EE461

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FARICIMAB VS AFLIBERCEPT 8MG IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION: A COST-UTILITY ANALYSIS IN ITALY

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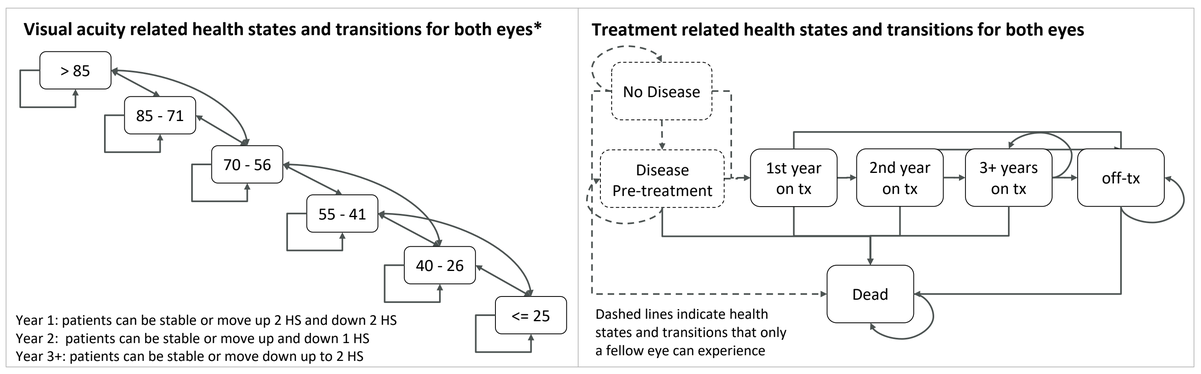
Objective

- Faricimab in a treat&extend (T&E) regimen demonstrated non-inferiority to aflibercept 2mg at 1 year in the TENAYA/LUCERNE trials for neovascular age-related macular degeneration (nAMD) [1, 2].
- Recently, aflibercept (8mg) was investigated in the PULSAR and CANDELA trials [3, 4]. PULSAR applied less stringent disease activity criteria (DAC) for treatment interval extensions requiring both vision and anatomical worsening.
- This study assessed the cost-utility of faricimab versus aflibercept 8mg in nAMD patients under different DAC assumptions, from the perspective of Italian national health service (NHS) and society.

Methods

- A 28-day cycle Markov model was adapted to the Italian setting to estimate lifetime clinical outcomes and costs of nAMD patients receiving faricimab or aflibercept 8mg (*Figure 1*).
- Transition probabilities and treatment discontinuation were informed by faricimab trials [1, 2], assuming equal efficacy between treatments.

Figure 1 – Model scheme



Patients enter the model based on the initial visual acuity (VA), with distribution derived from faricimab clinical trials. To model 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 achieved 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.

Patients who discontinued treatment were treated with the best SoC, with an assumed average loss of 10.9 letters [5].

*7.3% of patients were assumed to have both eyes affected, with respective second-eye development incidences of 1.4% per model cycle [5].

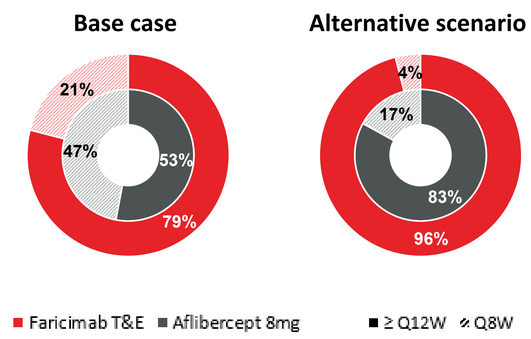
- General population mortality rates were adjusted to account for increased mortality in patients with visual disabilities, in line with NICE analysis [5].
- Health state utilities, based on the VA level of both eyes, were derived from a published regression model [6]. Consistent with NICE guidelines, the disutility related to intravitreal (IVT) injections was also considered [5].
- A lifetime horizon (25 years) was considered, with costs and health outcomes discounted at 3% annually.
- In the base-case analysis, injection frequencies for faricimab and aflibercept were derived from the TENAYA&LUCERNE trials [1, 2] and CANDELA trial [4], respectively, in line with DAC used in clinical practice [7]. Alternative scenario analysis applied PULSAR data for aflibercept 8mg [3], with faricimab injection intervals simulated to reflect PULSAR's DAC [8] (*Table 1* and *Figure 2*).

Table 1 – Disease activity criteria for treatment intervals

	Base case	Alternative scenario
Disease activity criteria*	Visual acuity OR anatomical findings	Visual acuity AND anatomical findings
Reference Faricimab	TENAYA&LUCERNE, year 1	TENAYA&LUCERNE, year 1¶
Reference Aflibercept 8mg	CANDELA, week 44	PULSAR, week 48

*For treatment interval reduction/extensions; ¶Based on disease activity assessment at week 20.

Figure 2 – Treatment interval distribution



- Direct costs comprised drug acquisition and administration, while indirect costs included productivity loss. Unit costs were retrieved from Italian sources (*Table 1*) [9-13].

Table 2 – Unit costs

Category	Item	Value (€)
Direct	Faricimab*	700.19
	Aflibercept 8mg*	740.00
	IVT administration	268.15
Indirect	Productivity loss/injection day	85.08

* List price.

Indirect costs

The cost of productivity loss for patients and caregivers was estimated based on the mean time required for administration (6.5 hours [11]), assuming that 65% of patients were accompanied by a caregiver [11].
Hourly monetary value of paid and unpaid work and employment rates for both patients and caregivers were sourced from the literature [12, 13].

