



ARCEPOCIII

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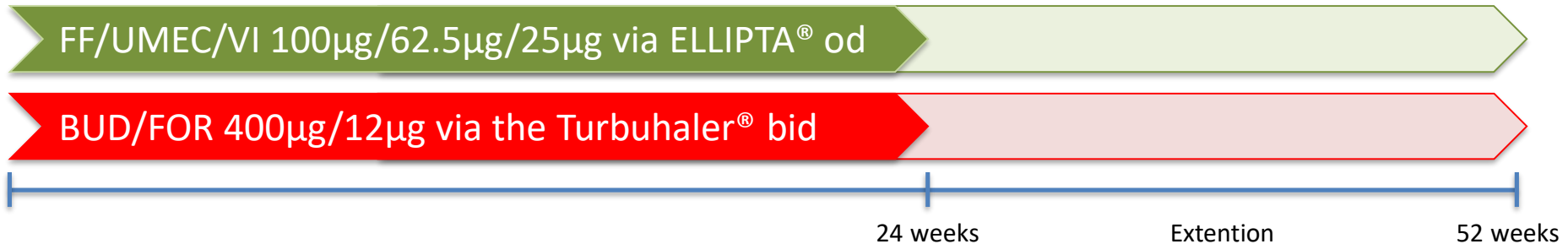
Descubriendo lo nuevo en EPOC presentado en ATS, ERS y SEPAR

ERS - Clinically important deterioration in advanced COPD patients using single inhaler triple therapy: results from the FULFIL study

Naya I

Methods

A prospective analysis of clinically important deterioration (CID), a composite measure (lung function, health status and exacerbations) of worsening COPD (Singh, et al. Int J COPD 2016; 11:1413), in the FULFIL study is reported.



Co-primary endpoints were at week 24:

- Change from baseline in trough FEV1
- Change from baseline in SGRQ Total score

Methods

CID was assessed for 24 weeks (intent-to-treat population; ITT) and 52 weeks (extension study; EXT) and defined as:

- D1, deterioration from baseline of:
 - ≥ 100 mL in FEV1 or
 - ≥ 4 units in St Georges Respiratory Questionnaire (SGRQ) score or
 - a moderate-severe exacerbation.
- D2, replaced SGRQ with a >2 unit deterioration in COPD assessment test (CAT) score.

Risk reduction was derived from time to first event analysis using a Cox proportional hazard model.

Results

In the ITT (N=1810) and EXT (n=430), FF/UMEC/VI significantly reduced the risk of a CID by 47–52% vs. BUD/FOR ($p < 0.001$).

| Study | CID | FF/UMEC/VI | BUD/FOR | HR | CI |
|-------|-----|------------|---------|------|-----------|
| ITT | D1 | 50% | 73% | 0.48 | 0.43–0.55 |
| | D2 | 51% | 73% | 0.50 | 0.44–0.56 |
| EXT | D1 | 60% | 81% | 0.52 | 0.41–0.66 |
| | D2 | 63% | 80% | 0.53 | 0.42–0.67 |

Median time to first CID was ≤ 31 days for BUD/FOR and ≥ 169 days for FF/UMEC/VI.

Conclusions

In this prospective analysis, FF/UMEC/VI reduced the risk of CIDs vs. BUD/FOR, and CAT and SGRQ provided comparable results.



The image features the Ferrer logo, which consists of a stylized 'F' icon in teal and lime green, followed by the word 'ferrer' in a bold, black, lowercase sans-serif font. The logo is centered in the upper half of the frame. The background is a vibrant landscape of a green field with wheat stalks in the foreground, extending to a distant horizon under a bright blue sky with scattered white clouds. The entire scene is framed by a solid purple border.

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