European Crohn's and Colitis Organisation

Effectiveness and Safety of Reference Infliximab and Biosimilar in Crohn Disease: A French Equivalence Study

Antoine Meyer, MD; *Jérémie Rudant, MD, PhD; Jérôme Drouin; Alain Weill, MD; Franck Carbonnel, MD, PhD; and Joël Coste, MD, PhD*

Conflict of interest of the speaker: none

Copenhagen, March 07 2019

Methods

- There is still uncertainty as to whether infliximab biosimilar is equivalent to the reference brand

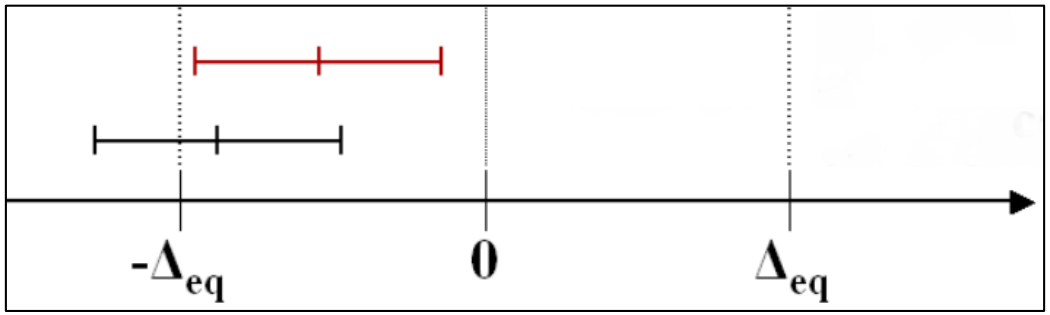
- **Design**: Comparative equivalence cohort study

- **Data**: French nationwide health administrative database
- 99% of the French population, around 65million people

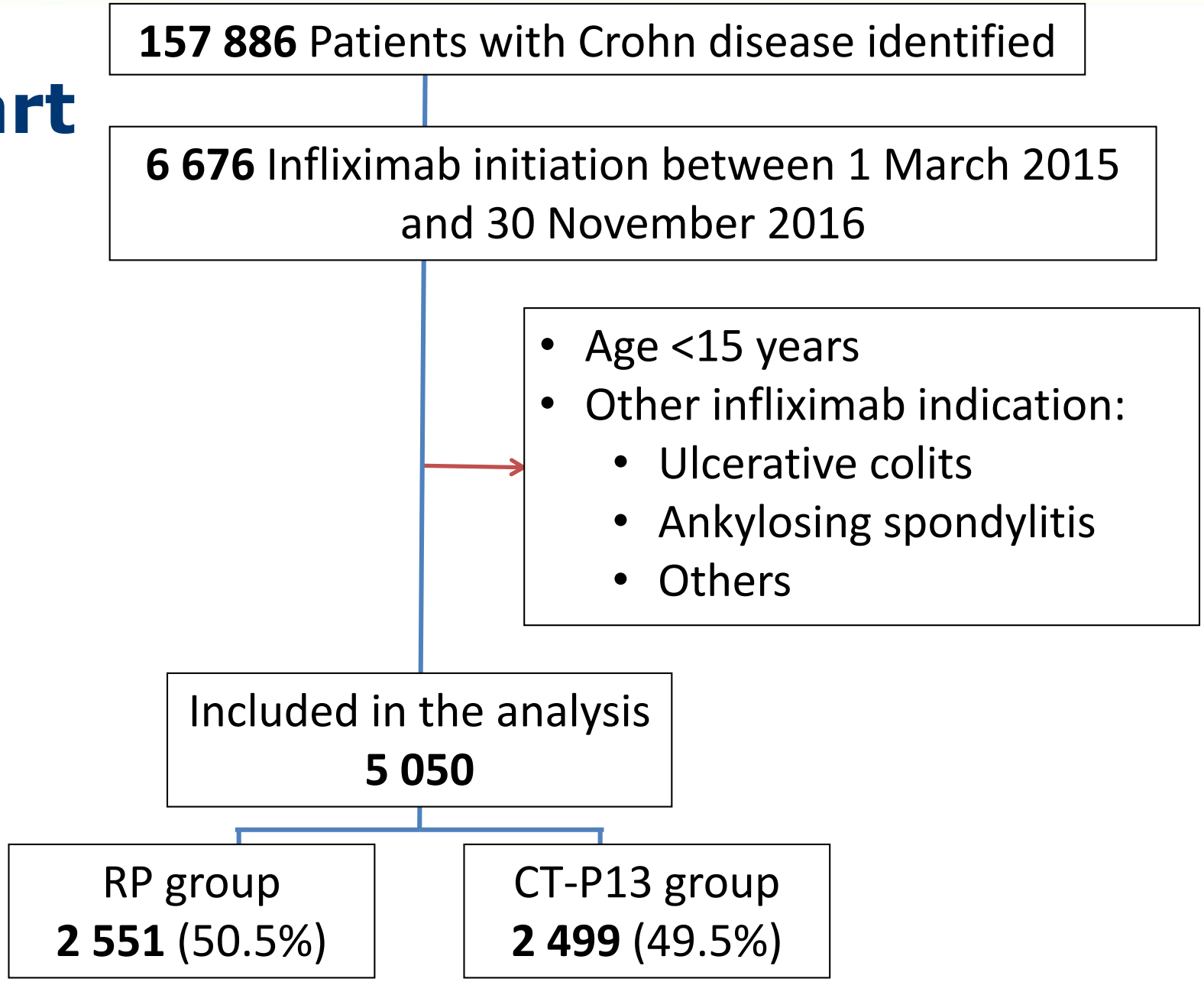
- **Objective:** To compare the effectiveness and safety of CT-P13 and reference product in infliximab-naive patients with Crohn’s disease.

