EE190

Ghetti G[1], Porta C[1], Bührer C[2], **Fascì A**[3]

FROM CLINICAL TRIALS TO RWE: DEFINING FARICIMAB VALUE DRIVERS IN NEOVASCULAR AGE RELATED MACULAR DEGENERATION THROUGH A COST UTILITY ANALYSIS

[1]AdRes - Health Economics and Outcome Research, Turin, Italy; [2]F. Hoffmann-La Roche Limited, Basel, Switzerland, [3]Roche spa, Monza, Italy

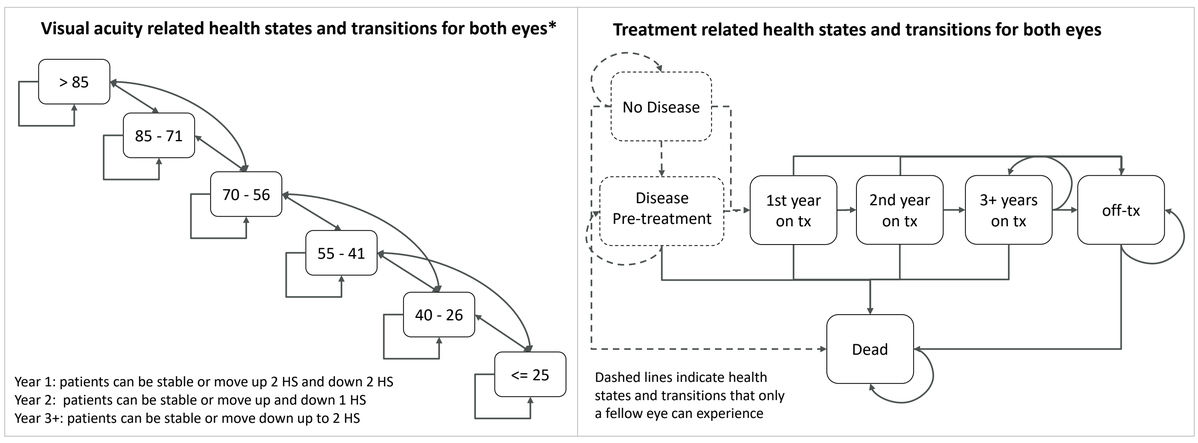
Objective

- Real-Word Evidence (RWE) revealed that adherence and persistence to anti-Vascular Endothelial Growth Factor (anti-VEGFs) therapies among patients with Neovascular Age-related Macular Degeneration (nAMD) is suboptimal, leading to potential poor visual outcome [1].
- In TENAYA & LUCERNE Clinical Trials (CTs), faricimab showed its ability to extend injection intervals while achieving vision gains comparable to Standard of Care (SoC), leading to a positive Cost Utility Analysis (CUA) in CTs setting [2, 3].
- This study aimed to evaluate the cost-utility of faricimab under potential RWE full adherence and persistence conditions vs current SoC in a real-world setting from the perspective of the Italian National Health Service (NHS).

Methods

- A 28-day cycle Markov model was used to estimate lifetime clinical outcomes and costs of nAMD patients treated with faricimab and SoC (*Figure 1*).

Figure 1 – Model scheme



Patients enter the model based on the initial visual acuity (VA). VA-level distribution was derived from faricimab CTs. To model the clinical progression, three time periods were considered: (i) year 1, the induction phase during which most of the visual improvements occur; (ii) year 2, defined by disease stabilization and maintenance of previously achieved visual improvements; (iii) year 3+, characterized by the possibility of reducing treatment intensity and long-term maintenance.

The transition probabilities are assumed to be independent of the VA and are held constant after the second year.

*7.3% of patients were assumed to have both eyes affected, with respective second-eye development incidences of 1.4% per model cycle [6].

- SoC was defined as a mix of on-label anti-VEGFs according to the RADIANCE observational study [4].
- Comparative effectiveness data were obtained from propensity score weighting analysis [4].
- Injection frequency and treatment discontinuation rates were elaborated from pivotal CTs and a RADIANCE sub study for faricimab and SoC, respectively, assuming CTs adherence and persistence for faricimab [3,5] (*Figure 2*).
- General population mortality rates were adjusted to account for increased mortality in patients with visual disabilities, in line with NICE analyses [6].
- Health state utilities, based on the VA level of both eyes, were derived from a published regression model [7]. Consistent with NICE guidelines, the disutility associated with intravitreal injection discomfort was also considered [6, 7].
- Direct costs, including drug acquisition and administration, were retrieved from Italian sources [8, 9] (*Table 1*). Ranibizumab direct cost used rely on biosimilar usage.

