

VT-1953 in Treating Symptoms of Malignant Fungating Wounds (MFW)

PHASE 2 IST STUDY RESULTS & NEXT STEPS

VYOME HOLDINGS, INC. (“Vyome”)

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Key Takeaways From Phase 2 Study

Clear efficacy and safety signals to support further clinical development.



1

An investigator-initiated Ph2 study to test VT-1953, a topical dual DNA Gyr and MD2/TLR interaction inhibitor, for safety and efficacy in treating the symptoms of MFW

2

VT-1953 achieved a significant improvement ($P=0.002$) in the primary endpoint of malodor on Day 14 vs baseline as scored by investigators. The improvement seen with VT-1953 was statistically significant ($P=0.0015$) compared with vehicle-treated patients.

3

VT-1953 resulted in a significant improvement ($P=0.0256$) in the secondary endpoint of patient-reported impact of malodor on the quality of life compared to vehicle-treatment by Day 14.

4

Patients treated with VT-1953 also reported a clinically significant improvement in lesion pain symptoms (exploratory endpoint) by Day 14 ($P=0.002$ compared with baseline; $P=0.0026$ vs vehicle-treated patients).

5

VT-1953 was well-tolerated by patients.

What is MFW?



An MFW patient from our Phase 2 study

MFW is a rare condition seen in ~10% of advanced cancer patients.* Patients suffer from **distressing symptoms**, including:

Malodor (like "rotten meat")**

Pain

Extremely poor quality of life (social withdrawal, depression)

~58,000¹

New patients/year in US alone

\$55,000²

Lifetime value per patient

~\$2.2B³/year

US market opportunity

*The Microbiome, Malignant Fungating Wounds, and Palliative Care. Front. Cell. Infect. Microbiol., November 2019, EASED study (2023).

** BMC Cancer. 2025 Feb7;25(1):219.

Phase 2 IST testing VT-1953 2% gel in MFW

15 patients with moderate to severe malodorous MFW

Sex: 10 male, 5 female. Age: median 50, mean 52.6, range 31–77)

Diagnosis counts: Oral/Head and Neck cancer: 10; Breast cancer : 4; Vulval cancer: 1

Male or female subjects aged ≥ 9 years old, with a diagnosis of malodorous malignant fungating wound malodor corresponding to 0, 1 and 2 on the TELER odor scale (where 0= Malodor detected upon entering room ($>3\text{m}$ or $>10\text{ft}$) with dressing on; 1= Malodor detected at $>2\text{m}<3\text{m}$ (between 6-10ft) distance from patient with dressing on; and 2= Malodor detected at $\sim 1\text{m}$ or arm's length to the patient with dressing on, as judged by the investigators). ECOG status ≤ 3 . Anticipated survival > 3 months.

Active arm (VT-1953 b.i.d): 10 patients

Sex: 7 male, 3 female. Age: median 50.5, mean 56, range 37–77)

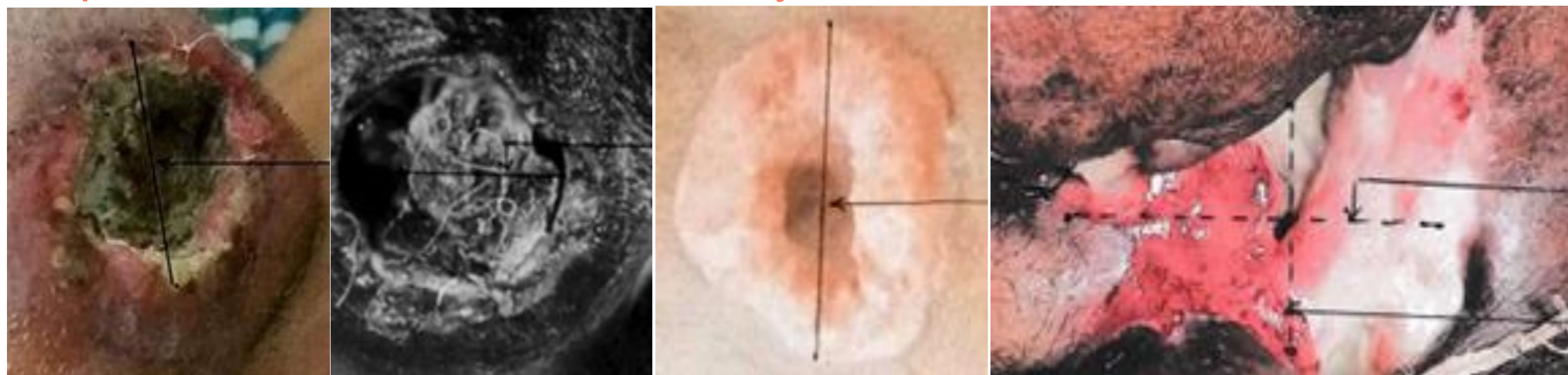
Diagnosis counts: Oral/Head and Neck cancer: 7; Breast cancer : 2; Vulval cancer: 1

Vehicle arm (5 patients)

Sex: 3 male, 2 female. Age: median 47, mean 45.8, range 31–61)

