The IMPACT study: Informing the Pathway of COPD Treatment

Trelegy Ellipta is not approved for use anywhere outside the US.

IMPACT in numbers

Around 10,000 COPD patients randomized
Approx 1,070 study centers worldwide
37 countries
52 weeks

GSK’s latest COPD study

• One of the largest phase III pre-registration COPD studies ever conducted
• The first study to compare three different classes of COPD medications with the same molecules in the same inhaler type and with the same dosing frequency
• Will expand the evidence base for GSK’s broad portfolio of once-daily treatments delivered via the Ellipta inhaler

Single inhaler triple therapy

All treatments administered once daily via the Ellipta inhaler

Study design

IMPACT was a phase III, randomised, double-blind, three-arm, parallel-group, global multicenter study comparing the rate of moderate and severe exacerbations between FF-UMEC/VI (Trelegy) and FF/VI (Breo) or UMEC/VI (Anoro) over 52 weeks:

Key inclusion criteria:

• Patients ≥40 years
• Established clinical history of COPD
• Spirometry confirmed COPD diagnosis
• 2-week run-in on current treatment

AND either:

Post-BD FEV₁, ≥50% predicted normal
Exacerbations in prior year:
• ≥1 severe or hospitalised
• ≥2 moderate or 
  ≥1 severe (hospitalised)

At study entry

Key exclusion criteria:

• Pregnancy
• Current diagnosis of asthma or other respiratory disorders/risk factors
• Alpha₁-antitrypsin deficiency as cause of COPD
• Other diseases or abnormalities as specified

Primary endpoints

Annual rate of on-treatment moderate and severe exacerbations for:
• Trelegy vs Anoro
• Trelegy vs Relvar/Breo

Other endpoints

• Change in FEV₁ for Trelegy vs Breo
• Change in quality of life as measured by SGRQ for Trelegy vs Breo

Safety assessments including:

• Incidence of adverse events
• Incidence of pneumonia
• Incidence of cardiovascular events

References


Ellipta, Relvar, Breo and Anoro are registered Trade Marks of Glaxo Group Limited.