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Real-World Eligibility for Vericiguat According to Trial, Guideline, and Labeling Eligibility Criteria: Data From the Swedish Heart Failure Registry

Announcer:
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Dr. Fudim:
Hi, my name is Marat Fudim I'm a cardiologist, at Duke University in Durham, North Carolina. And the topic of this presentation is real-world eligibility for Vericiguat according to trial guideline and labeling eligibility criteria. This is from the Swedish Heart Failure Registry and was recently presented at ESC by Severasian and colleagues. So, I'll just get going right into the presentation itself. And you know, the problem at hand is that heart failure reduce ejection fraction has seen a lot of gains in the improvement of morbidity mortality, but the residual risk on heart failure hospitalization and death remains quite significant. So, to date, we are treating patients with heart failure with reduced ejection fraction with what we call four pillars. You know, the ARNIs, beta-blockers, MRAs, SGLT2s. Having said that, in the United States and in Europe we are also now the approval for the drug, Vericiguat. And that's the topic of the day-to-day.

Vericiguat is a soluble guanylate cyclase stimulator. Well, what is that? Well, in heart failure, as in some other conditions the endothelium, the inner lining of the verciguat of arteries and veins secrets endogenous NO. NO is nitric oxide. This gas is then actually stimulating the guanylate cyclase to produce cGMP. And cGMP has many, many roles and function in the body, including being a vasodilator, has some diuretic properties to it, et cetera, et cetera. So now when you have heart failure, you actually have an insufficient amount of the endogenous NO. You don't produce enough of it. So, you do not generate through the guanylate cyclase GMP. And thus the Vericiguat stimulates directly that cascade bypasses the need for NO. And thus Vericiguat could have, which has the stimulate function could increase cGMP production in human body, improve vascular function, mycardial function, et cetera, et cetera.

So Vericiguat was tested in a Victoria trial, which was one of the largest heart failure trials done to date on top of those four drug pillars, and found that there was a reduction in heart hospitalization and death when used compared to placebo. So that then led to the approval of this agent in the United States, specifically earlier this year. So, what the investigators from Sweden did and that's part of that Swedish HF registry, they said, "Well, what is the real-world eligibility for this agent in this population wide registry?" And what they've done is this, they took 41,000 plus patients with heart failure reduced ejection fraction over the last decade. And they compared two specific scenarios. One scenario was, as it is currently labeled in the guidelines, you know you need to have a heart failure duration of grade on six months. You ideally already on optimal medical therapy, you have still symptomatic heart failure and you had a heart failure hospitalization within the recent six months. The other criteria were the trial scenario. The trial scenario is where you add on additional criteria, inclusion, exclusion criteria. But the key exclusion criterion is that, if your BNP, the brain natriuretic peptide is too low. You really wanted to have a thousand or greater in patients in sinus rhythm. So that was the second set of criteria they applied and then they looked at endpoints such as CV death and hospitalizations for heart failure, CV death, non-CV death and heart failure hospitalizations.

So, no surprises there. But so, when they looked at the eligibility what they found is that the overall eligibility for patients with heart failure and reduced ejection fraction was relatively low. I mean, maybe surprisingly low particularly when you apply to trial scenarios. So of course, remember trial scenarios are very intentionally narrowing down the population. So, you generate in a relatively homogeneous population the best possible outcome. So there the eligibility was 12.4% and this population of Swedes. And then if you apply the guideline and the label indication they found eligibility of all patient, 27%. Interesting, on the right side, what you see, is that patients that met eligibility were actually quite high-risk. So intentionally as it was done with the trial the population that was chosen for Vericiguat was really a population at a greater risk for CV death and heart failure hospitalizations and non-CV death, compared to the patients that did meet eligibility. So, it really would apply this agent to a very high-risk population. I think that's a very important and interesting finding.

So, the second part of the results is shown here. And here the investigators wanted to know what was the main reasons patients got excluded from being eligible for Vericiguat using either of those two populations. The trial population or the guideline criteria. And what they found is that the recent heart failure hospitalization needs. So, the need for being hospitalized within the last six months was actually the number one criteria people got excluded. Here only 50.2% of patients met that eligibility criteria. And the second most common was, the presence of heart failure of at least six months and the use of guideline-directed medical therapy. So that was only met in 57.6% of cases. And last but not least, you had the elevated NT-proBNP cutoff which remember in this trial was actually relatively high. That engineer was met in 76% of cases. So, I think that's actually pretty good. Then some other criteria such as, blood pressure that couldn't be too low or the use of nitrates, which is contraindicated in this setting of Vericiguat. Those were other criteria that excluded an additional several percent points of patients.

Eligibility for Vericiguat amongst patients with heart failure reduce ejection fraction was overall limited. So found the investigators and this is specifically as applied by guidelines and or the trial scenario. Then further eligibility criteria in all scenarios successfully selected for population at high-risk for both CV and non-CV events. Meaning if you qualified for this drug, you were really in trouble as a patient. I mean, your outcomes would be significantly worse than patients that wouldn't be actually eligible for this drug. And recent heart failure hospitalizations. So, within the last six months that you had a heart failure hospitalization or chronic heart failure diagnosis or with OPT medical therapies were the key criteria for ineligibility. I would like to thank you for your attention, and you have a good day.

Announcer:
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