

Aclidinium bromide: Phase III update

Professor Bartolome Celli

*Tufts University
Boston, MA, USA*

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The logo for the ACCLAIM COPD trial is centered in the upper right quadrant. It features the word "ACCLAIM" in a bold, dark blue, sans-serif font. A white vertical bar is positioned between the "I" and "M". Below "ACCLAIM" is a dark blue horizontal line that ends in a white circle. To the right of this circle, the letters "COPD" are written in a smaller, dark blue, sans-serif font. The entire logo is set against a light green circular background.

ACCLAIM
COPD

AClidinium **CL**inical trial **A**ssessing efficacy
and safety **I**n **M**oderate to severe COPD
patients (ACCLAIM/COPD)

ACCLAIM/COPD: Study objectives

**To evaluate inhaled aclidinium, 200 µg QD,
in patients with moderate to severe COPD
with respect to:**

- Long-term efficacy
- Long-term safety

Efficacy endpoints

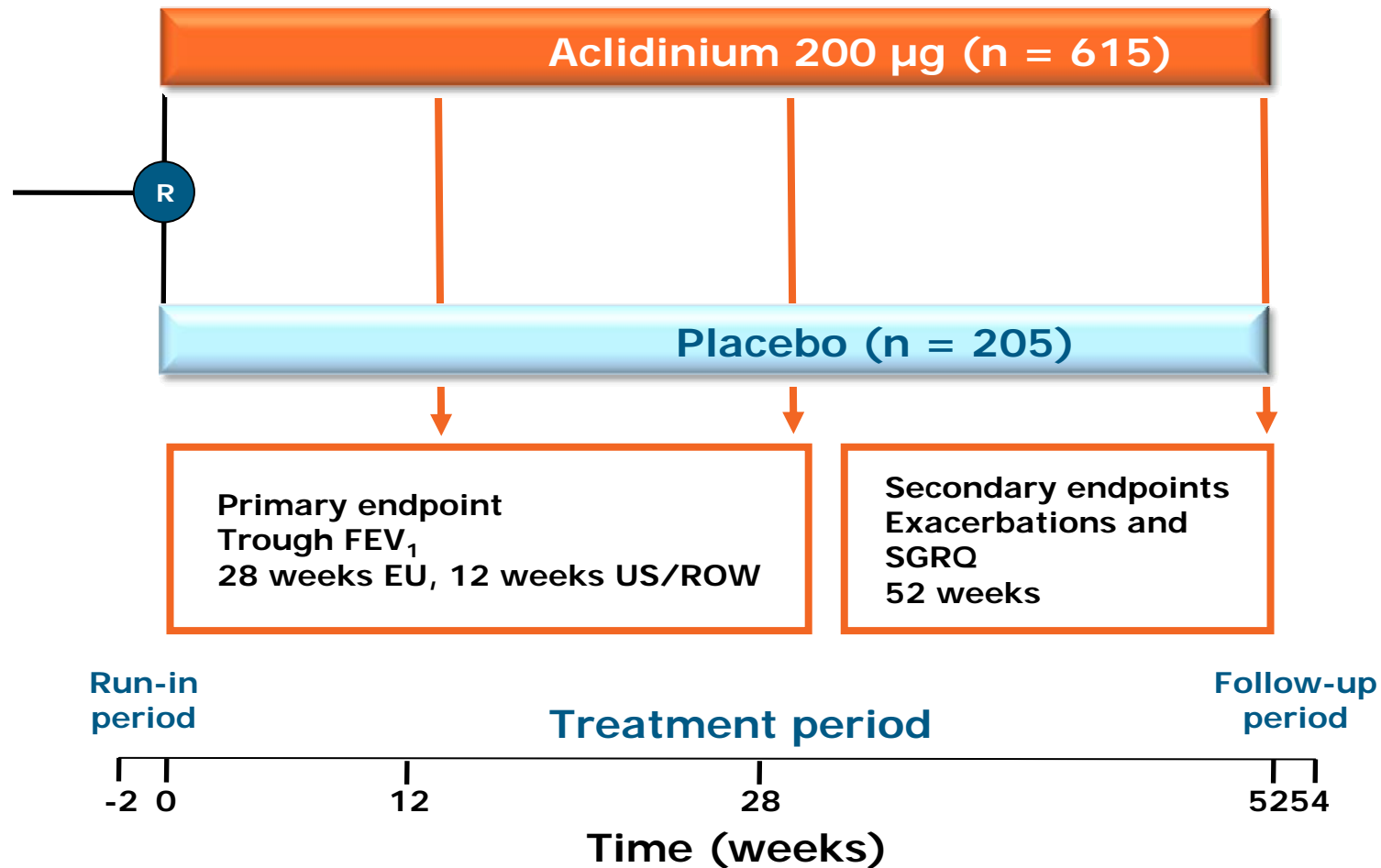
- **Primary endpoint**

- 24-h bronchodilation: trough FEV₁ (23-24h post dose)