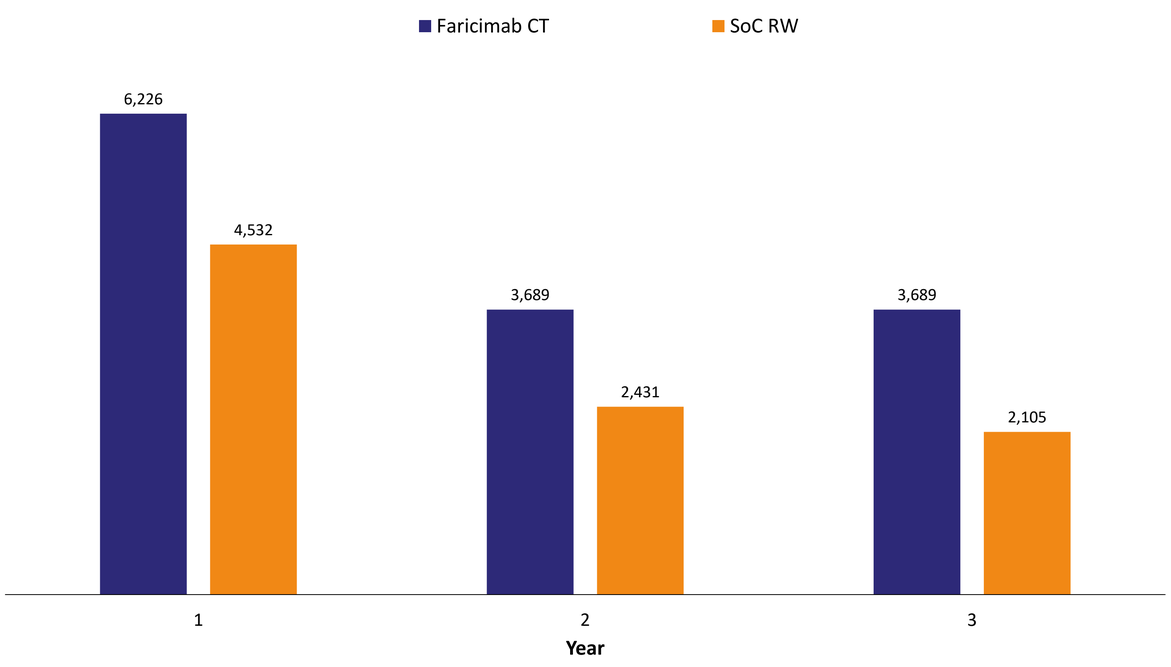
- A lifetime horizon (25 years) was considered. Costs and health gains were discounted at an annual 3% rate.
- Probabilistic and Deterministic Sensitivity Analyses (PSA and DSA) were conducted to evaluate the uncertainty of input parameters.

Table 1 – Unit costs

Cost item	Value (€)
Faricimab*	700.19
Aflibercept*	740.00
Ranibizumab*	494.91
SOC	612.79
IVT administration	268.15

* Ex-factory gross price.

Figure 2 – Injection direct costs (€): calculated as the number of injections per year multiplied by the total injection cost, including both drug and IVT costs.



