

Improvement in Lung Function with Rademikibart in Eosinophilic Driven, Type 2 Asthma

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Rademikibart (CBP-201), a monoclonal antibody targeting interleukin-4 receptor alpha (IL-4R α), has shown promising results in treating asthma characterized by elevated eosinophil (EOS) counts¹. This abstract summarizes improvement in lung function data from a global Phase 2b trial that evaluated the efficacy of rademikibart in patients with moderate to severe persistent asthma with baseline blood EOS levels exceeding 150 or 300 cells/ μ L. The primary endpoint was the absolute change in forced expiratory volume in one second (FEV1) at Week 12.

In the trial, a total of 322 patients were randomized into three groups: 600 mg loading dose followed by rademikibart 150 mg, rademikibart 300 mg, or matched placebo, administered every two weeks for 24 weeks.

The results in the full population demonstrated significant improvements in lung function at Week 12 with among patients receiving rademikibart 150 mg or 300 mg compared to the placebo group (140 mL [$p=0.005$] and 189 mL [$p<0.001$] improvement over placebo, respectively). For patients with EOS counts ≥ 150 cells/ μ L, the mean improvement in FEV1 at Week 12 was 203 mL and 270 mL, respectively ($p<0.001$ for both rademikibart doses). Furthermore, in patients with baseline EOS levels ≥ 300 cells/ μ L, the effects were even more pronounced, with an average improvement in FEV1 of 243 mL and 328 mL, respectively ($p<0.001$ for both rademikibart doses).

Beyond the primary endpoint of FEV1, in the EOS ≥ 150 population, we also observed enhancements lung function as measured by Percent Predicted FEV1, with improvements over baseline of 8.8% (ending value 72.9%) and 10.7% (75.5%), respectively, compared to placebo (0.90%; 61.8%). Even greater improvements were noted in the EOS ≥ 300 population, with improvements over baseline of 10.7% (ending value 76.0%) and 12.2% (79.0%), respectively, compared to placebo (1.4%; 63.7%).

Importantly, rademikibart was generally well tolerated, with no new safety signals reported. Common treatment-emergent adverse events included mild respiratory symptoms and injection site reactions, which were consistent across treatment groups.

This trial's outcomes indicate that rademikibart may offer another treatment option for patients with eosinophilic asthma and highlight the importance of eosinophil counts as potential biomarkers for individualized therapy. Further studies are warranted to confirm these findings and explore the long-term implications for asthma management using rademikibart in eosinophilic asthma populations.

References

- (1) Kerwin, E. M.; Guo, J.; Adivikolanu, R.; Longphre, M.; Wang, J.; Yun, J.; Pan, W.; Wei, Z.; Collazo, R. Improved Lung Function and Asthma Control Observed With Rademikibart in Patients With Moderate-to-Severe Uncontrolled Asthma (CBP-201-WW002). *Am J Respir Crit Care Med* **2024**, *209* (1_MeetingAbstracts), A7003. https://doi.org/10.1164/ajrccm-conference.2024.209.1_MeetingAbstracts.A7003.

