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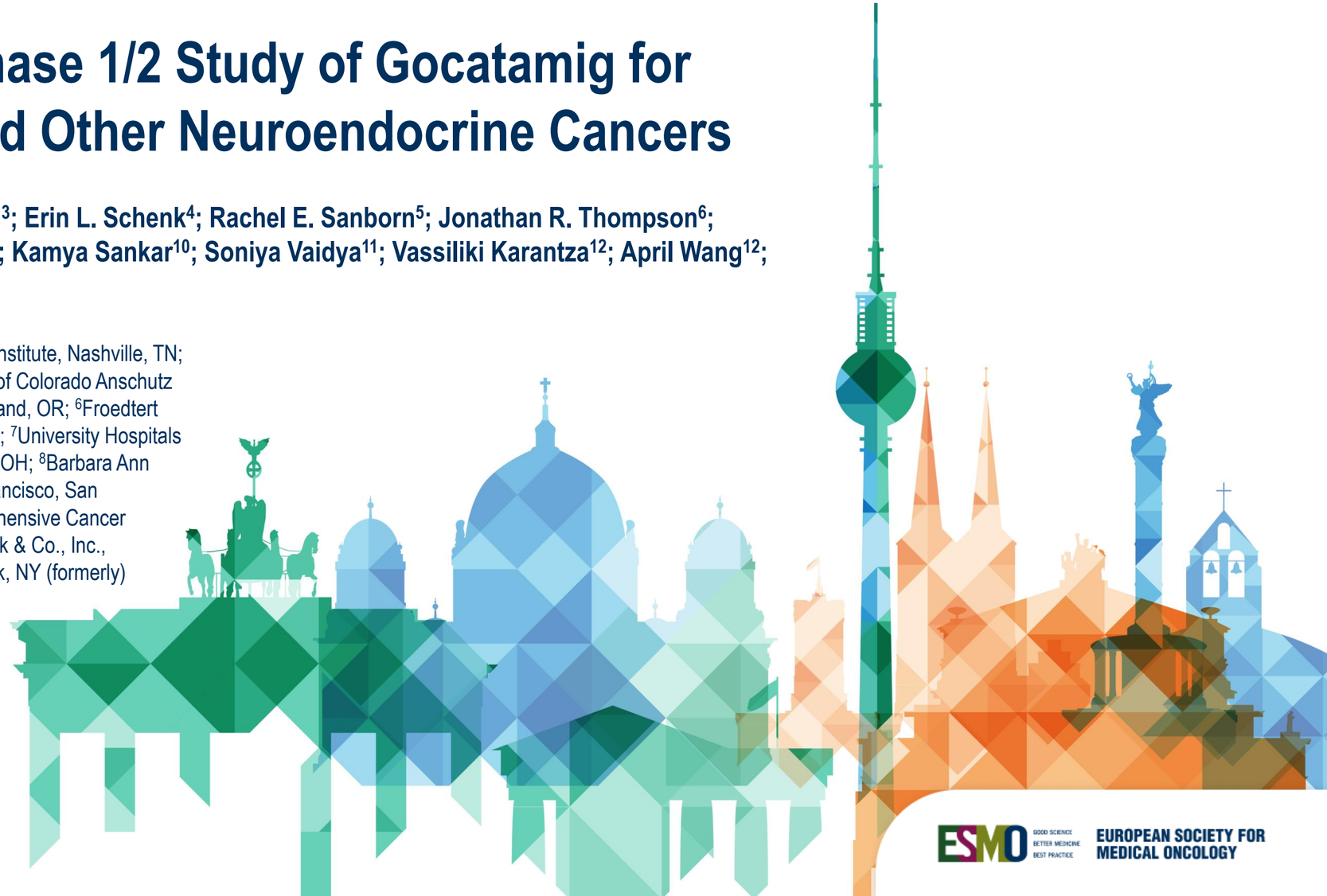
Updated Results from a Phase 1/2 Study of Gocatamig for Small Cell Lung Cancer and Other Neuroendocrine Cancers

