Mesa 3

[ATS] Improvement in lung function with indacaterol/glycopyrrolate (ind/gly) in patientswith moderate to severe COPD from the Us: a subgroup alalysis from the Flight1 and Flight2 studies

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Introduction.-

IND/GLY 27,5/15,6 µg demostrated superior improvement in lung funtion along with rapid onset versus its monocomponents (IND27,5 µg and GLY 15,6 µg) and placebo in patients with moderate-to-severe COPD. **Here we present the lung function data in the subgroup of patients from the US.**

Methods.-

- FLIGHT1 and FLIGHT2 were replicate, 12 week, multi-center. Randomized, double-blind studies that evaluated the safety and efficacy of IND/GLY.
- Lung funtion was evaluated in terms of the area under the curve up to 12 h for forced expiratory volumen in 1 second (FEV_1 $AUC_{0\text{-}12H}$), TROUGH FEV_1 and peak FEV_1 during 4 hours post dose with IND/GLY versus its monocomponents and placebo.
- Onset of action was evaluated by measuring the improvement in FEV_1 at 5 min post-morning dose on Day1.

Results.- (I)

- Of 2038 patients from the overall pool, 1104 were fron the US an included in this analysis (IND/GLY, n=274; IND, n=256; GLY, n=292; placebo, n=278).
- IND/GLY showed superior improvement in lung function with a statistically significant (p>0,001) improvement in $FEV_1AUC_{0\text{-}12H}$ at week 12, compared with placebo, IND and GLY (Table 1).

Results.- (II)

- Improvements in trough FEV_1 and peak FEV_1 were also statistically significant with IND/GLY versus placebo, and its monocompnents at Week 12 (all p<0,001).
- In addition, IND/GLY showed rapid onset of action as indicated by a statistically significant improvement in FEV_1 at 5 min post-dose on Day 1 versus placebo (p<0,001).

Parameters	Treatment difference, mL [LS mean (95% confidence interval)]					
	Day 1			Week 12		
	IND/GLY vs IND	IND/GLY vs GLY	IND/GLY vs Placebo	IND/GLY vs IND	IND/GLY vs GLY	IND/GLY vs Placebo
FEV_1 AUC 0-12h	99 (76, 121)	48 (26, 70)	181 (159, 203)	118 (81, 156)	111 (75, 147)	267 (230, 305)
Trough FEV_1 †	101 (72, 129)	93 (66, 121)	208 (180, 235)	91 (52, 130)	113 (76, 151)	239 (201, 278)
Peak FEV_1	102 (79, 125)	31 (9, 54) ‡	173 (150, 195)	139 (99, 179)	116 (77, 154)	299 (259, 339)
FEV_1 at 5 min post dose	42 (25, 59)	50 (33, 66)	117 (101, 134)	-	-	-
All p<0.001 except ‡p=0.006; †trough FEV_1 was measured at Day 2 and Day 86						

Conclusions.-

- In this post-hoc analysis, IND/GLY b.i.d. Demonstrated superior improvement in lung fuction with a rapid onset of action compared with monocponents and placebo.


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