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Efficacy and Safety Deep Dive What Latest Data Tell Us

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Dr. Ballantyne:
Welcome to CE with GLC. I'm Kristi Ballantyne. I'm the chief of cardiology and cardiovascular research at Baylor College of Medicine, and I'm delighted to have a chance to review with you the phase 3 clinical trial data on a new CBT inhibitor, obicetrapib. Let's start off with the BROOKLYN. This was a phase 3 study in heterozygous familial hypercholesterolemia.

We know that's a very important group. They're hard to treat. You frequently have to use more than a statin. These people were all on maximally tolerated therapy. It was a 2-to-1 randomization, a 1-year study, 354 patients, so a good-sized study to look at a hard-to-treat patient group.

The reduction in LDL at week 84 was 36% and at 365 days was 41.5%. So robust additional reductions on top of the baseline therapy seen in this study. Other parameters that are also very important, non-HDL cholesterol went down 34.5 at day 84, 37.5 at day 365.

ApoB went down 24% and almost 26%, at the one-year point. Looking at LDL particle concentration, with NMR spectroscopy, there's a reduction about 52%. A very dramatic reduction of the LDL-P pretty much obliterated the LDL, small LDL particles. There's a favorable trend of reductions in CRP and which was nice to see here because a lot of these patients with FH have high levels of Lp, there was a reduction in the levels of lipoprotein A of around, 45%, 54% at one year.

Okay, that's an important group. Now, a larger group is people who are basically have atherosclerotic cardiovascular disease, and or have heterozygous FH. That was most of these people had ASCVD. That's the Broadway study. Phase 3 trial, a larger study, 2,532 patients in this study.

Similar design, 2-to-1 randomization. These people were also treated on maximum tolerated lipid-modifying therapy, had to have LDLs over 55. And let's look at the results here. You can see that the primary endpoint was a reduction about at day 84. Placebo subtracted about 33% in LDL cholesterol ApoB was reduced.

This is a summary of all the other things. ApoB goes down around 19%, non-HDL cholesterol 29%, Lp(a) around 33.5%. Big increase in HDL cholesterol, as we see with CETP inhibitors, goes up a hundred and 36%. so very favorable effects on atherogenic lipoproteins, and as we've seen with other ones, a big increase in HDL.

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Well, what about safety? There had been some concerns going way back with the first one, which had an off-target effect. So with obeticholic acid, there's no impact on blood pressure. One thing that really I look at, the first thing I look at is, any treatment-emergent adverse event leading to study discontinuation.

And, this is to me really important for clinical practice. Do people have to stop the drug because of side effects? What was seen in this study, which is a pretty good-sized study, was that fewer people stopped obeticholic acid than placebo, 4% versus 5.1%. So that's always encouraging to see in terms of safety, and that the drug looks to be extremely safe from the studies that have been done thus far.

Well, how does it work in combination? We know frequently we need combination therapy, and this is looking at the, a fixed-dose combination of obeticholic acid with ezetimibe. That's one of the ways this drug would be available if it gets approved in the future. And you get about a 50%, 48.6% reduction in LDL cholesterol with the combination.

So in summary, what's been shown in this Phase 3 program of LIPIDS, with I've shown BROOKLYN, BROADWAY, TANDEM, consistent results, good reductions in LDL, non-HDL, ApoB, Lp(a). There are 2 other, very important trials in progress. PREVAIL is an outcome study, has about 9,000 people looking at MACE.

And REMBRANDT is using CT angiography to look at the impact of the combination therapy on the progression of coronary atherosclerosis. Thank you very much.

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