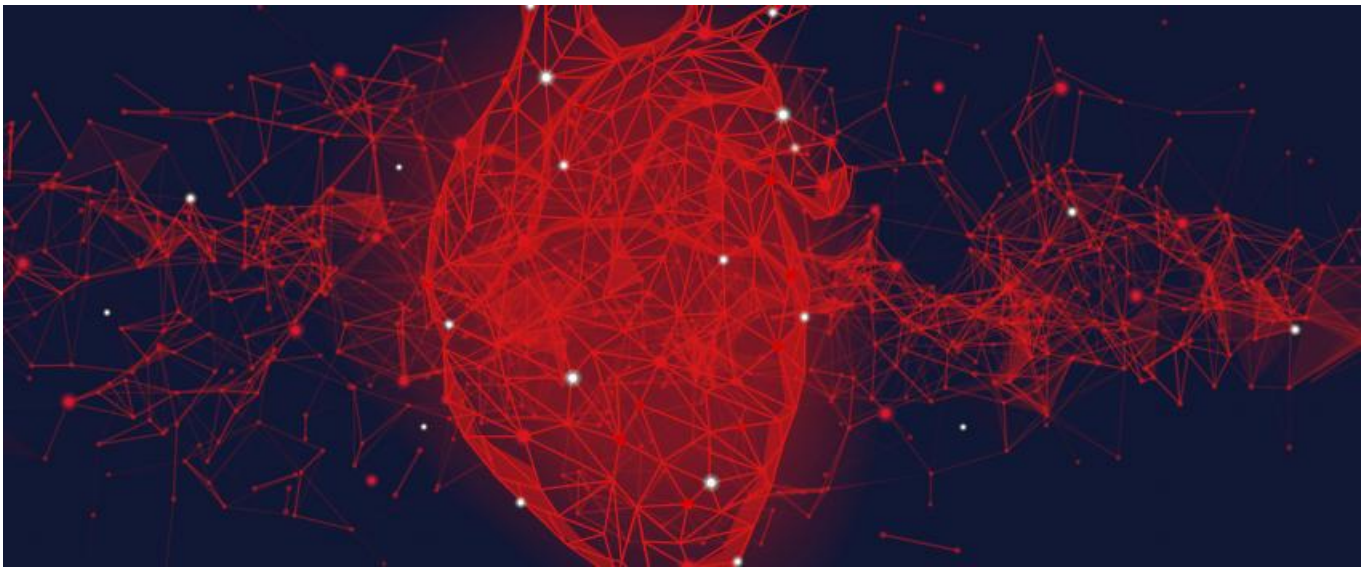

After spending years insisting that its cholesterol-lowering medicine has a place between statins and PCSK9 inhibitors, Esperion must now prove it.

At Esperion's 2013 Nasdaq flotation investors were offered a chance to buy into a cholesterol-lowering project that could treat those intolerant to statins or those who need an extra LDL-lowering boost. Given the time that has passed, and the development U-turns that are so common in biopharma, it is surprising how little that message has changed.

Last Friday the FDA approved the project in question, bempedoic acid, which is now trademarked Nexletol. A decision on the drug's use in combination with ezetimibe is due in the coming days, and anything other than another green light would be a huge surprise.

What has shifted over the years is the company's focus on the relative affordability of Nexletol. The arrival of the PCSK9s in particular means that the post-statin space has become highly competitive, and Esperion arguably had little choice but to go in hard on price. The pill will cost around $10 per day, the company confirmed today, which equates to around $3,650 a year; by comparison, the PCSK9 agents are thought to cost around $6,000 annually.

More relevant to US patients is out of pocket costs, which Esperion claims will be substantially lower than $10 per day thanks to access programmes that it will offer. On a call today executives said there were "no plans to sunset" these schemes, which could see some patients paying as little as $10 for a three-month supply.

Race to the bottom?

The ability of Esperion to make money from such a strategy will be a major focus for investors in the coming months. Much will depend on demand, and on how much money the company needs to spend to generate those sales. Consensus numbers from *EvaluatePharma* have $42m in sales this year, rising to $716m by 2024, with the company starting to turn a profit in 2023.

Similar cost-lowering arrangements are in place for the PCSK9s, of course, though it seems unlikely that the developers of these antibodies – Amgen, Sanofi and Regeneron – will be willing to come down much lower. Aside from the fact that these companies have already had to slash their prices by more than half to drive demand, these drugs are more potent cholesterol-lowerers.

But Esperion also has a strong convenience argument to make: Nexletol is a once a day pill and it is easy to see how this regimen might be more appealing than an injected PCSK9. This is also why approval of the

ezetimibe combination is important: this takes the all-oral regimen closer to the PCSK9s in terms of LDL lowering.

On the downside, however, Esperion has a couple more years to wait before it knows whether a crucial cardiovascular claim is in its grasp. Clear Outcomes, testing Nexletol versus placebo in 12,600 statin-intolerant patients, will not yield results until at least 2022. Experion's affordability and convenience arguments will mean little should this trial fail to yield a convincing signal.