

Net Treatment Benefit in ARTEMIA trial comparing OSE2101 to docetaxel in patients with Non-Small Cell Lung Cancer (NSCLC): outcomes prioritization based on investigators' preferences

Pascal Piedbois¹, Sarah Kosta¹, François Montestruc², Marc Buyse¹, Samuel Salvaggio¹, Federico Cappuzzo³, Rafal Dziadziuszko⁴, Santiago Viteri Ramirez⁵, Adeline Pierache², Stéphanie Perot², Silvia Comis⁶, Valerie Gabarre⁶, Berangere Vasseur⁶, Stephen V. Liu⁷, Benjamin Besse⁸

¹One2Treat, Louvain-la-Neuve, Belgium. ²eXYSTAT, Malakoff, France. ³Department of Medical Oncology, IRCCS Regina Elena National Cancer Institute, Roma, Italy; ⁴Department of Oncology & Radiotherapy and Early Phase Clinical Trials Centre, Medical University of Gdańsk, Gdańsk, Poland. ⁵UOMI Cancer Center. Clínica Mi Tres Torres, Barcelona, Spain. ⁶OSE Immunotherapeutics, Paris, France. ⁷Georgetown Lombardi Comprehensive Cancer Center, Washington, DC. ⁸Gustave Roussy Cancer Campus, Villejuif, France



INTRODUCTION

Patients with metastatic NSCLC who develop secondary resistance to immune checkpoint inhibitors (ICI) face competing priorities across survival, disease control, quality of life (QoL), and toxicity¹. ARTEMIA is a phase III trial comparing OSE2101 with docetaxel (primary endpoint: overall survival, OS). To complement the primary endpoint with an exploratory analysis that provides a quantitative, holistic estimate of the benefits and risks, we planned a Net Treatment Benefit (NTB) analysis².

A distinctive feature of this work is the prospective, systematic elicitation of investigators' expertise, an element rarely formalized in clinical research. Trial investigators were appraised through an elicitation software to identify which outcomes should be prioritized and which thresholds represent a clinically meaningful difference for each. These outcomes correspond to the main endpoints of the trial (primary, secondary, and exploratory), ensuring alignment with the protocol.

These elicited priorities and thresholds will directly inform the planned NTB exploratory analysis that allows integration of multiple prioritized outcomes into a single, interpretable assessment of overall treatment effect, thereby aligning the exploratory analysis with day-to-day clinical practice in this setting.

OBJECTIVES

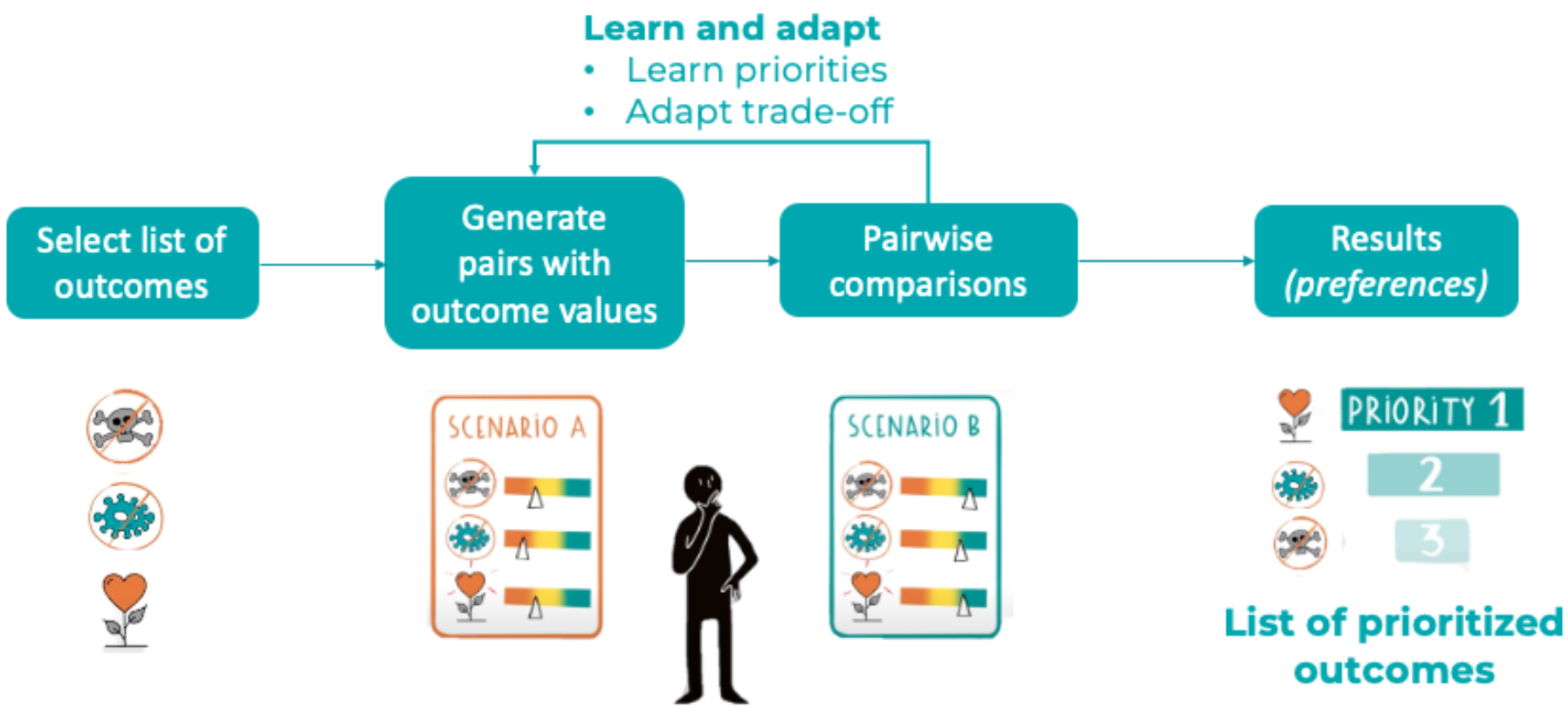
- Elicit investigators' preferences via an adaptive paired-comparison of hypothetical patient profiles.
- Translate their inputs to predefine prioritized outcomes and clinically meaningful thresholds for NTB.
- Providing a comprehensive view of treatment effects by integrating investigators' expertise

