

1629e

Long-Term Results of ASP-1929 Photoimmunotherapy With Pembrolizumab in Patients with Recurrent/Metastatic Head and Neck Squamous Cell Carcinoma

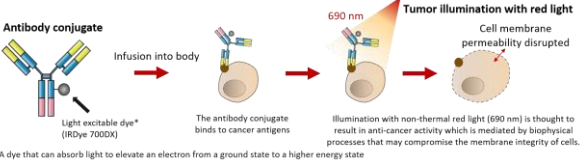
A. Gillenwater¹, J. Curry², J. Johnson², J. Valentino³, S. Arnold³, A. Maniakas¹, H. Danesi⁴, T. Suzuki⁴, A. Thorne⁴, R. Cheng⁴, H. Dong⁴, D. Cognetti²

¹MD Anderson Cancer Center, Houston, United States of America, ²Thomas Jefferson University, Philadelphia, United States of America, ³University of Kentucky, Lexington, United States of America, ⁴Rakuten Medical Inc.

BACKGROUND

• ASP-1929 photoimmunotherapy (PIT) is a combination of an antibody-drug conjugate (ADC) and a device, in which cetuximab is conjugated with IR700 dye and uses red-light illumination to activate its tumor-disrupting effects (Figure 1).

Figure 1. ASP-1929 PIT Mechanism of Action

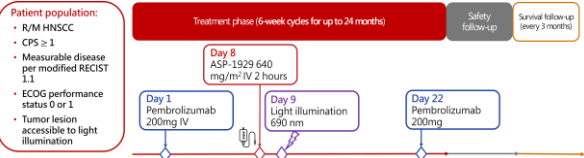


- Prior efficacy and safety findings from a Phase Ib/II study (NCT04305795) conducted in the United States of ASP-1929 PIT plus pembrolizumab in recurrent and/or metastatic head and neck squamous cell carcinoma (R/M HNSCC) showed durable clinical activity and a manageable safety profile after a median follow-up of 31.7 months (Cognetti D, et al. Head Neck. 2025;48(1):160-174).
- Current analysis reports efficacy and safety at 53.1-month follow-up and exploratory subgroup analysis by PD-L1 expression, HPV status, and tumor size.

METHODS

- Study Design**
- Phase Ib/II, single-arm study of ASP-1929 PIT + pembrolizumab

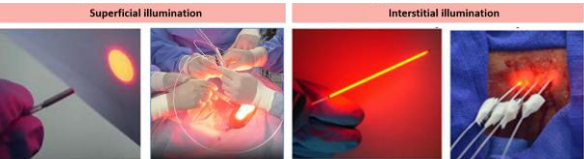
ASP-1929 Study Design and Treatment Schedule



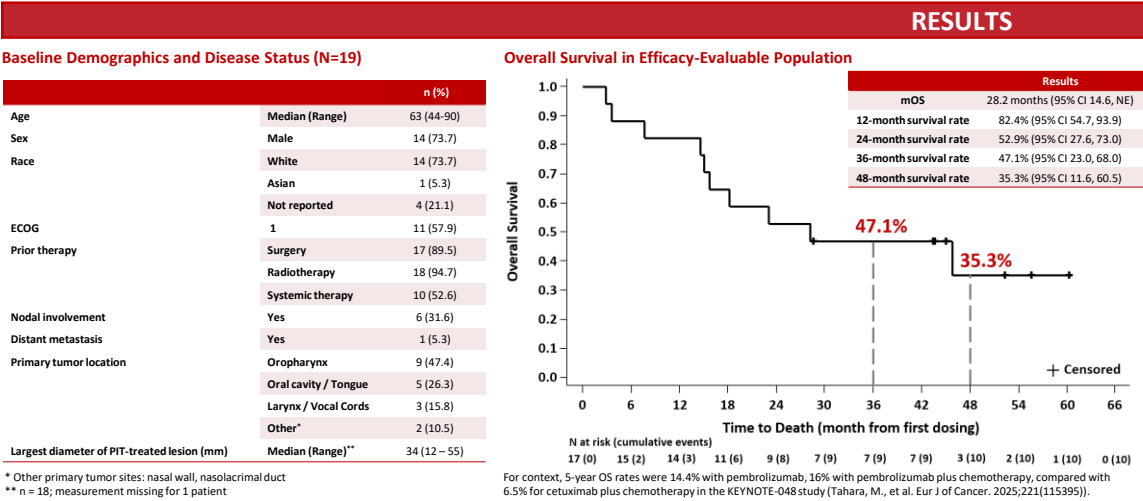
- Key Endpoints**
- Primary endpoints: TEAE, serious TEAEs , ORR
 - Key secondary endpoints: OS, DOR

- Analysis populations**
- Safety population: Patients who received either illumination or pembrolizumab
 - Efficacy-evaluable population: Patients who had at least one post-baseline tumor assessment

Light Illumination Techniques for ASP-1929 Photoimmunotherapy



Abbreviations: BOR= best overall response, CI= confidence interval, CPS= combined positive score, CR= complete response, CT= chemotherapy, DOR= duration of response, ECOG= Eastern Cooperative Oncology Group, EGFR mAb = epidermal growth factor receptor inhibitor monoclonal antibody, HPV= human papillomavirus, ICI= immune checkpoint inhibitor, mOS= median overall survival, NA= not available, N/A= not applicable, NE= not evaluable, PIT= photoimmunotherapy, PR= partial response, R/M HNSCC= recurrent or metastatic head and neck squamous cell carcinoma, ORR= overall response rate, OS= overall survival, PD= progressive disease



Summary of Long-Term Survivors (OS ≥ 24 months)