Diagnosis counts: Oral/Head and Neck cancer: 3; Breast cancer: 2

Representative MFWs from the study



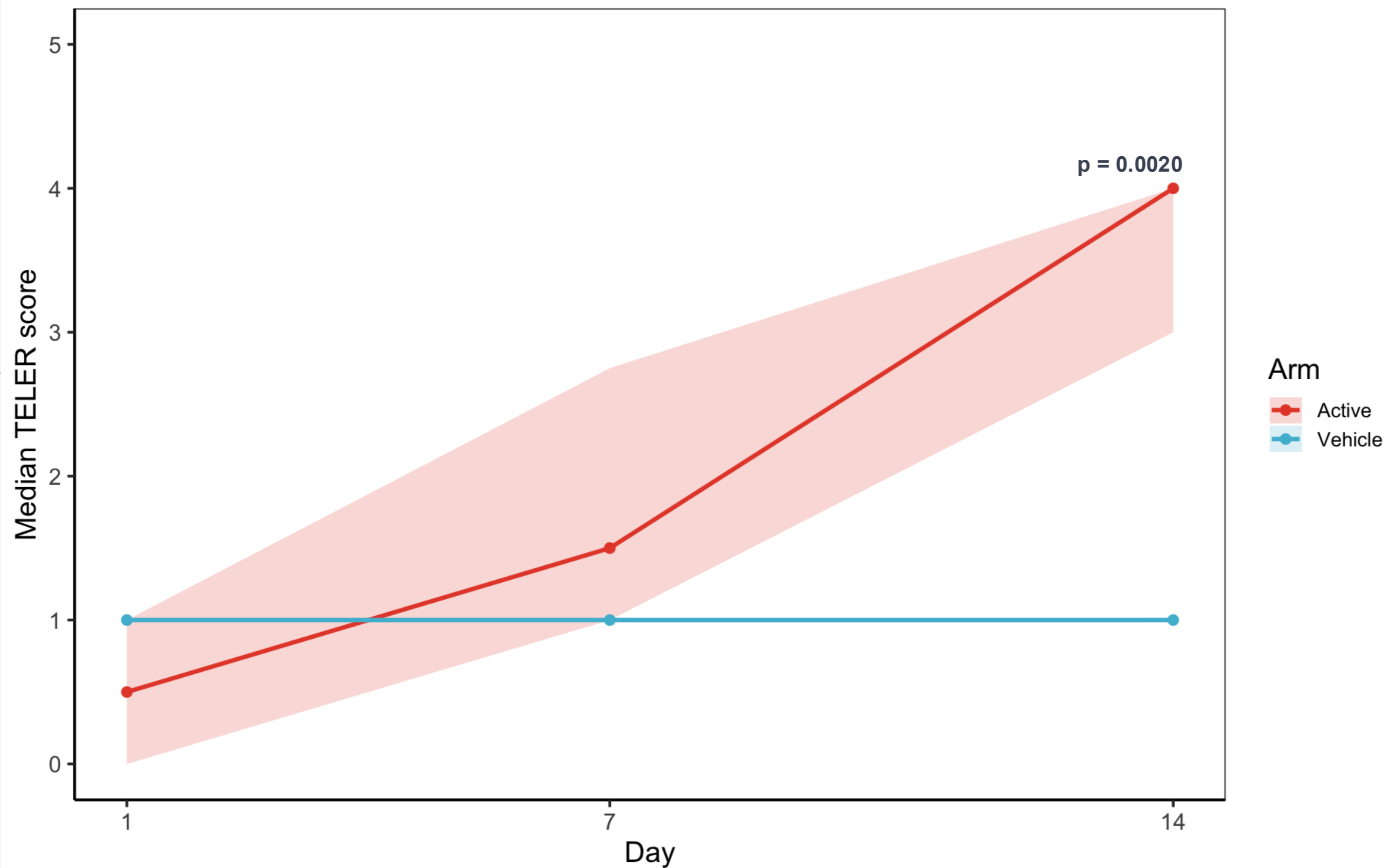
7.5 grams of gel spread evenly twice daily (B.I.D.) across the wound per application

Patients monitored every day over the 14 day study period. Measurements on Day 1 before start of treatment is considered as baseline.

VT-1953 treatment significantly reduced malodor (scored by investigator on Day 14): primary endpoint

By Day 14, participants treated with VT-1953 Topical Gel showed a marked improvement, achieving a median score of 4.0 (range 3.0-4.0), whereas the Vehicle group remained unchanged at 1.0 (range 1.0-1.0).

Median TELER score – Malodor by investigator using TELER scale (0–5)



Treatment with VT-1953 2% topical Gel resulted in a statistically significant improvement in malodor symptom by Day 14 ($p = 0.0020$, vs baseline. Wilcoxon Signed-Rank Test), while no significant change was observed in the Vehicle arm ($p > 0.9999$).