- Probabilistic sensitivity analysis (PSA) was conducted to evaluate parameter uncertainty.

Results

- Faricimab T&E was more efficient than aflibercept 8mg, as it required fewer IVT administrations (*Table 3*).

From the **NHS perspective**, **faricimab** was **cost-saving** in both base-case (**–€6,158**) and alternative scenario (**–€3,033**) analyses, mainly due to the reduced frequency of IVT injections.

When accounting for **indirect costs**, **faricimab** provided even **greater savings**: **-€6,476** in the base-case and **-€3,122** in the alternative scenario, due to reduced patient and caregiver time (*Figure 3*).

- Faricimab was **cost-effective across both perspectives and scenarios**.
- PSA confirmed the overall robustness of the results, with greater uncertainty in the alternative scenario (*Figure 4*).

Table 3 – Summary results

	Base case			Alternative scenario		
	Aflibercept 8mg	**Faricimab T&E**	**Δ**	**Aflibercept 8mg**	**Faricimab T&E**	**Δ**
QALY	6.133	6.135	0.0023	6.137	6.138	0.0004
NHS - Total costs (€)	56,012	49,854	-6,158	49,226	46,193	-3,033
Society - Total costs (€)	60,313	53,837	-6,476	53,004	49,882	-3,122

Figure 3 – Cost breakdown (€): base case vs alternative scenario

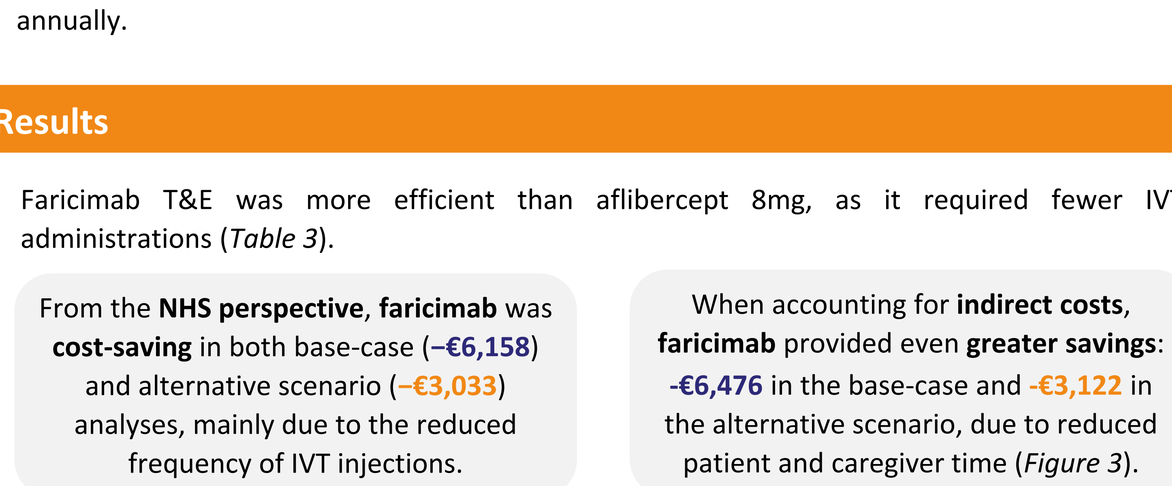
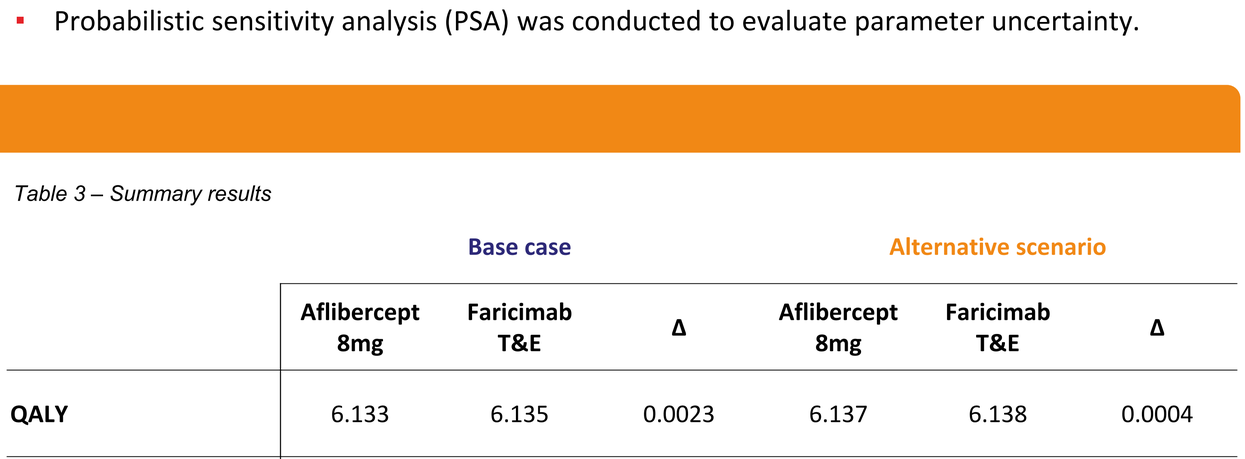


Figure 4 – PSA results (NHS perspective)



Conclusions

- This analysis indicates that **faricimab T&E** might be a **cost-effective strategy** in the treatment of nAMD in Italy when **compared to aflibercept 8mg** using treatment criteria aligned with clinical practice, from both NHS and societal perspectives.
- Those results also highlight **the importance of treatment criteria** and their harmonization conducting economic comparisons between anti-VEGF products.

References

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