Methods

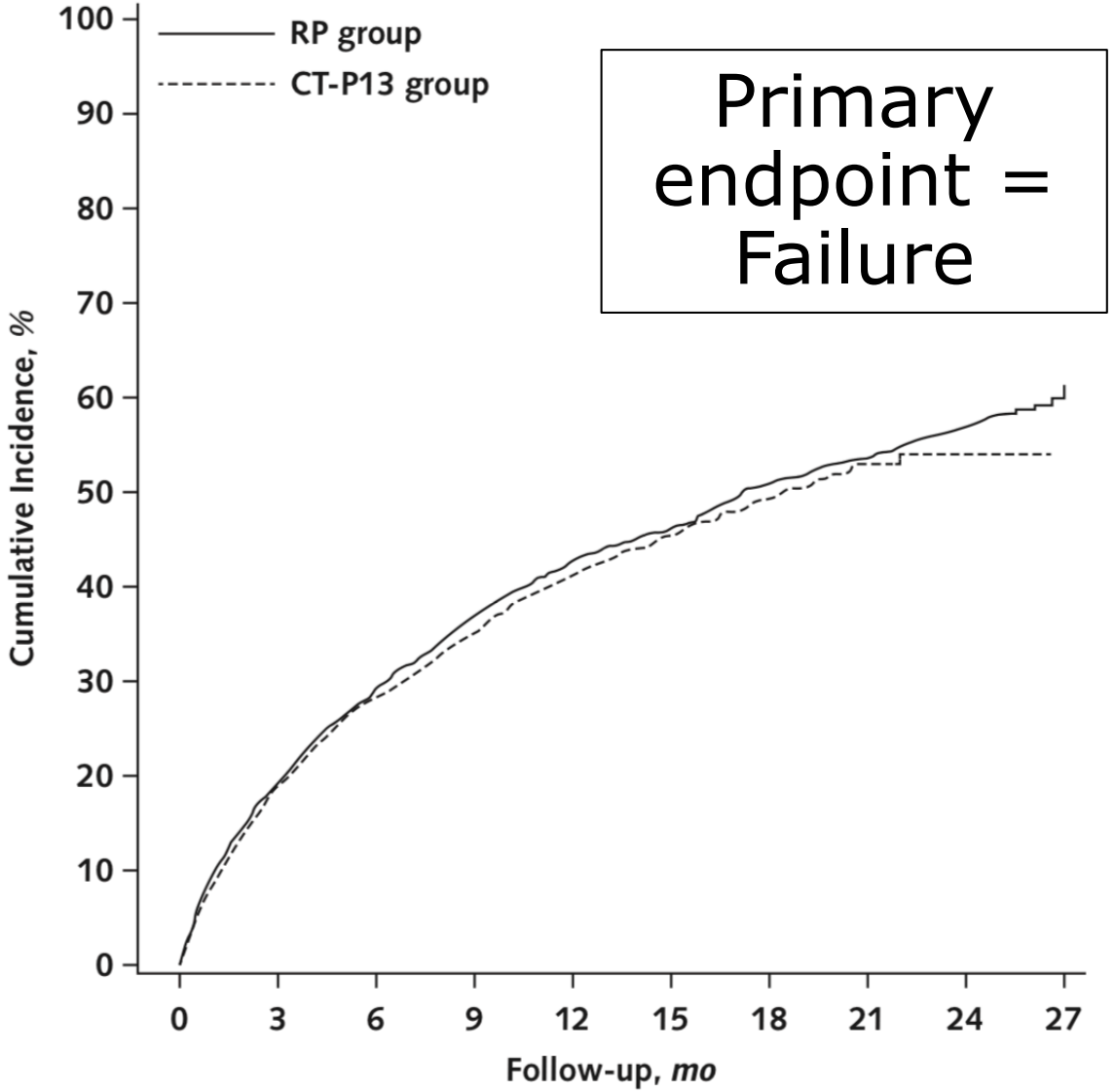
- **Patients**: Infliximab-naive patients with Crohn's disease who had started treatment with infliximab
- **Primary outcome** = Failure = At least one of the following items:
  - Death
  - Crohn's disease-related surgery
  - All-cause hospitalization
  - Reimbursement of another biologic therapy
- **Equivalence** was defined as a 95% CI of the HR of CT-P13 versus reference product in a multivariable marginal Cox model situated within prespecified margins (0.80 to 1.25)