Himisha Beltran[1]; Melissa L. Johnson[2]; Prantesh Jain[3]; Erin L. Schenk[4]; Rachel E. Sanborn[5]; Jonathan R. Thompson[6]; Afshin Dowlati[7]; Hirva Mamdani[8]; Rahul R. Aggarwal[9]; Kamya Sankar[10]; Soniya Vaidya[11]; Vassiliki Karantza[12]; April Wang[12]; Ann Gramza[12]; Alissa J. Cooper[1, 13]

[1]Dana-Farber Cancer Institute, Boston, MA; [2]Sarah Cannon Research Institute, Nashville, TN; [3]Roswell Park Comprehensive Cancer Center, Buffalo, NY; [4]University of Colorado Anschutz Medical Campus, Aurora, CO; [5]Earle A. Chiles Research Institute, Portland, OR; [6]Froedtert and the Medical College of Wisconsin Workforce Health, Milwaukee, WI; [7]University Hospitals Seidman Cancer Center, Case Western Reserve University, Cleveland, OH; [8]Barbara Ann Karmanos Cancer Institute, Detroit, MI; [9]University of California San Francisco, San Francisco, CA; [10]Cedars-Sinai Medical Center, Samuel Oschin Comprehensive Cancer Institute, Los Angeles, CA; [11]Daiichi Sankyo, Basking Ridge, NJ; [12]Merck & Co., Inc., Rahway, NJ, USA; [13]Memorial Sloan Kettering Cancer Center, New York, NY (formerly)



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ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY

Declaration of Interests

HIMISHA BELTRAN

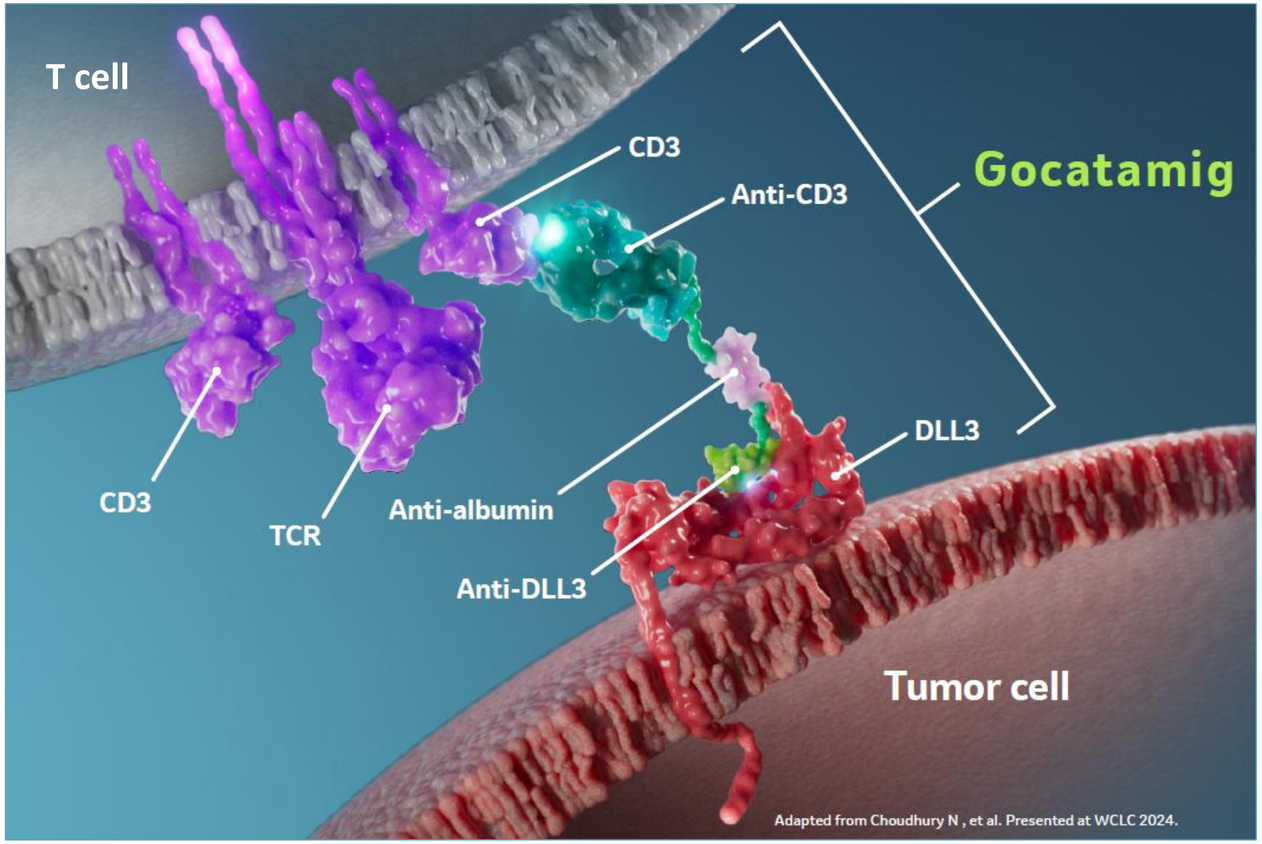
- **Grants or contracts** (to the institution): Bristol Myers Squibb, Circle Pharma, Daiichi Sankyo, Novartis
- **Advisory role**: AstraZeneca, Amgen, Bayer, Daiichi Sankyo, Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA, Novartis, Pfizer, Sanofi