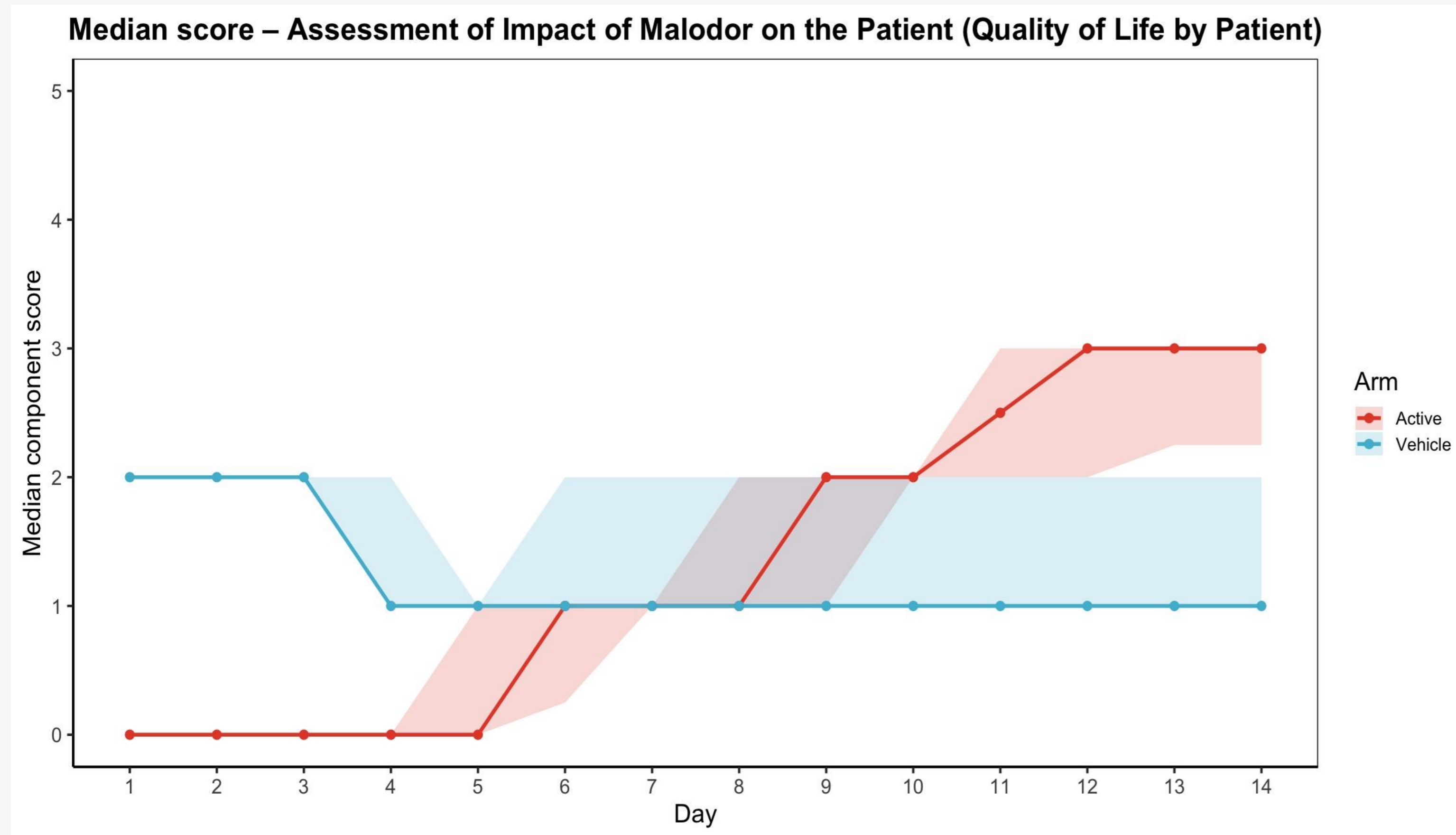
VT-1953 treatment is significantly superior to vehicle treatment ($p = 0.0015$, Wilcoxon Rank-Sum Test).

80% of patients on VT-1953 had a >2 point improvement over 14 Days vs 0% on vehicle arm.

There was a statistically significant improvement in the VT-1953-treated patients as early as 7 days ($P=0.0156$ vs baseline).

$P < 0.05$ is considered as statistically significant.

VT-1953 reduces the negative impact of malodor on quality of life (patient reported): secondary endpoint



Scored on 5 components:

- Awareness of malodor

- Concern about malodor noticed by others

- Reluctance to socialize because of odor

- Nauseated by the odor

- Odor affects appetite



Percentage of patients reporting improved Quality of Life (Malodor) composite scores (3–5) on Day 14 *P=0.0256 (Fisher’s Exact Test)

VT-1953
70%*
 95% CI for Proportion (41.6, 98.4)

Vehicle
0%
 95% CI for Proportion (0, 0)

VT-1953 significantly reduced malodor (scored by patients on VAS Scale): exploratory endpoint

Statistical summary of malodor Visual Analog Scale (VAS) scores, evaluated on a 0–10 scale, at baseline (Day 1) to Day 14 for both treatment groups.

Patients scored a reduction in malodor with VT-1953, median scores decreasing to 2.5 (Q1: 2.0, Q3: 3.0) by Day 14 from a baseline median malodor score of 7.5 (Q1: 7.0, Q3: 9.0) ($p = 0.0020$, Wilcoxon Signed-Rank Test). A statistically significant reduction was seen as early as Day 6-7 ($P=0.002$).

