

# IMPACT: Informing the Pathway of COPD Treatment



GSK's landmark study of the first once-daily single inhaler triple therapy in COPD: Trelegy Ellipta (FF/UMEC/VI)<sup>1</sup>

## A unique landmark study

- One of the **biggest studies** ever conducted in COPD (10,355 patients)<sup>1</sup>
- **First study** undertaken to compare single inhaler triple therapy with its component dual therapies; all delivered once-daily in the Ellipta inhaler enabling direct comparisons to be made between the molecules in each of the medicines studied<sup>1</sup>



Conducted to explore the effect of treatment to reduce the annual rate of moderate/severe exacerbations ('flare ups')<sup>1</sup>



**An exacerbation is** the most common reason for hospitalisation with COPD<sup>2</sup>



Patients in the study had experienced at least one exacerbation in the past 12 months, which is representative of around 50% of the COPD population<sup>3</sup>



## Trelegy Ellipta was superior in reducing exacerbations vs both comparators<sup>1\*</sup>

Primary endpoint: the annual rate of on-treatment moderate and severe exacerbations at week 52



**15%**

reduction  
Vs Breo  
Ellipta  
= 0.91 vs 1.07



**25%**

reduction  
vs Anoro  
Ellipta  
= 0.91 vs 1.21

p<0.001 for both comparisons

\* FF/UMEC/VI, 100/62.5/25mcg (Trelegy Ellipta); FF/VI, 100/25mcg (Relvar/Breo Ellipta); UMEC/VI, 62.5/25mcg (Anoro Ellipta).

## Trelegy Ellipta: superiority across a range of clinically important secondary endpoints<sup>1</sup>

Annual rate of on-treatment severe (hospitalised) exacerbations with Trelegy Ellipta compared to Breo Ellipta and Anoro Ellipta



**13%**

lower  
Vs Breo Ellipta  
-1%, 24% p=0.064



**34%**

lower  
Vs Anoro Ellipta  
22%, 44% p<0.001

Numerical improvement was not statistically significant for Trelegy Ellipta vs Breo Ellipta on this endpoint

## Change from baseline at 52 weeks

Lung function improvement with Trelegy Ellipta compared to Breo Ellipta and Anoro Ellipta



**97mL**

greater  
Vs Breo  
Ellipta  
p<0.001

Trough Breo Ellipta



**54mL**

greater  
Vs Anoro  
Ellipta  
p<0.001

Improvement in quality of life with Trelegy Ellipta compared to Breo Ellipta and Anoro Ellipta



**1.8 units**

greater  
Vs Breo  
Ellipta  
p<0.001

St George's Respiratory  
Questionnaire  
(SGRQ) total score



**1.8 units**

greater  
Vs Anoro  
Ellipta  
p<0.001

The safety profile of Trelegy Ellipta was consistent with the known profile of the individual medicines and their dual combinations.<sup>1</sup>

The most common adverse events across the treatment groups were viral upper respiratory tract infection, worsening of COPD, upper respiratory tract infection, pneumonia and headache.

As with all ICS-containing products approved for the treatment of COPD, there was a higher rate of pneumonia seen with the fluticasone furoate (FF) containing arms (Trelegy Ellipta and Breo Ellipta) compared to Anoro Ellipta.<sup>1</sup>