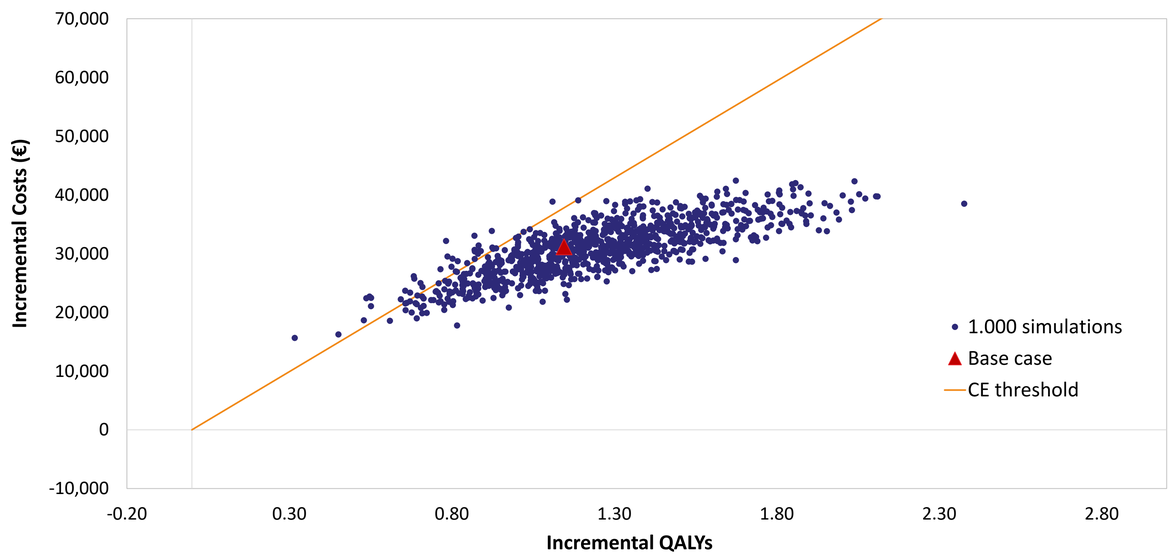
Results

- Faricimab was associated with **improved** Quality Adjusted Life Year (**QALY**) (+1.15) compared to SoC, with **additional cost** of 31.170 €/patient (*Table 2*).
- Cost increase was mainly driven by the enhanced adherence and persistence with faricimab.
- The Incremental Cost-Utility Ratio (**ICUR**) was **27.217 € per QALY gained**.
- PSA and DSA results confirm the main analysis (*Figure 3 and 4*).

Table 2 – Summary results

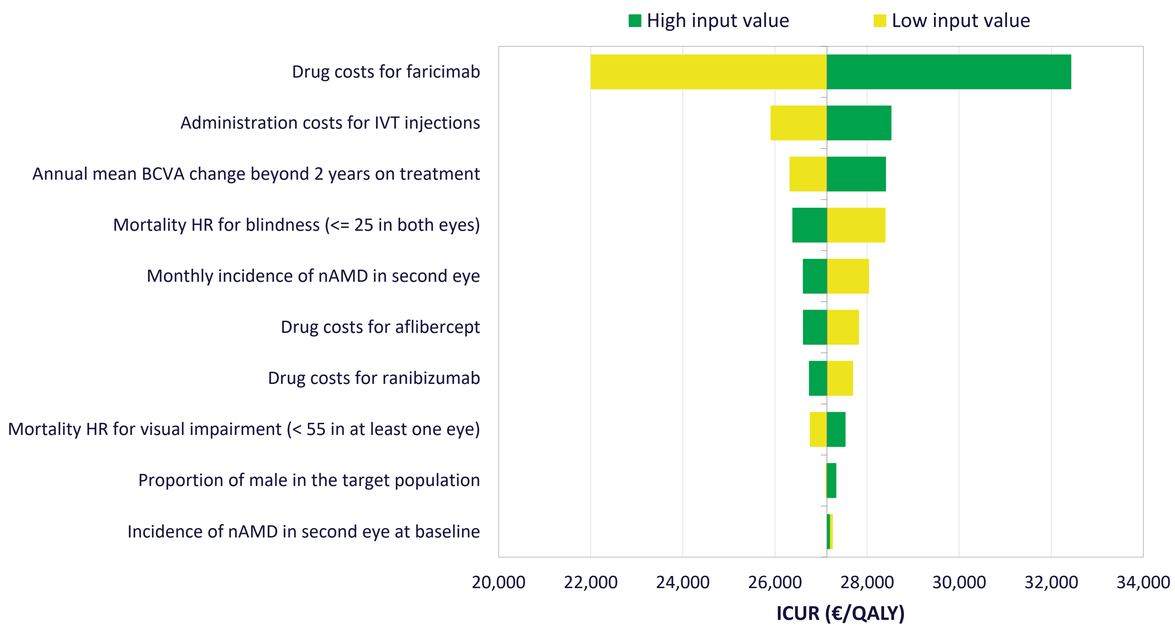
	Faricimab	SoC	Δ
LYs	9.60	9.26	0.34
QALY	6.02	4.87	1.15
Costs (€)	39,855	8,685	31,170
Drug	*29,828*	*6,119*	*23,709*
Administration	*10,027*	*2,566*	*7,461*

Figure 3 – PSA results: incremental cost-effectiveness plan



CE threshold was set at 33.000 € per QALY.

Figure 4 – DSA results: tornado chart



Conclusions

- **Faricimab**, with **CTs-based compliance**, is a **cost-effective option** compared to **real-world SoC** for Italian nAMD patients, with a deterministic ICUR below the recently proposed thresholds for the health technology assessment.
- This study will also allow to further investigate **real world anti-VEGFs measured appropriateness impact on CUA**.

References

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