

# European Respiratory Society Annual Congress 2012

**Abstract Number:** 2323

**Publication Number:** 3083

**Abstract Group:** 5.1. Airway Pharmacology and Treatment

**Keyword 1:** Anti-inflammatory **Keyword 2:** COPD - management **Keyword 3:** Pharmacology

**Title:** The safety and tolerability of twice-daily oral doses of AZD5069, a novel CXCR2 antagonist, in patients with moderate-to-severe COPD

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**Body:** BACKGROUND: This Phase IIa study evaluated the safety and tolerability of the CXCR2 antagonist AZD5069 in patients with moderate-to-severe COPD. METHODS: This was a 4-week, randomised, double-blind, placebo-controlled, parallel group, multi-centre study. Patients were aged 40–80 years, with a diagnosis of moderate-to-severe COPD for >1 year. Patients received placebo (PBO) bd (n=29), AZD5069 50 mg twice-daily (bd) (n=30) or AZD5069 80 mg bd (n=28) for 4 weeks. Primary safety and tolerability outcome variables included adverse events (AEs), ECG, haematology, clinical chemistry, urinalysis, vital signs, and lung function. The pharmacokinetics (PK) of AZD5069 and the effect of exposure on circulating neutrophils were assessed as secondary objectives. RESULTS: Patients had a mean age of 64 years (69% male; all white). There were no deaths. Two SAEs (one with 50 mg and one with 80 mg) were assessed by the investigator as not related to AZD5069. The number of patients with AEs was evenly distributed across treatment groups. Discontinuation due to AEs was also similar across treatment groups, but highest in patients receiving AZD5069 50 mg (3, 5 and 2 patients receiving PBO, AZD5069 50 mg and 80 mg respectively). The PK was as predicted from healthy volunteers, but with higher variability. As expected, there was an exposure-related, reversible reduction in circulating neutrophils with AZD5069. No other clinically important changes in primary variables, including infection rates, were observed with AZD5069. CONCLUSIONS: AZD5069 was well tolerated with no safety issues identified in this 4 week Phase IIa COPD patient trial.