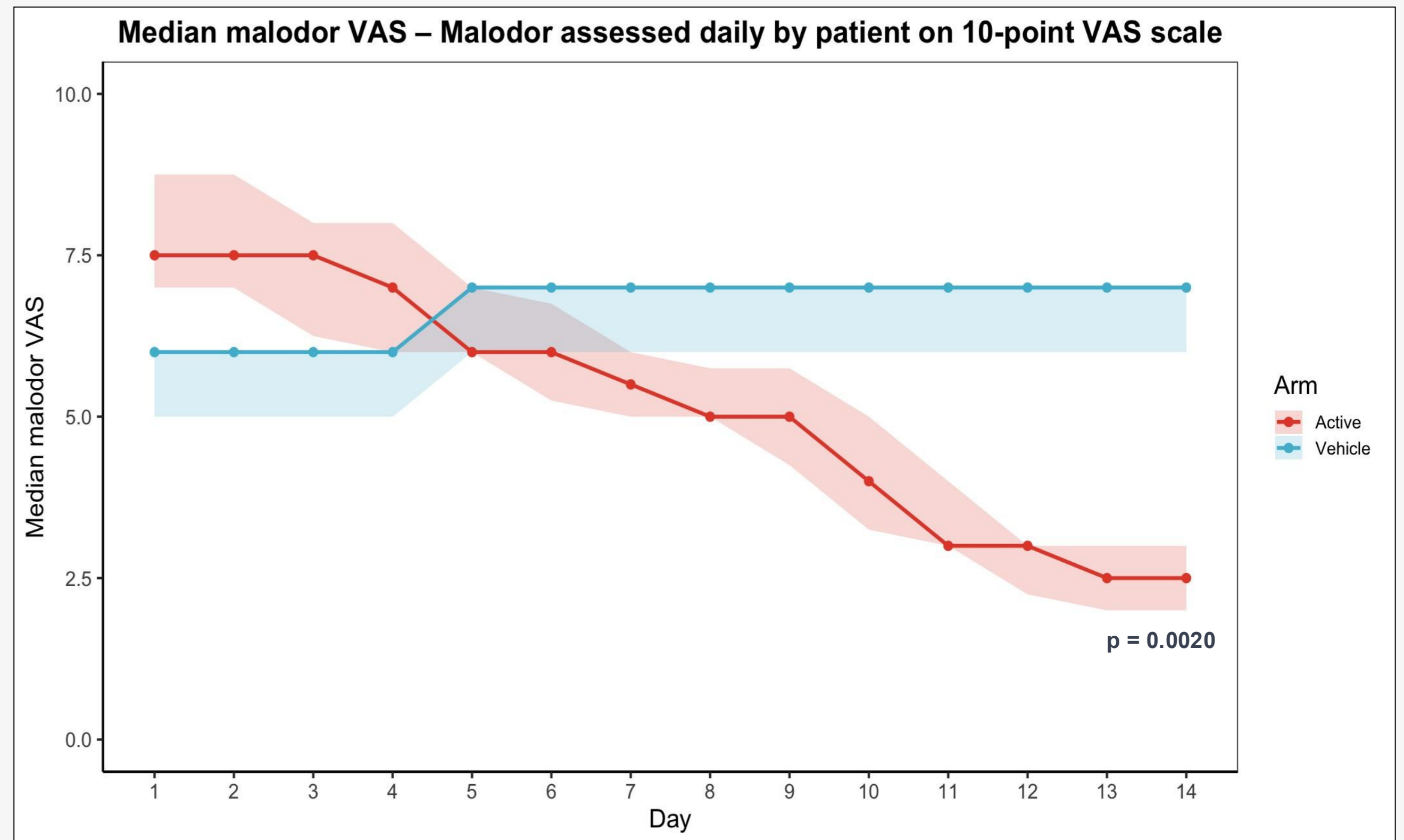
Vehicle Topical Gel group reported no significant improvement, with median scores increasing slightly to 7.0 (Q1: 6.0, Q3: 7.0) from baseline 6.0 (Q1: 5.0, Q3: 6.0).

VT-1953 was found to be statistically significantly superior to vehicle treatment on Day 14 ($p = 0.0023$, Wilcoxon Rank-Sum Test) as well as Day 7 ($P=0.048$).

Severe malodor

Improvement

No odor



$P < 0.05$ is considered as statistically significant.

VT-1953 significantly reduced lesion pain (scored by patients on VAS Scale): exploratory endpoint

