

Reduction in Annualized Exacerbations with Rademikibart in Eosinophilic Driven Type 2 Asthma

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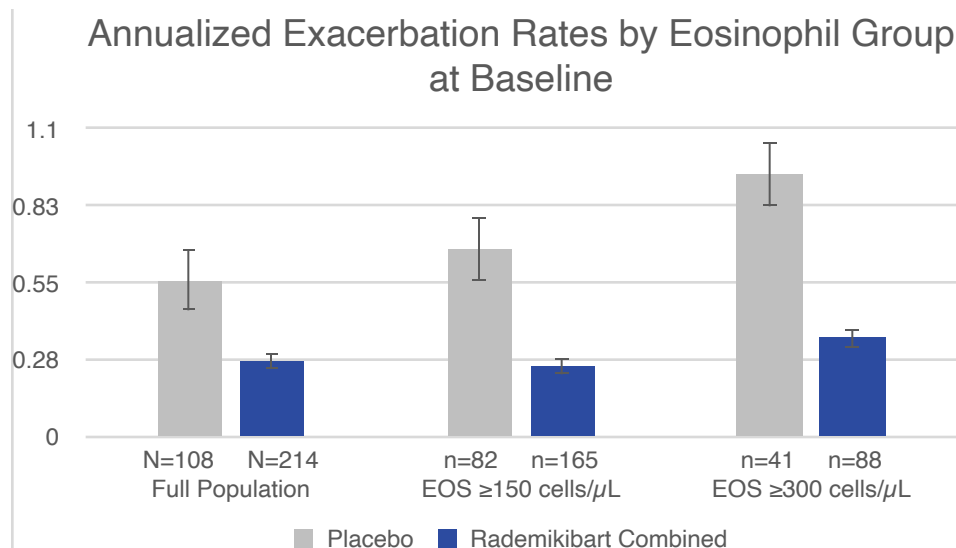
Rationale: Rademikibart (CBP-201), a monoclonal antibody targeting interleukin-4 receptor alpha (IL-4R α), has shown promise in treating asthma with elevated eosinophil (EOS) counts. This abstract summarizes findings from a Phase 2b trial evaluating rademikibart's efficacy in moderate-to-severe asthma patients with baseline blood EOS levels ≥ 150 or ≥ 300 cells/ μ L. Annualized exacerbation rate (AAER) was an exploratory endpoint.

Methods: A total of 322 patients were randomized to receive a 600 mg loading dose followed by 150 mg or 300 mg rademikibart, or placebo, every two weeks for 24 weeks. Due to previously reported consistencies in lung function response in the 150 mg and 300 mg dose groups¹, the rademikibart groups were combined for this *post hoc* analysis.

Results: Although the trial was not powered to see differences in annualized exacerbations, the results in the full population demonstrated reductions in AAER, with rates of 0.27 in the rademikibart groups versus a placebo rate of 0.56 (51% reduction; $p=0.0341$). Subgroup analyses revealed stronger effects in patients with EOS ≥ 150 or EOS ≥ 300 at baseline. In the EOS ≥ 150 population, an AAER of 0.25 (rademikibart) was observed versus a placebo rate of 0.67 (63% reduction; $p=0.0108$) while AAERs of 0.35 and 0.94 (65% reduction; $p=0.0324$), respectively, were observed in the EOS ≥ 300 population. Annualized incidence rates were non-significant in those patients with EOS less than 300 EOS.

Safety profiles were consistent with IL-4R α inhibitors. Treatment-emergent adverse events (TEAEs) occurred in 59, 73 and 71% of all patients in the placebo, 150 mg and 300 mg groups, respectively. Relatively similar findings were noted in the EOS ≥ 150 (63, 74 and 78%, respectively) and the EOS ≥ 300 (66, 76 and 84%, respectively) populations. More adverse events (AEs) occurred in the higher EOS subgroups regardless of treatment (rademikibart or placebo). Serious adverse events (SAEs) and discontinuations due to an AE were rare and evenly distributed regardless of baseline EOS count.

Conclusion: In conclusion, rademikibart (CBP-201) shows promise as a targeted therapy for type 2 inflammation-driven asthma. Although limited by its short duration and exploratory endpoints, this trial highlights rademikibart's potential in reducing exacerbations and improving asthma outcomes, particularly in EOS-high patients. Future studies are needed to confirm long-term efficacy and its position in the broader asthma treatment landscape.



References

1. Kerwin EM, Guo J, Adivikolanu R, et al. 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. doi:10.1164/ajrccm-conference.2024.209.1_MeetingAbstracts.A7003