

46289**Improved lung function and asthma control observed with rademikibart in patients with moderate-to-severe asthma**

Asthma - management, Severe asthma, Treatments

E. Kerwin¹, J. Guo², R. Adivikolanu³, M. Longphre³, J. Wang³, J. Yun², W. Pan², Z. Wei³, R. Collazo³**¹Clinical Research Institute, Allergy and Asthma Center of Southern Oregon - Medford (USA), ²Suzhou Connect Biopharmaceuticals - Taicang (China), ³Connect Biopharma - San Diego (USA)**Rademikibart (formally, CBP-201), an IL-4R α -blocker, was assessed for efficacy and safety in patients with uncontrolled moderate-to-severe asthma.This global Phase 2b trial (NCT04773678) was conducted in 79 sites with 322 patients randomized 1:1:1 to rademikibart 150 mg (Q2W; n=106), 300 mg Q2W (n=108) each with a loading dose of 600 mg or placebo (n=108). Primary endpoint was absolute change in FEV₁ at Week 12 pre-bronchodilator (Pre-BD) use.Pre-BD FEV₁ at Week 12 was significantly improved with both rademikibart doses with further improvement in patients with EOS \geq 300 cells/ μ l (see table). Significant percent predicted FEV₁ improvement was observed at Week 12 with a 7.9% and 9.1% improvement over placebo, respectively. Placebo-adjusted changes in the Asthma Control Questionnaire score at Week 24 were -0.44 (p<0.001) and -0.33 (p<0.01), respectively. All improvements started in Week 1 and were sustained through Week 24. Although not powered to detect differences in exacerbations, strong trends toward prolonging the time to first exacerbation and overall reduced exacerbations were observed. Treatment with rademikibart was generally well tolerated.

The trial met the primary endpoint of improvement in lung function with both rademikibart doses which were observed rapidly within the first week of treatment. Significant improvement in asthma control was also observed.

	Full Analysis Set			Baseline EOS \geq 300 cells/μL		
	Placebo (n=96)	Rademikibart Q2W		Placebo (n=37)	Rademikibart Q2W	
		150mg (n=96)	300mg (n=86)		150mg (n=33)	300mg (n=41)
<i>LS Mean Change in pre-BD FEV₁ at Week 12</i>	95mL	235mL	284mL	-8mL	235mL	320mL
<i>Difference in LS Means</i>		140mL p=0.005	189mL p<0.001		243mL p<0.001	328mL p<0.001