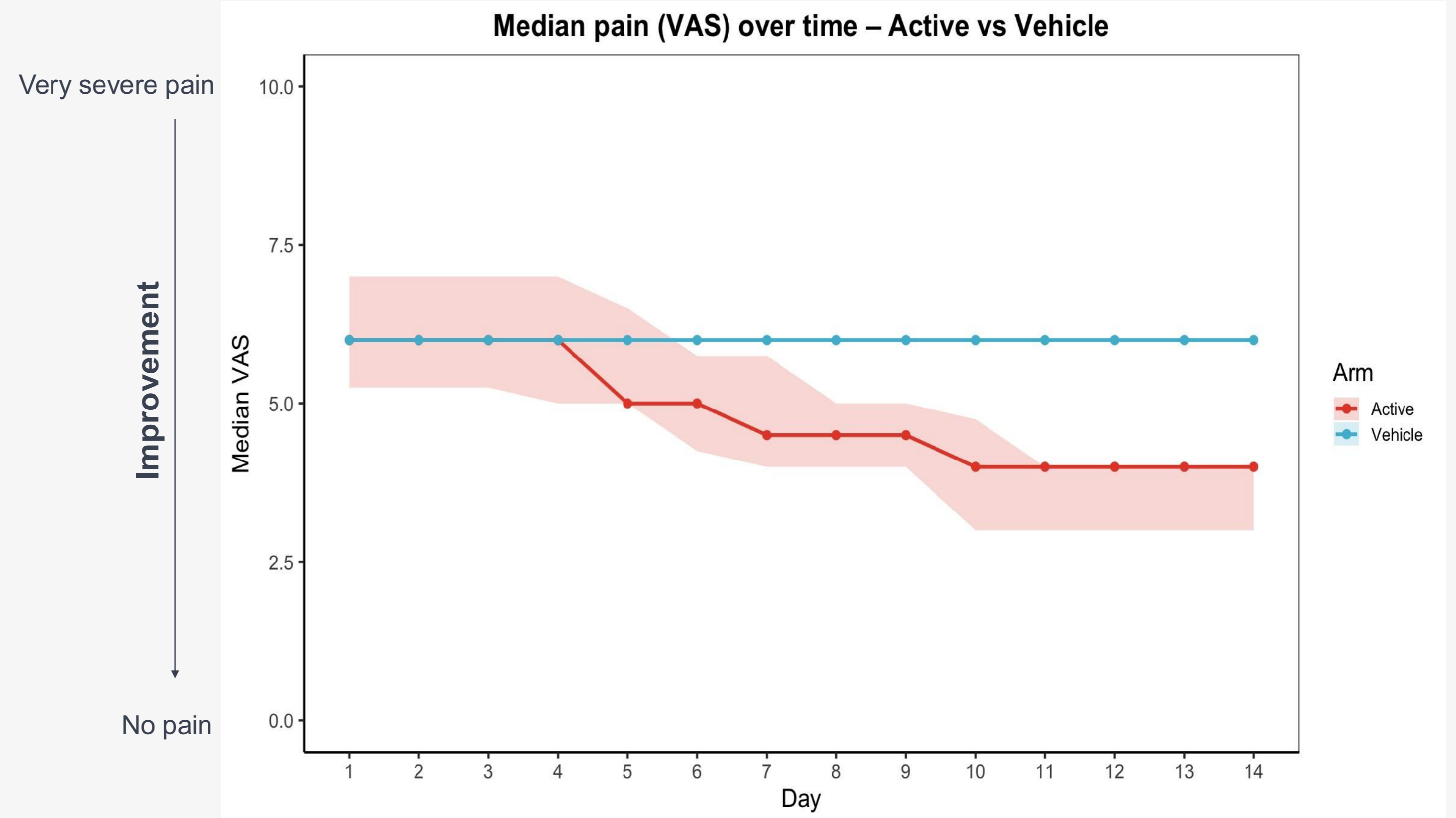
Statistical summary of Malodor Visual Analog Scale (VAS) scores, measured on a 0–10 scale, at Baseline (Day 1) to Day 14 for both treatment groups.

Patients treated with VT-1953 reported a statistically significant decrease in pain intensity by Day 14 to median score of 4.0 (Q1: 3.0, Q3: 4.0) from a baseline median score of 6 (Q1: 5.0, Q3: 7.0) ($p = 0.0020$, Wilcoxon Signed-Rank Test).

A statistically significant reduction in pain was seen as early as Day 7 in VT-1953-treated arm ($p=0.002$). Vehicle Topical Gel group showed no change in pain scores, remaining at 6.0 (Q1: 6.0, Q3: 6.0) ($p > 0.9999$).

