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# Rapid and sustained FEV<sub>1</sub> improvements with rademikibart in type 2 asthma: Impact of eosinophils and F<sub>E</sub>NO

Asthma - management, Treatments, Adults

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**BACKGROUND:** Rademikibart, targeting the IL-4 pathway, plays a key role in type 2 inflammation and in a Phase 2 trial (NCT04773678), significantly improved FEV<sub>1</sub> in moderate-to-severe asthma. The current analysis examined the improvement in participants with elevated baseline type 2 biomarkers (high vs low blood eosinophils [EOS] ≥300 cells/μL and high vs low fractional exhaled nitric oxide [F<sub>E</sub>NO] ≥25 ppb).

**METHODS:** 322 participants were randomized 1:1:1 to rademikibart 150 mg Q2W (n=106), 300 mg Q2W (n=108), or placebo (n=108) following a 600 mg loading dose or matched placebo. At Week 1, all treated participants had only received a loading dose and thus, Week 1 data are pooled. Week 24 data are presented for the 300 mg group, the expected Phase 3 dose. Endpoints of interest were change in pre-bronchodilator (BD) FEV<sub>1</sub> at Week 1 and 24.

**RESULTS:** At baseline, pre-BD FEV<sub>1</sub> ranged from 1836.3 to 1908.3 mL. At Week 1, rademikibart improved FEV<sub>1</sub> significantly over placebo (n=201, LS mean difference: 183 mL placebo-adjusted [PA], p<0.001). In those with high EOS/high F<sub>E</sub>NO (n=50), FEV<sub>1</sub> further improved to 425 mL PA compared to the low /low group (n=80, 47 mL PA). At week 24, rademikibart 300 mg treatment in the full population significantly improved FEV<sub>1</sub> (n=108, 189 mL PA, p<0.001), with the greatest increases observed in the high/high (n=24, 558 mL PA) vs the low/low group (n=27, -26 mL PA).

**CONCLUSION:** Rademikibart treatment leads to rapid and clinically meaningful improvements in lung function within the first Week in patients with type 2 asthma, particularly in those with elevated blood eosinophils and/or F<sub>E</sub>NO. This benefit was maintained for the entire 24-week treatment period.