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Real-world study on tebentafusp use in metastatic uveal melanoma in France: interim analysis of the PRIMUM.0 study

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Uveal melanoma (UM) is the most prevalent primary intraocular cancer. Although primary tumors can be effectively treated, up to 50% of patients eventually develop metastases, with initial metastases primarily developing in the liver as the most frequent site of spread (~90% of cases). Historically, median overall survival (OS) for metastatic cases ranged from 10 to 16 months depending on the treatment modality [1,2]

Tebentafusp is authorised as monotherapy for use in HLA-A*02:01-positive adults with unresectable or metastatic uveal melanoma (mUM), based on results from the pivotal IMCgp100-202 phase 3 trial, which demonstrated a 1-year OS rate of 73% for tebentafusp compared to 59% in the control group [2,3]

Tebentafusp has been available in France through early access since May 2021

Here, we present clinical outcomes of tebentafusp in patients with mUM in a real-world setting

PRIMUM.0 (RCB ID: 2023-A01490-45) is a retrospective, non-interventional, national, cohort study based on medical records collected from expert centres throughout France

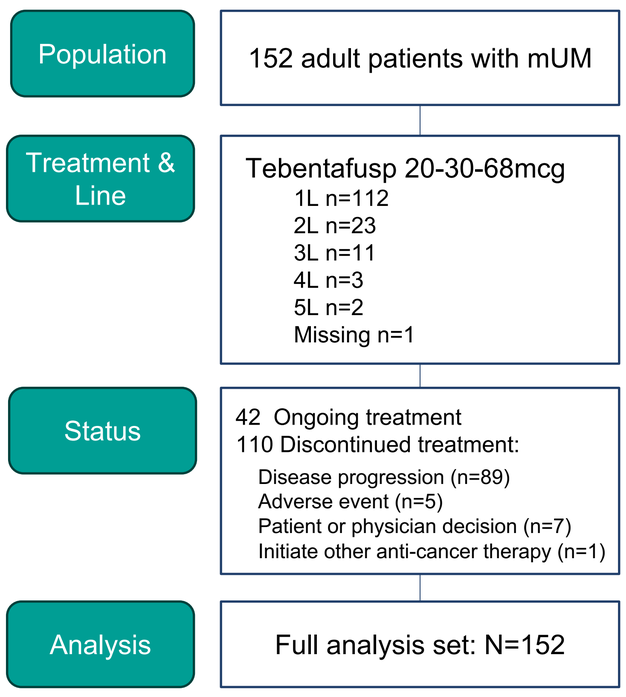
Eligible participants were HLA-A*02:01-positive adults with metastatic uveal melanoma (mUM) treated with tebentafusp monotherapy according to EMA guidelines. Patients received weekly intravenous tebentafusp with intra-patient dose escalation starting at 20mcg in Week 1, 30mcg in Week 2, and 68mcg from Week 3 onwards

Patient demographics and characteristics were summarized using descriptive statistics, expressed as median (1st quartile; 3rd quartile). Overall survival (OS) and progression-free survival (PFS) were estimated via the Kaplan-Meier method with 95% confidence intervals [95% CI]. Best overall response (BOR) was evaluated according to RECIST version 1.1 criteria

This report presents data from the second interim analysis, including 152 patients across 7 participating centres. At the data cut-off for this interim analysis in April 2025, the median follow-up duration was 12 months