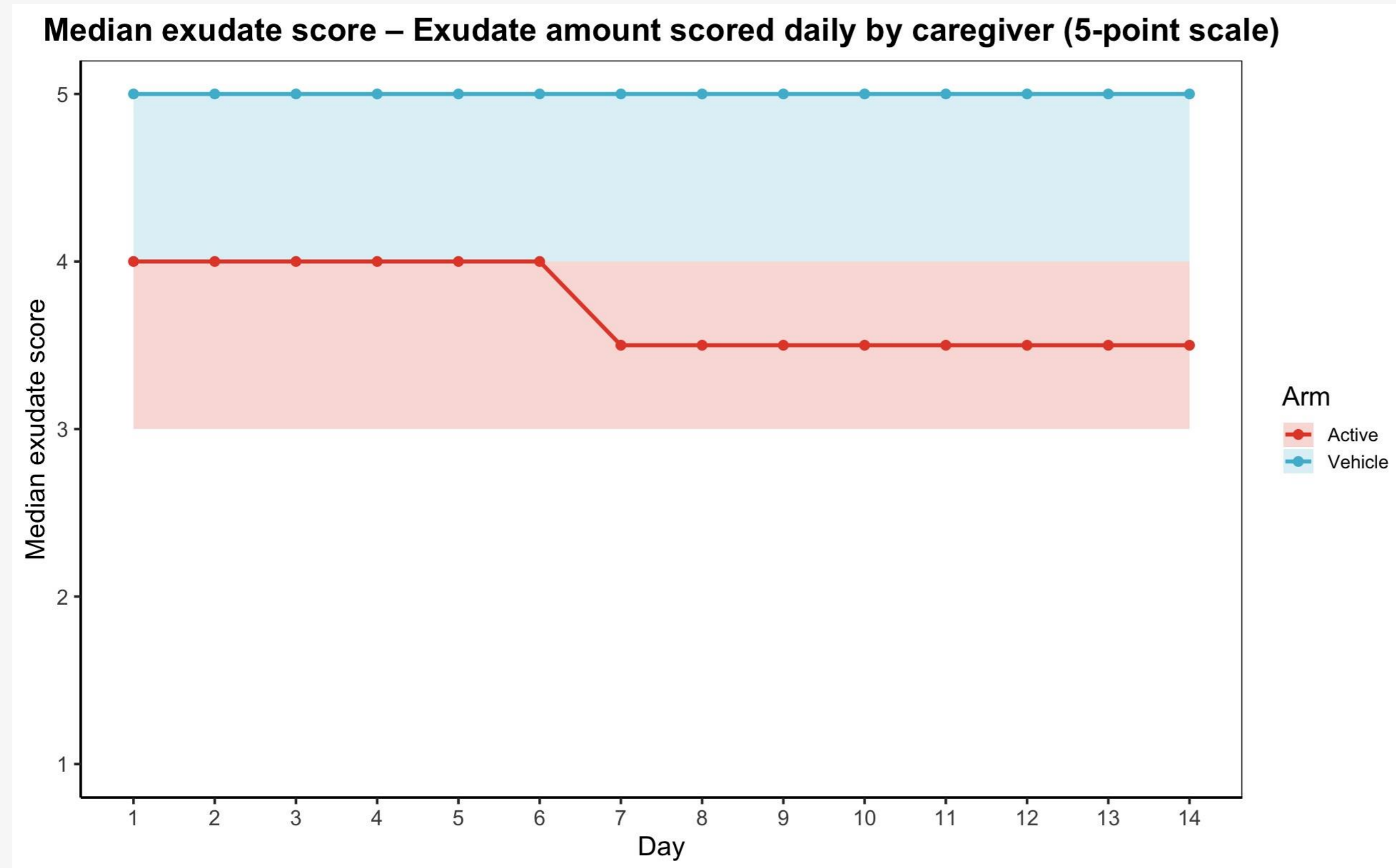
Treatment with VT-1953 was statistically superior in reduction of lesion pain compared to vehicle on Day 14 ($p = 0.0026$, Wilcoxon Rank-Sum Test).

90% of patients reported a 2-point reduction in pain intensity in VT-1953-treated arm vs 0% in vehicle-treated arm.



$P < 0.05$ is considered as statistically significant.

VT-1953 did not significantly reduce exudate: exploratory endpoint



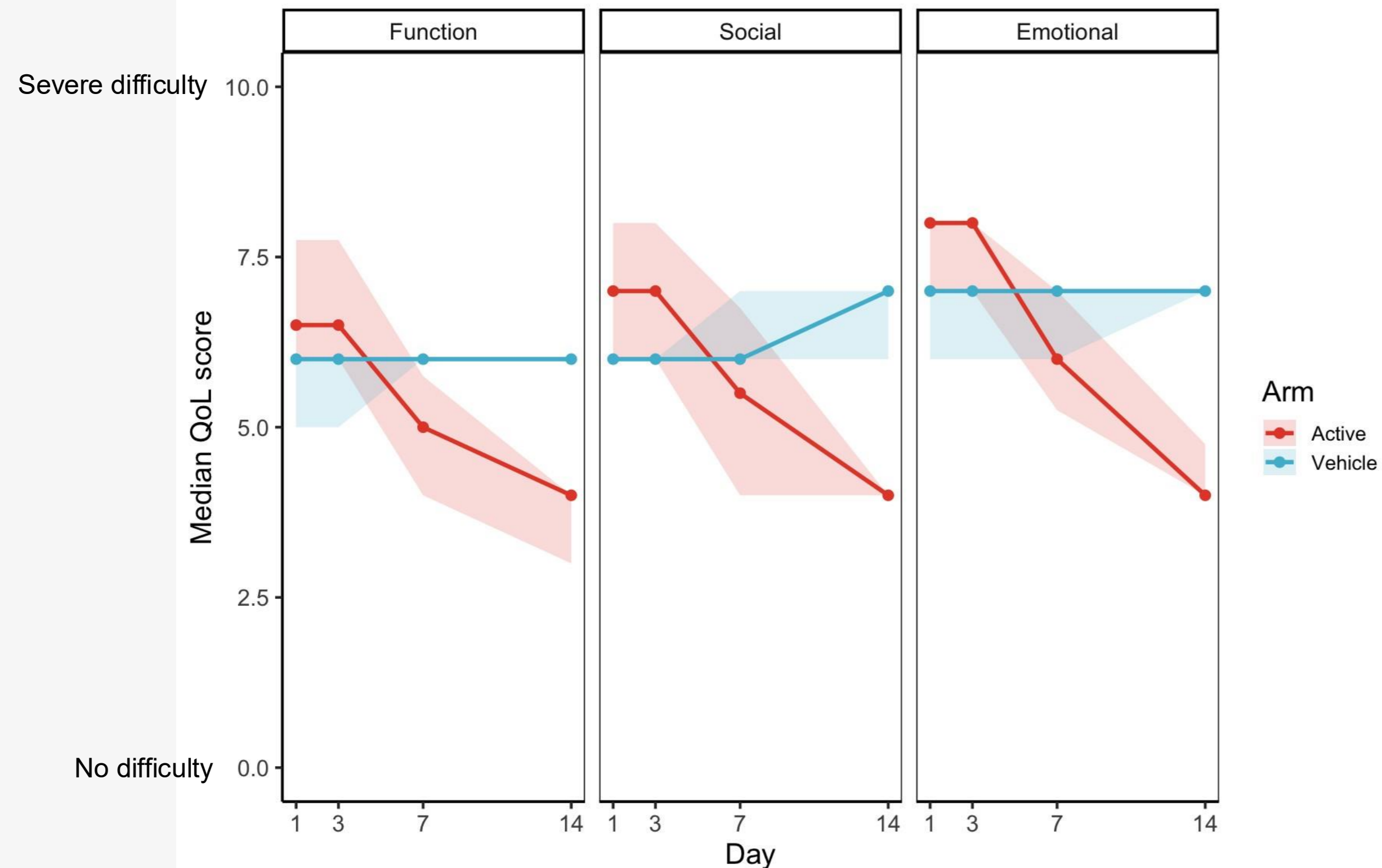
At Day 14, the overall median exudate amount remained unchanged compared to baseline. A statistically significant difference was observed between treatment groups at Day 14 ($p = 0.0268$), favoring the VT-1953 Topical Gel group. Within-group evaluations from baseline to Day 14 showed no statistically significant reduction in exudate scores in the VT-1953 Topical Gel group (Median change from 4.0 to 3.5; $p = 0.5000$).