MATERIALS AND METHODS

- Phase 3, randomized trial (ARTEMIA, NCT06472245)
- Cross-sectional, web-based preference elicitation among ARTEMIA investigators
- Investigators' participation was voluntary and anonymized.
- An adaptive paired-comparison exercise presented simulated patient profiles labeled only as "Patient A/B" (exercise was treatment agnostic).
- For each pair, investigators chose which patient, in their opinion, had the better overall profile. Pairs (N=20) were adaptively generated by an AI algorithm using prior choices to converge on investigators' priorities.

List of selectable outcomes

- Survival
- Progression-free Survival
- Serious Adverse Events
- Side-effects Burden – EORTC QoL Question 168
- Quality of life – EORTC QLQ C30 – Global Health Score
- Quality of life – EORTC QLQ C30 – Physical Function
- Quality of life – EORTC QLQ C30 – Role Function



RESULTS

- Participation rate = 29/145 (20%)
- Surveyed between 17–24 Mar 2025
- Mean completion of 9 min (range 4–24).

Investigators selected up to five outcomes from seven candidates; the top five in rank order were overall survival (OS) (chosen by 72%) followed by Global QoL Score, PFS, side-effect burden, and SAE occurrence.

The most frequent clinically meaningful thresholds were +3 months for OS, +6 months for PFS, and +1 level improvement for QoL and side-effect burden; SAEs were retained as a binary safety outcome.

The results from the exercise were then used to define an exploratory endpoint reflecting the investigators' choices and allowing to assess the NTB based on the below list of prioritized outcomes :

Priority	Outcome variable	Contribution to Net Treatment Benefit
1	Overall Survival (OS)	Longer overall survival (>3 months difference)
2	Quality of Life: Global Health Score	Better global quality of life (>5 points difference)
3	Progression-free Survival (PFS)	Longer time to progression (>6 months difference)
4	Side-effects Burden	Less impact of treatment-related side effects (>5 points difference)
5	Serious adverse events	No serious adverse events

CONCLUSIONS

- Investigators' preferences were prospectively formalized - an approach seldom used in phase III trials - and notably confirmed survival as the first priority followed by quality of life over progression-free survival (PFS).
- A short (~9 min) elicitation, completed across all investigators within one week, proved feasible; investigator-driven, pre-specified rules (hierarchy, thresholds, sensitivity), enhanced clinical relevance and practice alignment summarized within an endpoint.
- The exercise is transferable across indications and can be extended to patient, payors, caregiver elicitation to align risk and benefit assessment with lived experience.

REFERENCES

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DISCLOSURES

Prof. Pascal Piedbois is Chief Medical Officer and shareholder of One2Treat. This work has been supported by OSE Immunotherapeutics.

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Contact email address: info@one2treat.com

Learn more about the software used for this exercise