- **Secondary endpoints (symptom-related improvement)**

- Time to first moderate to severe exacerbation
- % patients achieving greater than or equal to a 4-point improvement in SGRQ

Study design: Replicated for ACCLAIM/COPD I and II

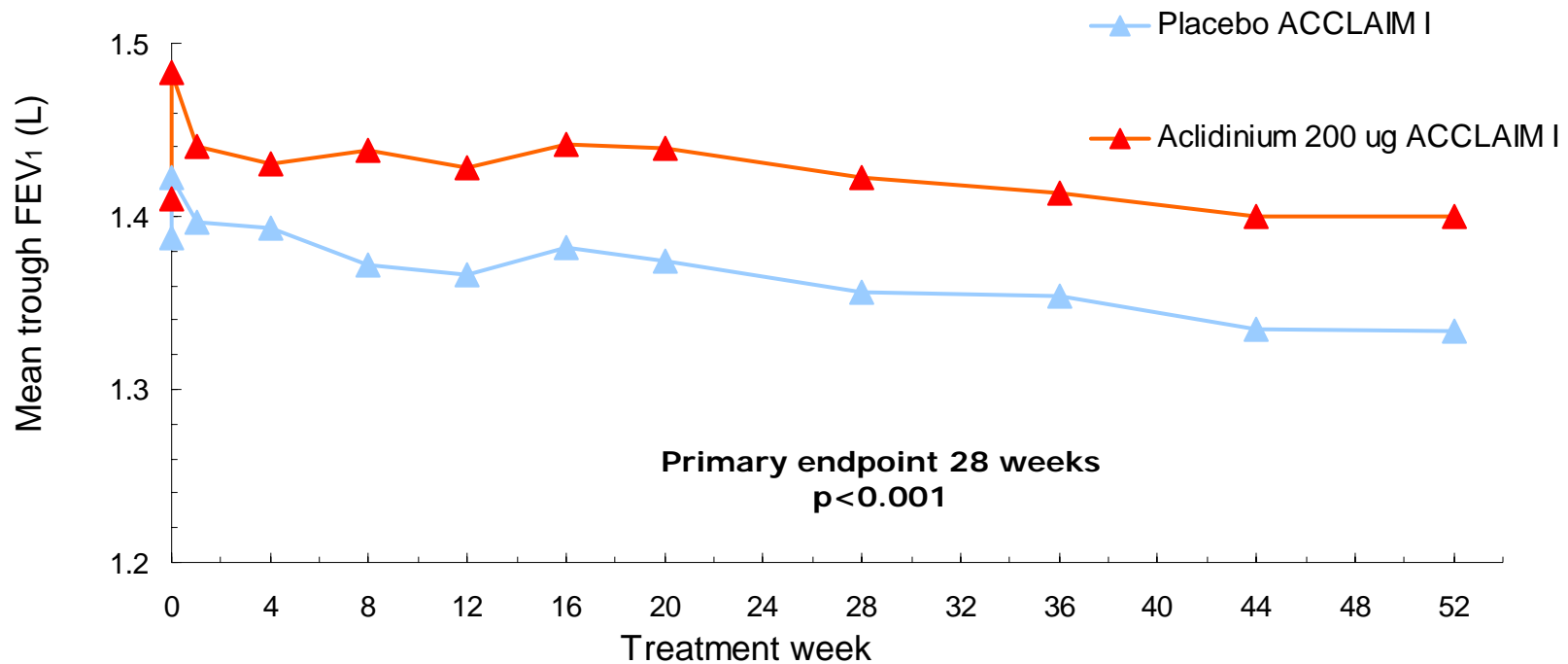


Patient populations

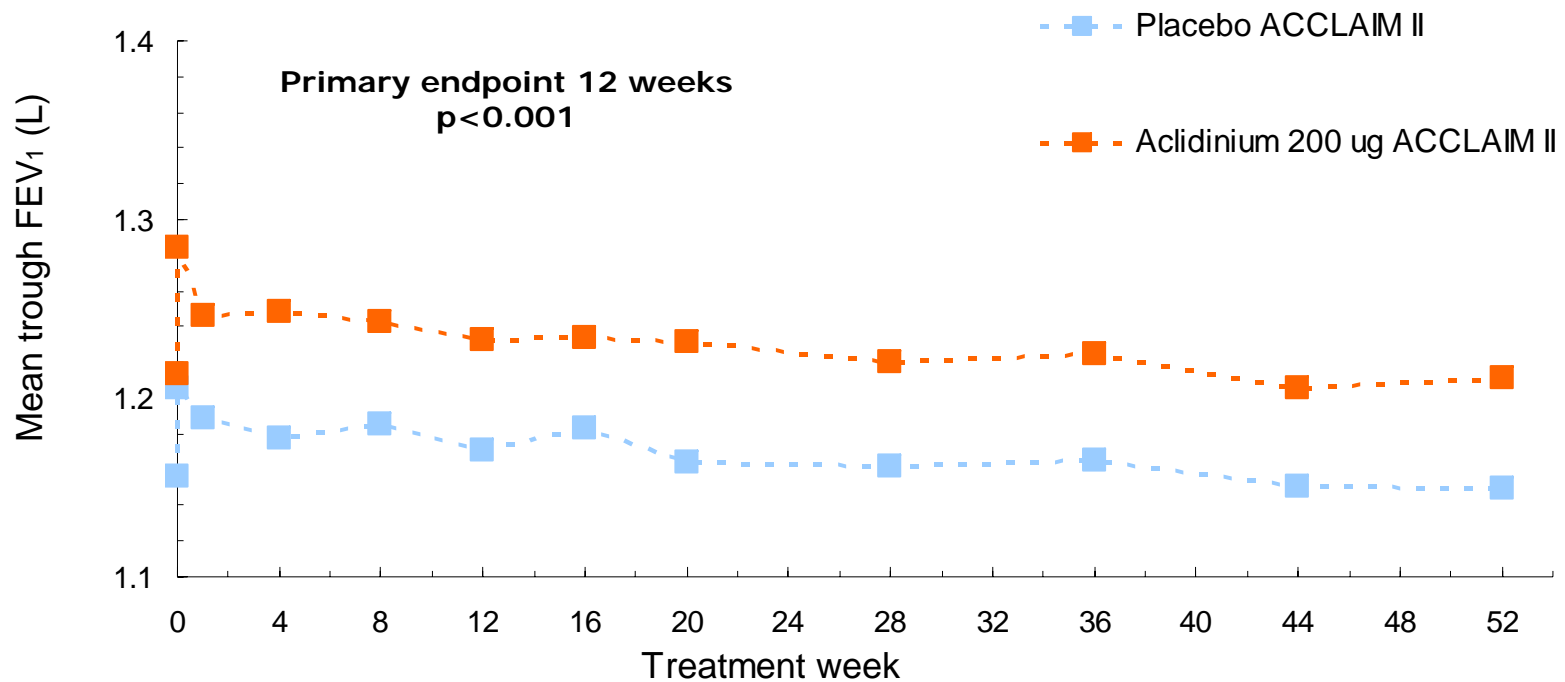
	ACCLAIM/ COPD I	ACCLAIM/ COPD II
Screened	1313	1456
Randomised	843	804
Completed	707	564
Discontinued	136 (16.1%)	240 (29.9%)
Safety population	843	804
ITT population	826 (98.0%)	795 (98.9%)

ACCLAIM I: Western and Eastern Europe; ACCLAIM II: USA, Canada, Australia...

ACCLAIM/COPD I – EU: Trough FEV₁ over time



ACCLAIM/COPD II – US, RoW: Trough FEV₁ over time



Secondary endpoints: Exacerbations and QOL

	Time to first moderate to severe exacerbation (52 weeks)	% patients with ≥ 4 -point improvement in SGRQ (52 weeks)
ACCLAIM/COPD I	p=NS	p=0.025
ACCLAIM/COPD II	p=0.01	p=0.074
Pooled	p=0.054	p=0.004

Incidence of adverse events (AEs) and serious adverse events (SAEs)

	ACCLAIM/COPD I and II	
	Aclidinium (n=1227)	Placebo (n=420)
Patients with AEs leading to treatment discontinuation, %	4.0	5.7
Patients with SAEs, %	9.1	10.7
Patients with fatal SAEs, %	1.1	1.7
Dry mouth, %	0.7	1.2

Conclusions

- **Aclidinium bromide showed a statistically significant difference vs placebo in the primary endpoint trough FEV₁**
- **Aclidinium bromide significantly delayed the time to first moderate to severe exacerbation in the ACCLAIM/COPD II study**
- **Aclidinium bromide significantly improved the percentage of patients showing a clinically relevant improvement in SGRQ in the ACCLAIM/COPD I study**
- **Similar tolerability demonstrated vs placebo**
- **Overall bronchodilatory effect demonstrated but further studies are warranted to better determine the optimal dosing regimen**

Thank you