The 6070-001 study (NCT04471727) was sponsored by Harpoon Therapeutics, Inc., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA, and Daiichi Sankyo, Inc.

Background

- Delta-like ligand 3 (DLL3) is highly expressed in small cell lung cancer (SCLC) and other neuroendocrine carcinomas (NEC)[1]
- Gocatamig (MK-6070/HPN328) is a DLL3-directed T-cell engager developed using the TriTAC® platform[2]
  - Small size (~50kDa)
  - Prolonged half-life (13.8 days)
- Initial results[3] from the phase 1/2 study 6070-001 showed promising antitumor activity and manageable safety with gocatamig monotherapy at target doses of 12 mg and 24 mg (N=41)

Here, we present updated results for 73 participants[a] with advanced SCLC and other NEC



1. Owen DH, et al. *J Hematol Oncol*. 209;12(1):61. 2. Austin RJ, et al. *Mol Cancer Ther*. 2021;20(1):109-120. 3. Beltran H, et al. *J Clin Oncol*. 2024;42(16_suppl):8090.
[a]Includes 39 participants with SCLC, 29 with neuroendocrine carcinomas, and 5 with high-grade neuroendocrine tumors; excludes participants with neuroendocrine prostate cancer.

Phase 1/2 6070-001 Gocatamig Monotherapy in SCLC and Other NEC

Key eligibility criteria

- Age ≥18 years
- SCLC relapsed/refractory to ≥1 prior line of platinum-based chemotherapy OR
- Other DLL3-expressing NEC relapsed/refractory to standard therapy (or standard therapy does not exist or is considered inappropriate)
- ECOG PS 0 or 1

Gocatamig monotherapy dosing

- 12 mg or 24 mg IV Q1W or Q2W with step-up dosing[a]

Key study objectives

- Safety and tolerability: AEs, DLTs
- Preliminary antitumor activity: ORR assessed by investigator per RECIST v1.1

Participants with SCLC or other NEC treated in a 12-mg or 24-mg Q1W or Q2W target dose cohort (N=73)[b]

- 12 mg Q2W (n=25)
- 12 mg Q1W (n=11)
- 24 mg Q2W (n=25)
- 24 mg Q1W (n=12)

[a]The target dose of 12 mg was administered Q1W or Q2W following a single priming dose of 1 mg. The target dose of 24 mg was administered Q1W or Q2W following sequential single priming doses of 1 mg and 12 mg.
[b]Includes 39 participants with SCLC, 29 with neuroendocrine carcinomas, and 5 high-grade neuroendocrine tumors; excludes participants with neuroendocrine prostate cancer.
https://clinicaltrials.gov/: NCT04471727

