Transcript Details

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Beyond the Primary Endpoint: What OCEANIC-STROKE Subtype Analyses Reveal About Asundexian's Potential

Announcer:
Welcome to DataPulse from ISC25 on ReachMD. This activity, titled "Beyond the Primary Endpoint: What OCEANIC-STROKE Subtype Analyses Reveal About Asundexian's Potential" is provided by Medcon International.

Dr. Shoamanesh:
Hello from ISC 2026 here in New Orleans. I'm Dr. Ashkan Shoamanesh. I'm a stroke neurologist at McMaster University and the co-principal investigator of the OCEANIC-Stroke trial. And I'm excited to share with you today insights from *P*-specified secondary analysis of this study looking at how stroke subtypes may influence response to asundexian, a factor XIa inhibitor, in development for secondary stroke prevention.

OCEANIC-Stroke was a large global initiative that enrolled 12,327 participants with non-cardioembolic ischemic stroke or high-risk TIA who presented within 72 hours of symptom onset. And these patients were randomized 1:1 to receive either asundexian 50 mg daily or matching placebo, and patients were followed up to 31 months to a common termination date in this event-driven trial.

The main purpose of these prespecified secondary analyses was to ensure that the top-line results and some of the key secondary endpoints of this trial were generalizable irrespective of ischemic stroke subtype at study entry. Just to review the primary efficacy endpoint for the overall study, asundexian led to a 26% reduction in time to first occurrence of ischemic stroke, and impressively, there was no offsetting harm regarding ISTH major bleeding or any of the prespecified secondary safety endpoints.

Of the 12,327 participants that entered the study, about 11,100 had ischemic stroke and were able to be analyzed according to ischemic stroke subtype. And the key stroke subtypes of interest were those patients with large artery atherosclerosis, small vessel occlusive disease, and those with strokes of undetermined etiology.

When we examined the efficacy of asundexian for primary endpoint of time to first occurrence of ischemic stroke, we found that the overall treatment effect was consistent, irrespective of underlying ideology, which was a bit of a surprise based on some of the earlier observations we had in our phase 2 PACIFIC-Stroke study. And all of these subgroups were shown to see significant reductions in ischemic stroke in isolation. However, the *P* value for the treatment interaction was negative, leading us to conclude that, really, the results are consistent and generalizable across all these 3 key subgroups.

In addition, it's worth noting that these were large subgroups, just due to the large nature of this trial. There were about 5,000 patients with large artery atherosclerosis disease, 3,500 patients with strokes of indeterminant etiology, and 2,500 patients with small vessel occlusive disease-related strokes.

On the safety side, we also saw consistency and no lack of excess risk of ISTH major bleeding, no lack of excess of intracranial hemorrhage, and no excess in hemorrhagic stroke across all 3 subtypes. And impressively numerically, the rates of hemorrhagic stroke, which is the bleeding outcome of greatest concern to us as stroke neurologists, were actually less with asundexian versus placebo across all 3 subtypes, including patients with small vessel occlusive disease who are at greatest risk for this outcome.

So overall, the trial results are generalizable across all stroke etiologies. We also performed sensitivity analysis in patients with embolic strokes of undetermined source, where there was a 47% reduction in ischemic stroke with asundexian versus placebo, really advancing stroke prevention, even in this subgroup where we've had unfortunate lack of success in improving their stroke prevention with factor X inhibitors and direct thrombin inhibitors to date.

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I think this is going to be a groundbreaking study. The overall message from the trial is consistency and generalizability, and they really don't need to tease out the stroke subtypes, because if they were eligible for this study, patients benefited.

From ISC 2026, I'm Dr. Ashkan Shoamanesh, and thank you for watching.

Announcer:
Thank you for listening to this DataPulse from ISC25 on ReachMD. This activity is provided by Medcon International. Thank you for listening.

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