Overall, these findings indicate that although exudate scores did not significantly improve within groups over 14 days, the VT-1953 Topical Gel group demonstrated comparatively better exudate status at Day 14 versus the vehicle control.

VT-1953 significantly improves QoL (patient-reported outcome measures): exploratory endpoint

Summary of patient-reported QoL outcomes scored using a 10-point Visual Analog Scale (VAS)

Median QoL – Exploratory Quality of Life assessments by Investigator



Patient-reported Quality of Life (QoL) scores derived from the mean of all QoL components

	Median Composite QoL	
	VT-1953	Vehicle
Baseline	5.5 (Q1: 4.5, Q3: 6.0)	4.8 (Q1: 4.3, Q3: 4.8)
Day 14	3.0* (Q1: 2.8, Q3: 3.3)	5.0 (Q1: 4.5, Q3: 5.0)

*Statistically significant within-group improvement from Baseline ($p = 0.0020$, Wilcoxon Signed-Rank Test).

VT-1953 treatment resulted in a statistically significant improvement vs vehicle-arm ($p = 0.0032$, Wilcoxon Rank-Sum Test)

Mean of all individual QoL components was computed by visit for each subject, and the median analysis was then performed on these mean composite scores.

VT-1953 did not exhibit any safety signals during the study period at doses used

- No TEAEs reported
- No changes in vital signs
- No reports of local skin reactions
- *Consistent with observations from prior clinical trials with VT-1953

* VT-1953 (2% topical gel) has been studied for safety and efficacy in 5 clinical studies, including chronic use for 90 days