Baseline Characteristics

	12 mg Q2W (n=25)	12 mg Q1W (n=11)	24 mg Q2W (n=25)	24 mg Q1W (n=12)	All Cohorts (N=73)
Median age (range), years	62.0 (42-79)	62.0 (48-77)	61.0 (37-75)	64.0 (43-77)	61.5 (37-79)
Male / female, %	60 / 40	55 / 45	36 / 64	75 / 25	53 / 47
ECOG PS 0 / 1, %	44 / 56	55 / 45	36 / 64	58 / 42	45 / 55
Tumor type: SCLC / other NEC, %	40 / 60	64 / 36	52 / 48	75 / 25	53 / 47
Median prior lines of therapy (range)	2.0 (1-6)	2.0 (1-3)	2.0 (1-6)	2.5 (1-5)	2.0 (1-6)
≥3 prior lines of therapy, %	28	45	36	50	37
Prior anti-PD-(L)1 therapy, %	76	82	80	83	79
Prior platinum therapy, %	92	100	92	100	95
Brain / liver metastases, %	52 / 56	45 / 27	44 / 48	50 / 58	48 / 49

Data cutoff date 28 February 2025.

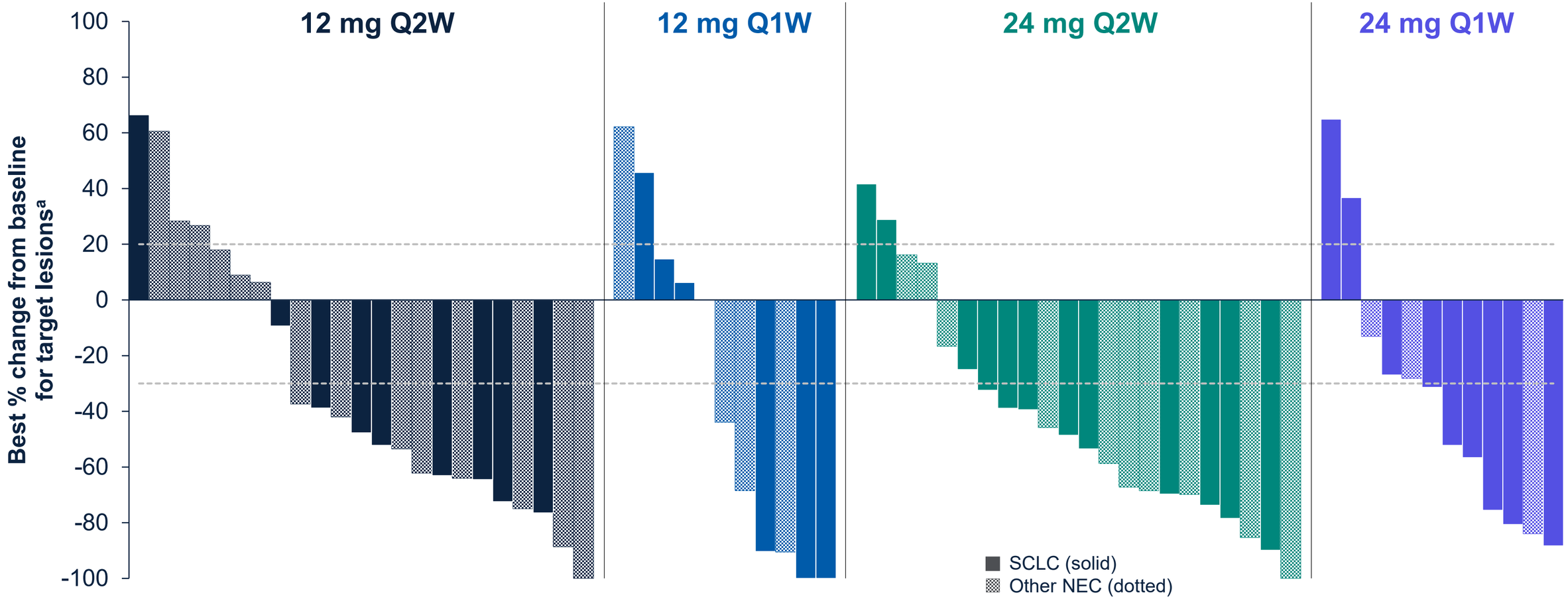
Best Confirmed Objective Response

	12 mg Q2W (n=25)	12 mg Q1W (n=11)	24 mg Q2W[b,c] (n=25)	24 mg Q1W[c] (n=12)	All Cohorts (N=73)