Patient	Age	Sex	Race	Primary tumor location	Tumor size* (mm)	TNM-M	P16	CPS	Number of cycles	Best response	Time to confirmed response	DOR (months)	OS (months)	Post-PIT non-study therapy
Case 1	44	Male	NA	Nasal wall	33	M0	-	10	10	CR**	4.18	3.2+	60.16+	NA
Case 2	68	Male	NA	Oropharynx	28	M0	-	5	2	CR	1.41	44.34	45.72	NA
Case 3	67	Male	White	Oropharynx	13	M0	+	3	2	CR	1.38	23.03+	44.97+	CT, ICI
Case 4	57	Female	White	Oral cavity	46	M0	-	88	1	CR	5.53	16.88+	52.27+	NA
Case 5	70	Male	White	Oral cavity	44	M0	-	>1	3	CR	1.45	41.02+	43.36+	NA
Case 6	48	Female	Asian	Tongue	15	M0	-	35	3	PR	1.38	2.83+	55.53+	Wide local resection
Case 7	52	Male	White	Oropharynx	33	M0	-	>20	6	SD	N/A	N/A	28.19	Investigational agent, ICI, EGFR mAb, CT
Case 8	55	Male	White	Oral cavity	55	M1	-	33	6	SD	N/A	N/A	43.52+	EGFR mAb, CT, ICI
Case 9	65	Female	White	Oral cavity	49	M0	-	20	1	PD	N/A	N/A	28.59+	ICI

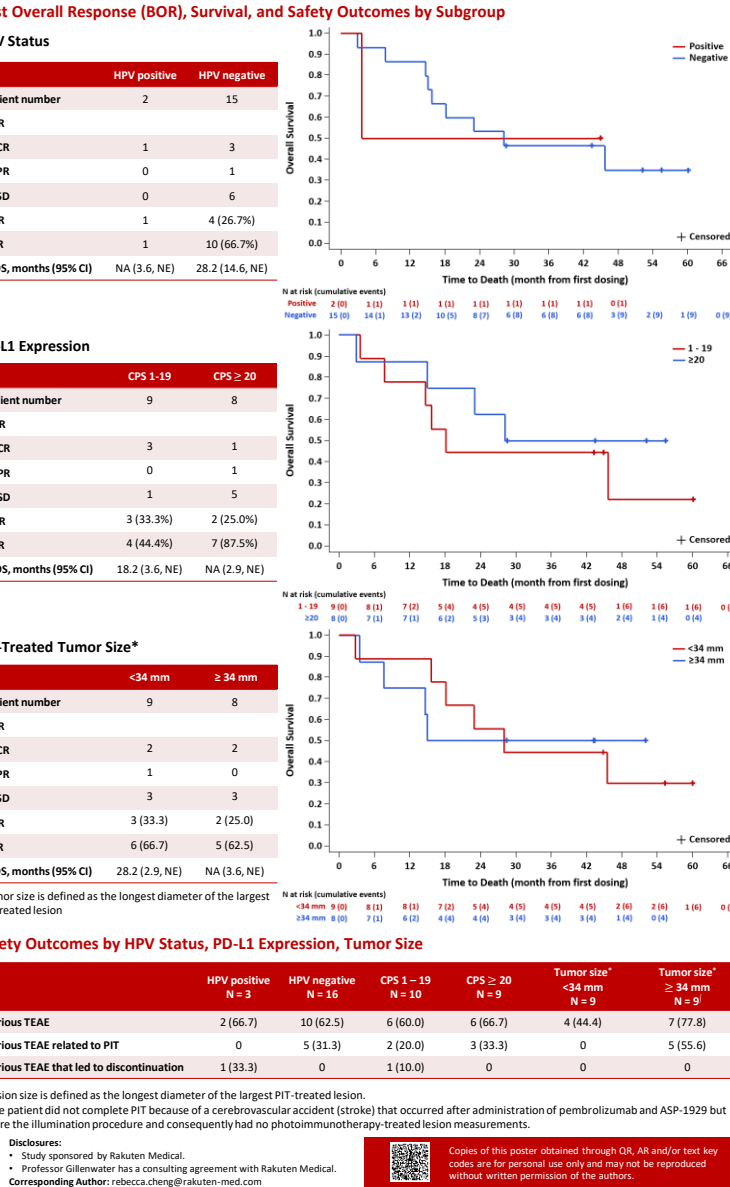
*The longest diameter of the largest PIT-treated lesion
** Patient was assessed with best response of PD but continued receiving ASP-1929 PIT and ultimately achieved a CR at the end of treatment visit

CONCLUSIONS

- With an additional 21.4 months of follow-up, 35.3% of 17 patients remained alive at the 4-year mark, demonstrating meaningful long-term survival in a subset of patients.
- The median duration of response was 44.3 months at data cutoff.
- Responders were alive without receiving subsequent anticancer therapy following study treatment discontinuation, supporting the durability of response.
- No distinct baseline characteristics were identified among long-term survivors (≥ 2 years), suggesting that observed results may not be limited to a clearly defined patient subgroup.
- Exploratory analyses showed generally consistent efficacy and safety findings across subgroups defined by HPV status, PD-L1 CPS expression, and baseline tumor size, with no new safety signals observed.
- These findings are exploratory and should be interpreted in light of the study's limitations, including the small sample size and limited patient numbers in some subgroup analyses. Nevertheless, the results support continued investigation of ASP-1929 photoimmunotherapy in combination with pembrolizumab in the ongoing Phase 3 ECLIPSE study (NCT06699212).

Acknowledgements:

- We thank the patients and their families, the investigators and their teams, Rakuten Medical colleagues, clinical research organizations, and vendors.
- Presented at 2026 ESMO Congress, October 23 - 27, 2026, Madrid, Spain



Copies of this poster obtained through QR, AR and/or text key codes are for personal use only and may not be reproduced without written permission of the authors.