Results

Figure 1. Patient population



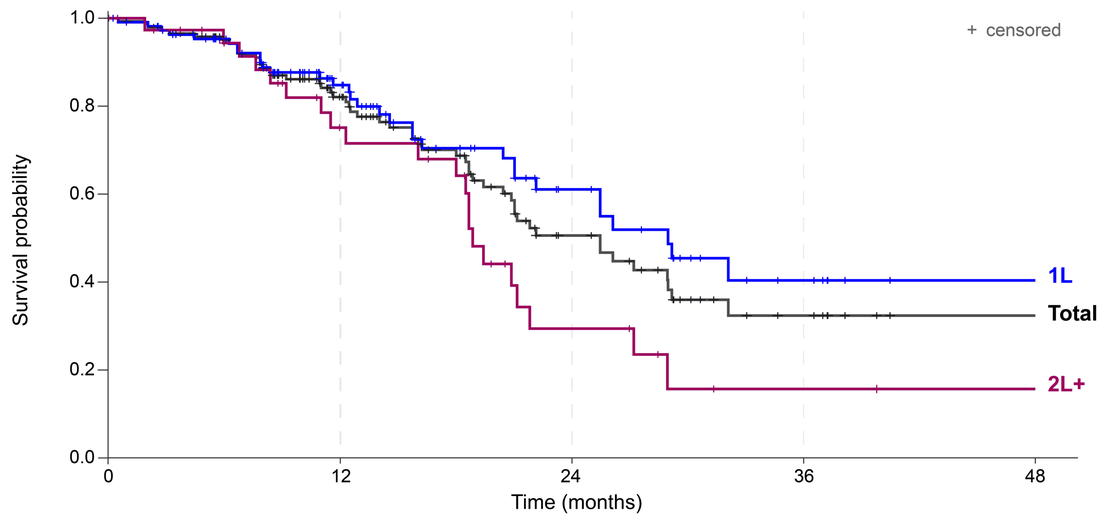
- Between May 2021 and April 2025, data from 152 patients have been collected, with median follow-up of 12 months
- Tebentafusp was administered as first-line (1L) therapy in 112 patients (74%) and as second-line or greater (2L+) in 39 (26%)
- Median duration of tebentafusp treatment was 9.7 (4.6; 15) months

Table 1. Demographics and baseline characteristics

Characteristic	1L N=112	2L+ N=39	Total N=152
Age, median yr	60 (52–66)	58 (49–66)	59 (51–66)
Male gender, n (%)	55 (49%)	22 (56%)	77 (51%)
ECOG performance-status, n (%)			
0	80 (78%)	31 (84%)	112 (80%)
1	20 (20%)	6 (16%)	26 (19%)
≥ 2	2 (2%)	0 (0%)	2 (1%)
Elevated lactate dehydrogenase (>ULN), n (%)	40 (36%)	18 (46%)	59 (39%)
Time since primary diagnosis to metastatic diagnosis, months	23.5 (12.7–41.9)	28.6 (13.8–65.3)	24.7 (13.1–52.8)
Median duration of follow-up, months	11.6 (7.9–21.1)	16.0 (7.6–20.5)	12.0 (7.9–20.9)

- At tebentafusp initiation, the majority of patients had an ECOG PS score of 0 and 61% had LDH in normal range
- Data on the location of metastases and size of largest lesion were not available at the time of data cutoff for this interim analysis

Figure 2. Overall survival



	1L (N=112)	2L+ (N=39)	Total (N=152)
OS, median months (95% CI)	29.0 (21.0-nr)	18.9 (16.0-21.8)	25.5 (19.4-29.0)
1-year OS	85% (76%-91%)	75% (56%-87%)	81% (73%-87%)
2-year OS	61% (47%-73%)	29% (13%-48%)	50% (39%-61%)
3-year OS	40% (24%-56%)	16% (3%-36%)	32% (20%-45%)

Table 2. Tumor response

	RECIST-evaluable N=143
Overall response rate	10 (7%)
Complete response	2 (1%)
Partial response	8 (6%)
Stable disease	83 (58%)
Progressive disease	50 (35%)

- The safety profile remained consistent with previously reported data for tebentafusp, with no new safety concerns identified

Figure 3. Progression free survival

	1L (N=112)	2L+ (N=39)	Total (N=152)
PFS, median months (95% CI)	3.0 (2.6-4.9)	3.1 (2.6-5.2)	2.8 (2.5-5.8)
1-year PFS	28% (20%-37%)	18% (8%-32%)	25% (18%-39%)
2-year PFS	14% (7%-24%)	3% (<1%-13%)	10% (5%-17%)
3-year PFS	12% (5%-21%)	-	9% (4%-16%)

Discussion & Conclusion

In this real-world cohort, overall survival was higher than that reported in the phase 3 trial of tebentafusp.

- This difference might indicate variations in monitoring and early detection of patients with metastatic uveal melanoma in France versus the international trial.
- Practice in France also suggests that tebentafusp may be continued for longer in case of secondary tumour progression (i.e., several months after initial response or stabilisation). [5]

This analysis is limited by its retrospective, single-country design and the fact that it is an interim analysis that does not yet include the complete patient dataset.

This retrospective real-world analysis supports the survival benefit and safety profile of tebentafusp observed in the pivotal phase 3 study, affirming its use as a first-line standard of care for HLA-A*02:01-positive patients with mUM

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