Transcript Details

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Rapid and Sustained Symptom Control in CSU with Remibrutinib

Ryan Quigley:

Welcome to *AudioAbstracts* on ReachMD. I'm Ryan Quigley, and today, I'll be discussing a pooled analysis of the REMIX-1 and REMIX-2 phase 3 studies evaluating remibrutinib in adults with chronic spontaneous urticaria, or CSU.

Before we dive into the data, I'd like to share some context. Even though CSU patients who remain symptomatic despite second-generation H1-antihistamines have seen treatment options expand in recent years, rapid symptom control remains a major clinical goal.

This is especially true because patients live with persistent itch and hives that can significantly impair quality of life.

Remibrutinib is an oral, highly selective Bruton's tyrosine kinase inhibitor that was recently approved for this patient population. The pooled analysis of REMIX-1 and REMIX-2 explored whether its clinical benefits are maintained over the course of a full year.

Together, the studies enrolled 909 adults with CSU that remained inadequately controlled despite second-generation H1-antihistamines.

Patients were randomized in a two-to-one ratio to receive oral remibrutinib, 25 milligrams twice daily, or placebo while continuing background antihistamine therapy.

After 24 weeks, patients in the placebo group transitioned to open-label remibrutinib, and outcomes were evaluated through week 52.

So what did the investigators find?

Clinical improvement appeared quickly. Patients randomized to remibrutinib experienced reductions in overall disease activity as early as week one, based on the weekly Urticaria Activity Score.

And by week two, average disease activity in this group improved by more than 50 percent. Those benefits continued to deepen over time, reaching approximately 75 percent improvement by week 52.

Patients who crossed over from placebo at week 24 demonstrated a similar pattern of improvement after starting active treatment.

The same rapid response was seen across the individual symptom domains. Mean itch severity improved by about 50 percent within the first two weeks, with sustained reductions approaching 74 percent by week 52.

Hive severity followed a nearly identical trajectory, exceeding 50 percent improvement by week two and remaining around 75 percent below baseline through one year of treatment.

Together, these findings suggest that remibrutinib delivers both early relief and durable symptom control across the major clinical manifestations of CSU.

Safety findings were also reassuring. During the 24-week double-blind period, the overall incidence of adverse events was similar between remibrutinib and placebo.

Serious adverse events and treatment discontinuations due to adverse events were uncommon in both groups. Across the full 52-week study period, the overall safety profile remained favorable, with no new safety signals identified.

As with any pooled analysis, there are important limitations to consider. This assessment focused primarily on descriptive, observed outcomes over time rather than formal statistical comparisons at later time points. In addition, after week 24, all participants received

remibrutinib, which limits long-term comparisons with placebo.

Taken together, these findings reinforce the clinical profile established in the individual REMIX studies. For adults with CSU who remain symptomatic despite second-generation H1-antihistamines, remibrutinib was associated with rapid improvements in itch, hives, and overall disease activity that were sustained through one year, while maintaining a favorable safety profile. As clinicians consider treatment strategies that prioritize both speed and durability of symptom control, these long-term data provide additional support for remibrutinib as an effective oral treatment option.

This has been an *AudioAbstract*, and I'm Ryan Quigley. To access this and other episodes in our series, visit ReachMD dot com, where you can Be Part of the Knowledge. Thanks for listening!

Reference:

Gogate S, Palumbo M, Giménez-Arnau A, et al. Abstract R083: Early and sustained efficacy of remibrutinib in adult patients with CSU: pooled analysis of REMIX-1/-2. *Ann Allergy Asthma Immunol*. 2025;135(5):S30. doi:10.1016/j.anai.2025.08.101