

SPEAKER: But the notable, novel finding in ODYSSEY Outcomes was also the fact that all-cause mortality was lower in patients receiving alirocumab. A second observation is that those patients who started off with a baseline LDL cholesterol equal to or above 100 milligrams per deciliter LDL cholesterol appeared to derive a bit, first of all, to have a greater baseline risk, as expected, but they appeared to derive a greater absolute benefit of treatment probably for a similar or quite similar relative risk reduction with treatment. So they appeared to be maybe one of the interesting target groups for treatment.

Finally, in both trials, it's remarkable that the safety profile of PCSK9 inhibitors has been really good over the duration of the trials, and those trials are modestly long-- between two and three years median or mean follow-up, maximum follow-up is five years in ODYSSEY Outcomes. But really, over the duration of the trial, there was no major adverse event that was noticed to be more frequent with alirocumab. The only one was local injection site reactions defined as itching, swelling, redness at the injection site, generally mild in nature and limited to the first few weeks of therapy.

So really, the benefit-risk ratio is remarkable for these agents. Now, there is a catch, as we all know, which is that these agents have a cost, and they're not cheap. There are monoclonal antibodies. And therefore, it's incumbent on clinicians, trialists, regulators, payers to better understand with the guideline committees, where are these agents best targeted, to which patients we should target them to make the most appropriate use of these novel and very effective agents.