Confirmed ORR,[a] % (95% CI)	36 (18-57)	45 (17-77)	48 (28-69)	50 (21-79)	44 (32-56)
DCR, % (95% CI)	60 (39-79)	64 (31-89)	72 (51-88)	67 (35-90)	66 (54-76)
Best confirmed OR, n (%)					
Complete response	0 (0)	2 (18)	0 (0)	0 (0)	2 (3)
Partial response	9 (36)	3 (27)	12 (48)	6 (50)	30 (41)
Stable disease	6 (24)	2 (18)	6 (24)	2 (17)	16 (22)
Progressive disease	8 (32)	4 (36)	4 (16)	4 (33)	20 (27)
No assessment	2 (8)	0 (0)	3 (12)	0 (0)	5 (7)

24 mg Q2W: SCLC ORR = 46%; other NEC = 50%

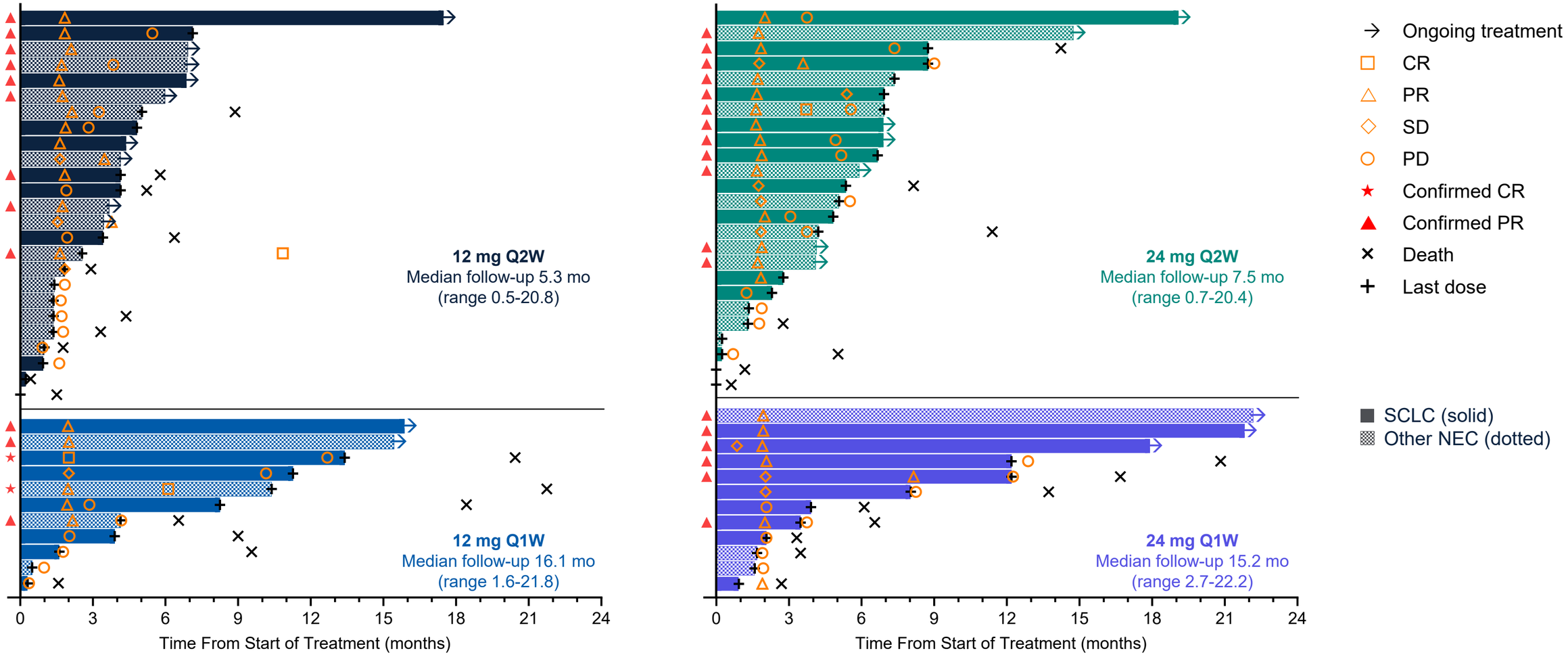
[a]Based on investigator assessment per RECIST v1.1.
[b]Confirmed ORR % (95% CI) for pts with SCLC (n=13) was 46% (19-75); for pts with other NEC (n=12) was 50% (21-79).
[c]Among 33 participants who received at least one 24-mg target dose, confirmed ORR % (95% CI) was 55% (36-72) and DCR % (95% CI) was 79% (61-91).
Data cutoff date 28 February 2025.

