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www.reachmd.com
info@reachmd.com
(866) 423-7849

What's on the Horizon for IRI Management?

Announcer:
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Dr. Patel:
This is CME on ReachMD, and I'm Dr. Manesh Patel, here today with a colleague, Dr. Deepak Bhatt. Deepak, thanks for joining me.

Dr. Bhatt:
Great to be with you.

Dr. Patel:
Well, let's get right into today's topic, Deepak. What can you tell us about the evolving landscape of ischemia-reperfusion injury management and potentially new opportunities to improve the outcomes of our patients with ST-segment elevation MI who undergo PCI for acute MI?

Dr. Bhatt:
Well, it's a great topic, one that you and I've been interested in for years. Primary PCI, I think everyone in the audience knows, is really the treatment of choice for a patient with ST-elevation MI. But a challenge is that ischemia-reperfusion injury can occur once the artery's open, rapid, or hopefully rapid restoration of blood oxygen, there can be the production of reactive oxygen species. FDY-5301 is a formulation of sodium iodide, and it's been designed to hopefully reduce ischemia-reperfusion injury. It has the capacity to catalytically destroy hydrogen peroxide, and there's a lot of evidence out there linking reactive oxygen species such as hydrogen peroxide to ultimately muscle damage and dysfunction. So we discussed in prior segments that there's no currently approved therapeutic agent for IRI; our hope is that FDY-5301 would be the first. And is there any reason to believe that might be the case? Well, there's preclinical models that show potential benefit of this compound.

As well, there's phase 2 clinical trial data. Now, obviously, phase 2 trials are designed for safety, not specifically for efficacy, but we thought there were some potential signals of efficacy. There were beneficial effects on biomarkers such as proBNP, myeloperoxidase, matrix metalloproteinase 2, so things that might portend benefits in terms of reducing cardiac dysfunction, reducing inflammation, adversely or actually impacting the adverse remodeling that can occur in a patient with a STEMI, in particular, a large ST-elevation MI. As well, the phase 2 data showed numerically lower rates of infarct size, so reductions in infarct size potentially in preservation of cardiac function. Now, obviously, all of that needs to be confirmed in well-powered phase 3 testing. Phase 2 is good mostly for safety; everything else is hypothesis-generating.

Dr. Patel:
Well, Deepak, that's a great overview, and describes really the unmet need and the challenge to get some of these therapeutics to market and to help our patients. And one of the exciting things about this compound, as you highlighted, sodium iodide, is that it's fairly

well tolerated and can be given to patients ahead of time. Because that is one of the challenges with ischemia reperfusion, patients are coming in at differential amounts of weighting, different amount of myocardium at risk, so having a safe compound really helps. Is that right?

Dr. Bhatt:
Yeah. So in the phase 2 trial, it certainly looks safe in terms of overall safety, adverse events, significant adverse events, so forth. So you know it does seem to be that it's a safe compound. Now we have to see whether the preclinical work, the signals in the phase 2 translate into actual clinical events in phase 3. But if it does turn out to be a positive trial, it would be, I think, a potential game changer to have a new therapeutic, something that is actually able to address ischemia-reperfusion injury, and a nice adjunct to percutaneous coronary intervention, which we know is a treatment of choice for ST-elevation MI.

But because of those positive signals on biomarkers and even imaging endpoints, we have indeed launched a phase 3 trial, the Iocyte AMI-3 trial. And that is a trial of a bit over 2,000 patients with anterior ST-segment elevation MI. It's a randomized, double-blind, placebo-controlled trial. Patients are given a single intravenous bolus prior to percutaneous coronary intervention because, of course, in ischemia-reperfusion injury, ideally, you get the agent on board before grading that reperfusion injury before opening up the artery. And it is hopefully going to be the first ischemia-reperfusion injury agent approved, assuming the trial is positive. The FDA obviously has signed off on the protocol, and our hope is that we have a broad STEMI indication, even beyond just anterior MI, if the trial is positive. So the trial is fully enrolled, but we have to see what the outcomes are. And I look forward to discussing that with you in the future, hopefully.

Dr. Patel:
Yeah, really, really exciting, given that we've done a lot to try to help with the failing heart and things to help at the time of opening, we'd love to have some things we could give before opening the artery to make the artery and the patient and hopefully the heart do better.

Well, this was brief, but I'm glad I had the opportunity to share this information with you, Deepak, and hear about this. Thank you all for listening.

Dr. Bhatt:
Thank you.

Announcer:
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