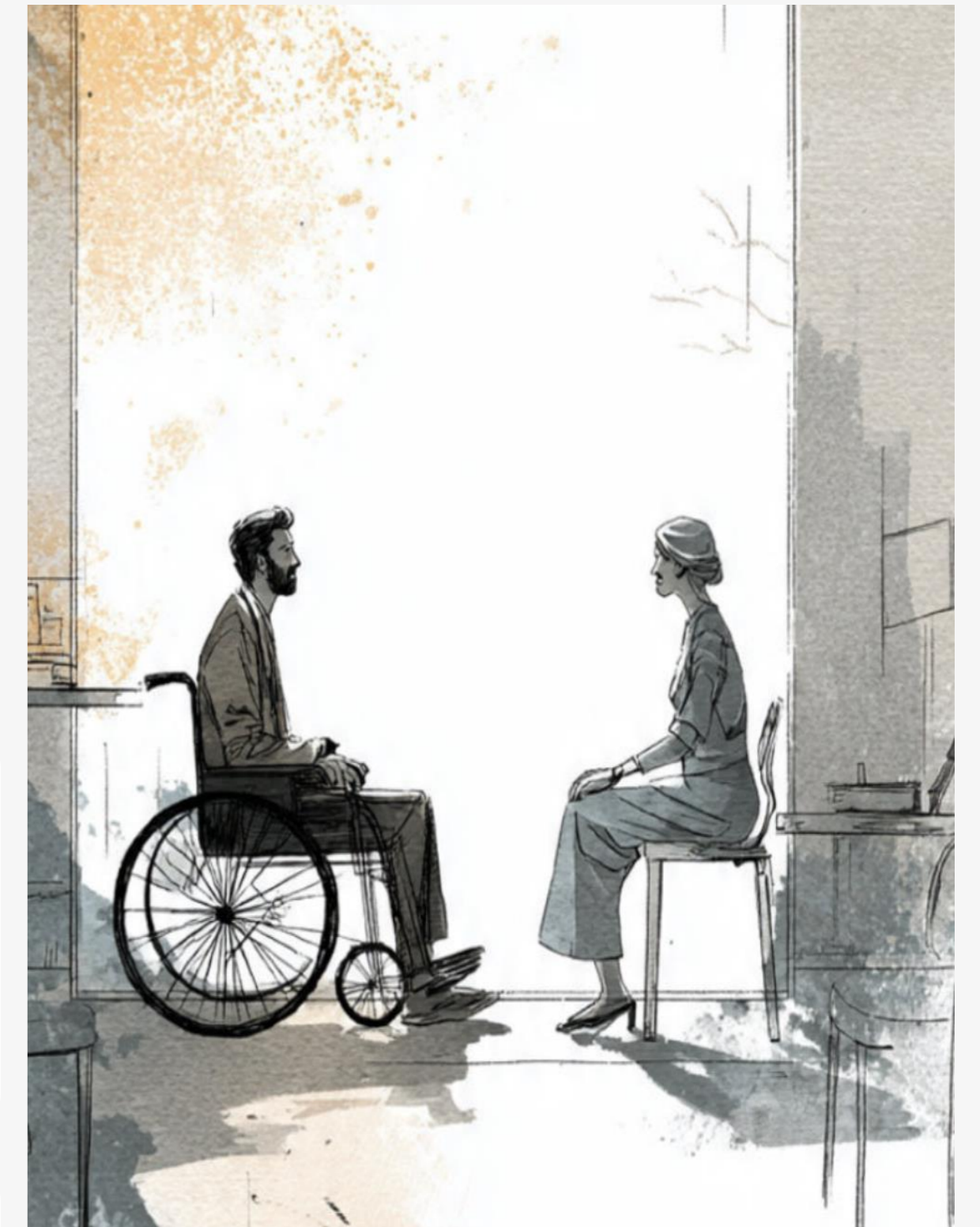
Summary

Treatment with VT-1953 for 14 days successfully met its primary endpoint of significantly reducing malodor associated with MFW as scored by investigators. There is consistency between investigator scores (on TELER score) and malodor scored by patients using VAS (exploratory endpoint)

Patients treated with VT-1953 for 14 days did not report any adverse effects or safety signals

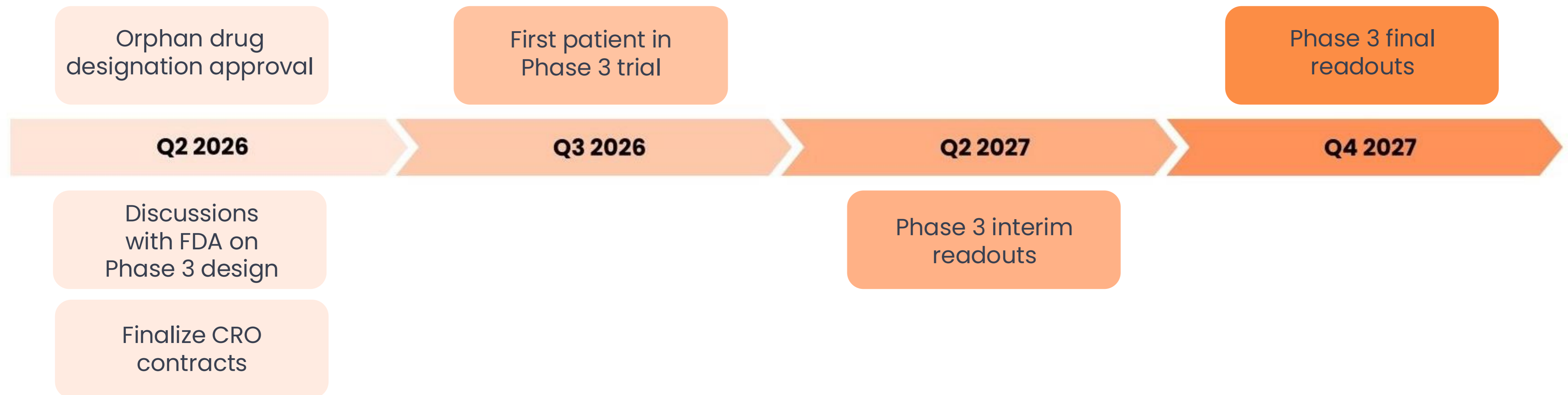
Treatment with VT-1953 for 14 days achieved its secondary endpoint of significantly reducing impact of malodor associated with MFW as scored by patients, and exploratory endpoints of reducing lesion pain (scored by patients), and improved QoL (patient reported outcome measure). There was no significant change in exudates.

These results provide a clear clinical rationale to advance VT-1953 to pivotal studies for the treatment of symptoms associated with MFW. Clear statistical significance in Ph2 and low variance suggests the need for fewer patients in a pivotal study.



VT-1953 Anticipated Milestones – Key Focus of Vyome

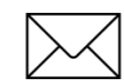
The orphan drug designation application for VT-1953 has been filed and discussions regarding CRO estimates ongoing



Capitalized to fund until Phase 3 Interim readouts

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