Biotech upstart gambles $150M believing it can succeed after Big Pharmas failed on CETP

by John Carroll |
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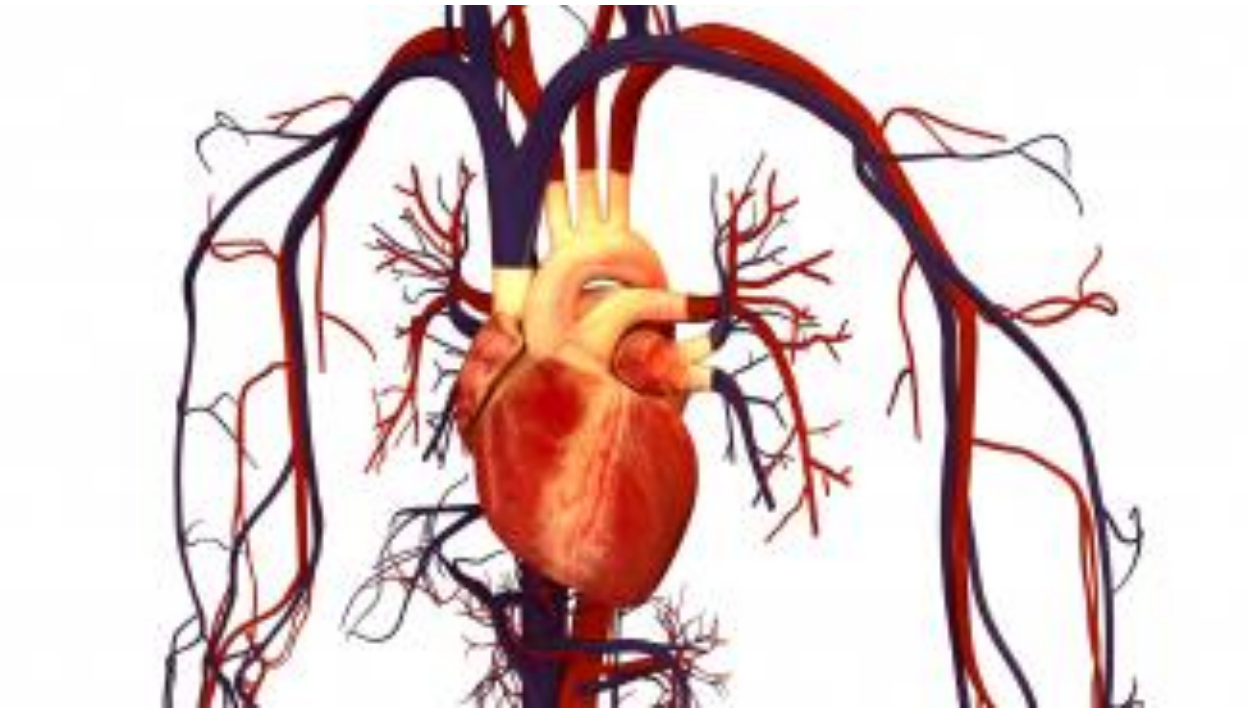

CETP inhibition has been an enormously expensive disaster zone for Big Pharma for the past decade. Just weeks ago Eli Lilly ($LLY) threw in the towel on evacetrapib after concluding that the drug did exactly what it wanted it to do, significantly raising good cholesterol and lowering bad cholesterol, without moving the dial on patients' risk of cardio events. That followed similar Phase III flops at Pfizer ($PFE) and Roche ($RHHBY), leaving Merck's ($MRK) big gamble on anacetrapib under a dark cloud as the pharma giant wraps a massive 4-year study.

But working with some genetic data mined from a Phase III study of Roche's dalcetrapib, scuttled three years ago, a group of heart drug researchers laid claim to a personalized approach that they believe will pay off for a significant slice of the market. And venture backers have now supplied $150 million to a startup to take that strategy back into another big Phase III trial.

The upstart DalCor Pharmaceuticals is beginning to recruit 5,000 patients who have experienced acute coronary syndrome for the study. And they'll be using a diagnostic test from Roche to identify the patients.

The bold move comes more than a year after a team of investigators led by Dr. Jean-Claude Tardif of the Montreal Heart Institute concluded that a genetic analysis of the dalcetrapib data points directly to a personalized approach that could succeed where everyone else had failed. Specifically, he

concluded that variations in the *ADCY9* gene dictated cardiovascular benefits or risks. That new analysis pointed directly to a significant group of patients who saw a 39% reduction in risk of the composite endpoint for a range of conditions, including coronary heart disease death, when compared to a placebo.

That genetic subgroup accounted for 20% of the patients in the big dal-OUTCOMES study, which enrolled 15,871 patients with ACS.

The money comes from Sanderling Ventures and André Desmarais together with new investors Caisse de dépôt et placement du Québec, the Fonds de solidarité FTQ and CTI Life Sciences. They put up a $50 million round late last year and recently followed up with another $100 million. But they'll likely need more. After the company licensed the drug from Roche last summer, DalCor CEO and Sanderling managing director Robert McNeil noted that the company will need $250 million to complete the study.

The biotech may be technically based in London, but the work is being spread around the globe. The research appears to be centered in Montreal, with McNeil based in San Mateo, CA, and an office in Switzerland as well, close to Roche.

The big wager comes as analysts have all but completely written off the entire field after all the big failures. A decade ago Pfizer was forced to write off its $800 million attempt with torcetrapib after concluding that its CETP drug raised risks for patients. And no one has felt that erosion of confidence more acutely than Merck, which spent big on its own huge Phase III test.

In a recent conversation with Bernstein's Tim Anderson, Merck R&D chief Roger Perlmutter acknowledged the declining confidence in their CETP drug. Anderson summarized Perlmutter's views on the subject, noting: (I)t's impossible to look at LLY's data and feel that LLY missed something and that there is a signal. There isn't. It's possible that CETP's reduction in LDL isn't the "right" sort of reduction, where differences in particle size or other aspects may have confounded the primary analysis. It's also possible, although less likely, that CETP has deleterious effects that net out the benefits provided by LDL reduction and HDL elevation. At this point, MRK doesn't know how the data will look, but finds it important to let the trial run its course. REVEAL's estimated primary completion is Jan 2017.

– here's the release