Flow Chart

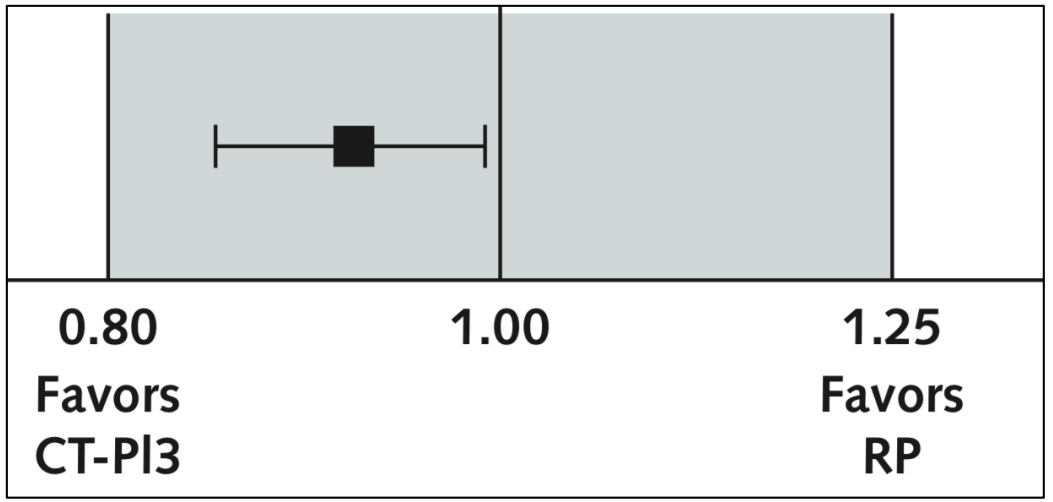

157 886 Patients with Crohn disease identified
6 676 Infliximab initiation between 1 March 2015 and 30 November 2016
• Age <15 years
• Other infliximab indication:
• Ulcerative colits
• Ankylosing spondylitis
• Others
Included in the analysis
5 050
RP group
2 551 (50.5%)
CT-P13 group
2 499 (49.5%)

Cumulative incidence plot



Primary endpoint = Failure

Multivariable model:
CT-P13 was equivalent to reference product
HR 0.92 ; 95%CI 0.85 – 0.99



Effectiveness and safety outcomes

Event	Multivariable Cox Model	
	Hazard Ratio (95% CI)	*P* Value
Primary outcome: composite end point*	0.92 (0.85–0.99)	
All-cause hospitalization†	0.92 (0.83–1.01)	0.088
CD-related hospitalization‡	1.00 (0.90–1.11)	>0.20
CD-related surgery§	1.09 (0.92–1.28)	>0.20
Colon/small-bowel surgery‖	1.10 (0.91–1.34)	>0.20
Dispensing of other biologic therapy¶	0.93 (0.79–1.08)	>0.20
Serious infection*	0.82 (0.61–1.11)	0.20
Tuberculosis†	1.10 (0.36–3.34)	>0.20
Cancer‡	0.66 (0.33–1.32)	>0.20

Conclusion

- Effectiveness of CT-P13 is equivalent to that of reference product in infliximab-naive patients.
- No difference was observed in safety outcomes.
- The choice between the two products can be based on cost only.
- Equivalence limits were more stringent than those used in trials (10% vs. 15% absolute difference)
- Another study will need to be conducted to assess the switch from reference product to CT-P13 (or *vice versa*).