

Transcript Details

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Sotatercept in PAH: Safety Signals from Real-World Data

Announcer:

Welcome to *Clinician's Roundtable* on ReachMD. On this episode, we'll hear from Dr. Parth Rali, who's a Professor of Thoracic Medicine and Surgery at the Lewis Katz School of Medicine at Temple University and the Director of the Temple University Health System Pulmonary Embolism Response Team Program. He'll be sharing the findings from a real-world propensity-matched analysis that he presented at the 2026 European Respiratory Society Congress, which focused on sotatercept in patients with pulmonary arterial hypertension. Here's Dr. Rali now.

Dr. Rali:

This came out as a research question because sotatercept—an activin signaling inhibitor, which is the fourth class of treatments for pulmonary arterial hypertension—got FDA approved. But in the real world, the patients that we see sometimes overlap between different disease groups, meaning they may have a Group 1 PAH, but they may have other comorbid conditions and overlapping group diseases with that. Obviously, those patients were never studied in clinical trials because they were purely designed for Group 1 PAH.

So to see what's happening post-FDA approval and how things were used, we decided to use a real-world data registry called TriNetX database, which allows us to look at the patients' prescriptions, their disease state, and their ICD codes from which we can at least see how the sotatercept has been used in mixed group real-world pulmonary arterial hypertension with overlapping phenotypes.

Looking at the outcomes of the study, I think the first thing that you always question if the physicians have used the drugs in a real-world setting which may not exactly mimic the clinical trial design is, are you doing any more harm? And that was the first question that we had; we wanted to make sure that the patients that we are looking up are among group patients and whether they had more side effects, like thrombocytopenia, GI bleed, intracranial hemorrhages, and pericardial effusion because those are the known side effects of the drug that can happen very infrequently. But we wanted to see when you start using sotatercept outside the clinical trial context in a mixed pulmonary hypertension population, do we see a greater signal of harm with that drug use?

So that was the main premise: to determine the safety of the drug. And I think what we showed is that there was no sign of increased harm in terms of side effects of the drug. Obviously, the patients who had mixed group diseases had more hospital admissions, which is not unexpected given these patients have multiple comorbid diseases. And we cannot pinpoint that those exacerbations related to heart failure or something else given the nature of the real-world registry-based database.

But I think our whole purpose and what I think we learned by doing this study is that there were no more side effects than what we see in Group 1 PAH patients in clinical trials compared to the Group 1 PAH patients with different pulmonary hypertension phenotypes in combination.

So it is, in my opinion, a very good real-world safety signal. You can always argue about the type of database that we used. It's not a prospective registry nor a real-world randomized controlled trial. These are patients in the real world as part of a large administrative dataset. So I think it is really encouraging to see the initial safety results, but this has to be confirmed in larger prospective randomized controlled trials or registries in coming times.

Announcer:

That was Dr. Parth Rali talking about propensity-matched real-world data on sotatercept in patients with pulmonary arterial hypertension. To access this and other episodes in our series, visit *Clinician's Roundtable* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!