Gocatamig Antitumor Activity



[a]Among 68 participants who received any amount of study treatment and had at least one postbaseline scan.
Data cutoff date 28 February 2025.

Duration of Treatment and Response[a]



Median DOR was 10.8 months (range 1.8-19.8 months) with 17/32 (53%) of responses ongoing at data cutoff

[a]Based on investigator assessment per RECIST v1.1. Imaging was scheduled Q8W. Shown are the assessments at which the first CR, PR, SD, or PD occurred.
Data cutoff date 28 February 2025.

Summary of Treatment-Related Adverse Events

	12 mg Q2W (n=25)	12 mg Q1W (n=11)	24 mg Q2W (n=25)	24 mg Q1W (n=12)	All Cohorts (N=73)
TRAEs, n (%)	23 (92)	11 (100)	24 (96)	11 (92)	69 (95)
Grade 3-5	6 (24)	1 (9)	8 (32)	6 (50)	21 (29)
Serious	2 (8)	3 (27)	4 (16)	4 (33)	13 (18)
Led to treatment discontinuation	0	0	1 (4)	1 (8)	2 (3)
Led to death	0	0	0	1[a] (8)	1[a] (1)

TRAEs of interest by highest grade, n (%)	All Cohorts (N=73)
CRS, any grade	40[b] (55)
Grade 1	24 (33)
Grade 2	15 (21)
Grade 4	1 (1)
ICANS, any grade	5 (7)
Grade 1	3 (4)
Grade 2	2 (3)

TRAEs with incidence ≥20%, n (%)	All Cohorts (N=73)	
	Any grade	Grade 3-5
CRS	40 (55)	1 (1)
Fatigue	38 (52)	2 (3)
Dysgeusia	33 (45)	0 (0)
Nausea	29 (40)	0 (0)
Diarrhea	23 (32)	3 (4)
Vomiting	23 (32)	0 (0)
Decreased appetite	21 (29)	1 (1)
Weight decreased	17 (23)	2 (3)

[a]One participant died from treatment-related pneumonitis. [b]90% of CRS events occurred on C1D1 or C1D8.
All AEs were graded per CTCAE v5.0 except for CRS and ICANS, which were graded per ASTCT 2019 criteria.
Data cutoff date 28 February 2025.

Conclusions

- **Gocatamig monotherapy continues to show promising antitumor activity in ES-SCLC and other NEC, with 24 mg Q2W emerging as the preferred monotherapy dosage**
  - Confirmed ORR was 44% in all participants and 55% in those who received the 24-mg target dose
  - Median DOR was 10.8 months with 53% of responses ongoing
  - DCR was 66%
- **There were no new or unexpected safety findings**
  - No DLTs occurred with target doses
  - Nearly all (98%) CRS events were grade 1 or 2
  - Discontinuations of gocatamig due to TRAEs were infrequent (3%)
- **Investigations of gocatamig as monotherapy and in combination with other cancer therapies (I-DXd, atezolizumab, and durvalumab) are ongoing[1-3]**

1. Bar J, et al. A phase 1b/2 study of gocatamig and ifinatamab deruxtecan for relapsed/refractory extensive-stage small cell lung cancer. ESMO 2025; Poster #2792TiP. 2. ClinicalTrials.gov. NCT06780137.
3. Jain P, et al. *J Immunother Cancer*. 2024;12. doi. 10.1136/jitc-2024-SITC2024.0656.

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Contact Dr Himisha Beltran at himisha_beltran@dfci.harvard.edu for questions or comments

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