

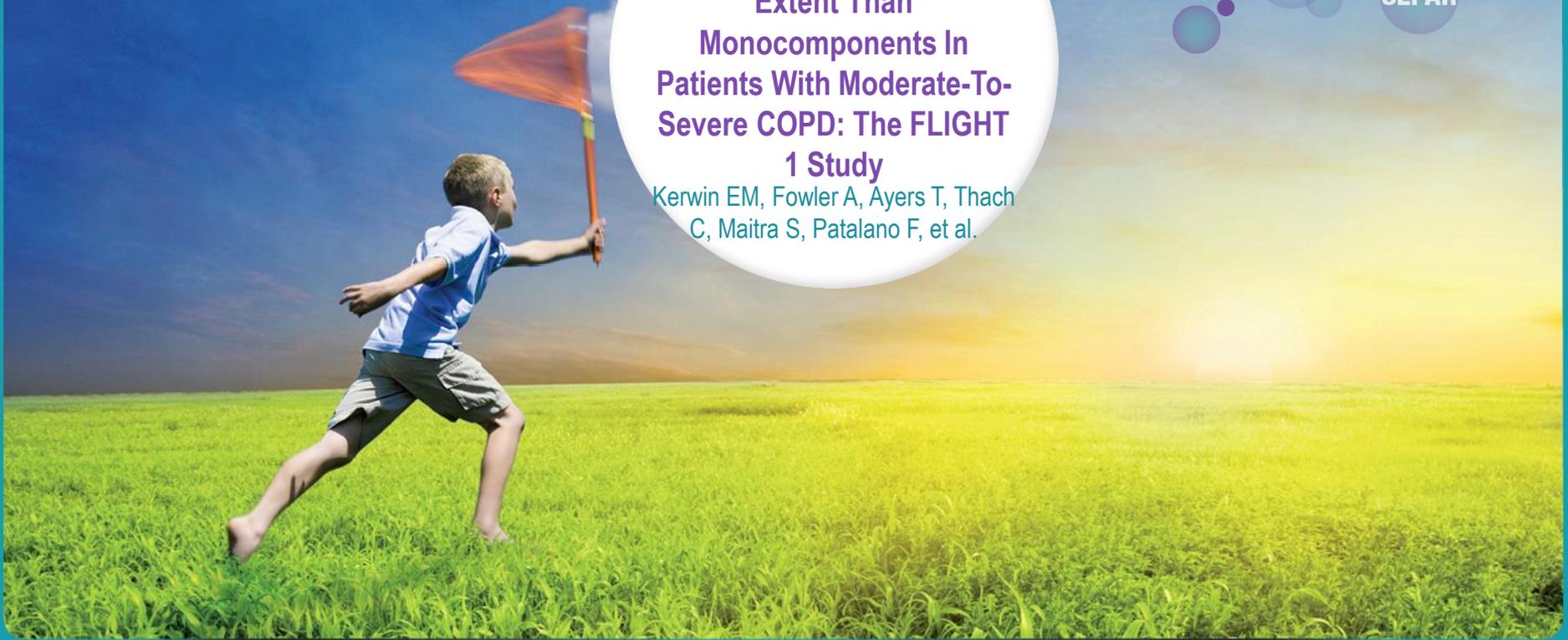
**[ATS] QVA 149 Improves
Lung Function To A Greater
Extent Than
Monocomponents In
Patients With Moderate-To-
Severe COPD: The FLIGHT
1 Study**

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Rationale



Managing symptoms in patients with moderate-to-severe COPD.1 QVA149 is a fixed-dose combination of indacaterol (a long-acting β 2-agonist [LABA]) and glycopyrronium (a longacting muscarinic antagonist [LAMA]) for maintenance treatment of COPD. The FLIGHT1 study evaluated the efficacy and safety of twice-daily (b.i.d.) QVA149 versus its monocomponents and placebo in patients with moderate-to-severe COPD.

Methods



This was a 12-week, multi-center, double-blind, parallel-group, placebo- and active-controlled study that randomized patients (1:1:1:1) to QVA149 (27.5 µg indacaterol/12.5 µg glycopyrronium), indacaterol 27.5 µg, glycopyrronium 12.5 µg or placebo, all administered twice daily via the Breezhaler® device. The primary objective was to compare QVA149 to its monocomponents (indacaterol and glycopyrronium) in terms of standardized area under curve from 0 to 12 h (AUC_{0-12h}) for forced expiratory volume in 1 second (FEV₁) at Week 12. Secondary endpoints included pre-dose FEV₁, trough FEV₁, peak FEV₁ and rescue medication use.

Results



Of the 1042 patients randomized, (QVA149, n=260; indacaterol, n=260; glycopyrronium, n=261; placebo, n=261); 1008 (97 %) patients completed the study. The primary objective was met with QVA149 showing statistically significant and clinically meaningful improvement in FEV₁ AUC_{0-12h} at Week 12 compared to monocomponents, indacaterol (least square mean [LSM] treatment difference: 94 mL; p<0.001) and glycopyrronium (LSM treatment difference: 98mL; p<0.001), and placebo (LSM treatment difference: 231 mL; p<0.001). QVA149 also demonstrated statistically significant (p<0.001) improvement in trough FEV₁ and peak FEV₁ compared to monocomponents and placebo after 12 weeks of treatment (Table).

Results



Summary of treatment differences in efficacy parameters at Week 12

	QVA149 vs placebo	QVA149 vs indacaterol	QVA149 vs glycopyrronium
FEV ₁ AUC 0-12 h (mL)	231 (20.2)**	94 (19.8)**	98 (19.9)**
Trough FEV ₁ (mL)	213 (20.8)**	81 (20.2)**	110 (20.2)**
Peak FEV ₁ (mL)	260 (21.6)**	109 (21.1)**	100 (21.2)**
Rescue medication (mean daily number of puffs)	-1.22 (0.183)**	-0.50 (0.181)*	-0.58 (0.181)*

**p<0.001; *p<0.05; LSM, least squares mean; SE, standard error, AUC, area under curve; FEV₁, forced expiratory volume in one second

Conclusion



In patients with moderate-to-severe COPD, dual bronchodilation with QVA149 was superior to monotherapy with indacaterol and glycopyrronium in improving lung function, reducing rescue medication use and had no additional safety risks compared to its monocomponents and placebo.

Muchas gracias
por su atención

