

Nemvaleukin Alfa: A Novel, Engineered Interleukin-2 (IL-2) Variant Immunotherapy

Clinical Data Updates from ARTISTRY-1 Trial

June 6, 2022

American Society of Clinical Oncology (ASCO) Annual Meeting



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Today's Agenda

1. Nemvaleukin Alfa: A Novel IL-2 Variant Immunotherapy with a Differentiated Design
Jessica Rege, Vice President, Oncology Clinical Research, Alkermes
2. Roundtable Discussion: ARTISTRY-1 Clinical Trial
Moderated by Elizabeth Dorn, Senior Medical Director, Alkermes
3. Advancing a Differentiated IL-2 Toward Potential Registration
Richard Pops, CEO, Alkermes
4. Q&A

Roundtable Discussion Panel



Ulka N. Vaishampayan, M.D.

*Professor, Internal Medicine, Division of Hematology/Oncology
University of Michigan*



Omid Hamid, M.D.

*Co-director of Cutaneous Oncology; Director of Melanoma Therapeutics and Phase I Immune-oncology Program;
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*Professor of Obstetrics and Gynecology, Deputy Director
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Nemvaleukin Alfa (Nemvaleukin): A Novel IL-2 Variant Immunotherapy With a Differentiated Design

Jessica Rege, Vice President, Oncology Clinical Research, Alkermes

High-Dose IL-2 Therapy Has Proven Anti-Tumor Efficacy

- Interleukin-2 (IL-2) is a natural regulator of the activity of lymphocytes involved in the immune response
- High-dose IL-2 (hdIL-2) monotherapy can drive complete and durable responses in certain tumor types, but its toxicity profile significantly limits its potential broader application
- A molecule that recapitulates the anti-tumor activity of hdIL-2, without its hallmark toxicity issues, could be complementary to a wide range of other therapeutic approaches

Dutcher et al. *Journal for ImmunoTherapy of Cancer* 2014, 2:26
<http://www.immunotherapyofcancer.org/content/2/1/26>



REVIEW

Open Access

High dose interleukin-2 (Aldesleukin) - expert consensus on best management practices-2014

Janice P Dutcher^{1*}, Douglas J Schwartzentruber², Howard L Kaufman³, Sanjiv S Agarwala⁴, Ahmad A Tarhini⁵, James N Lowder⁶ and Michael B Atkins⁷

Abstract

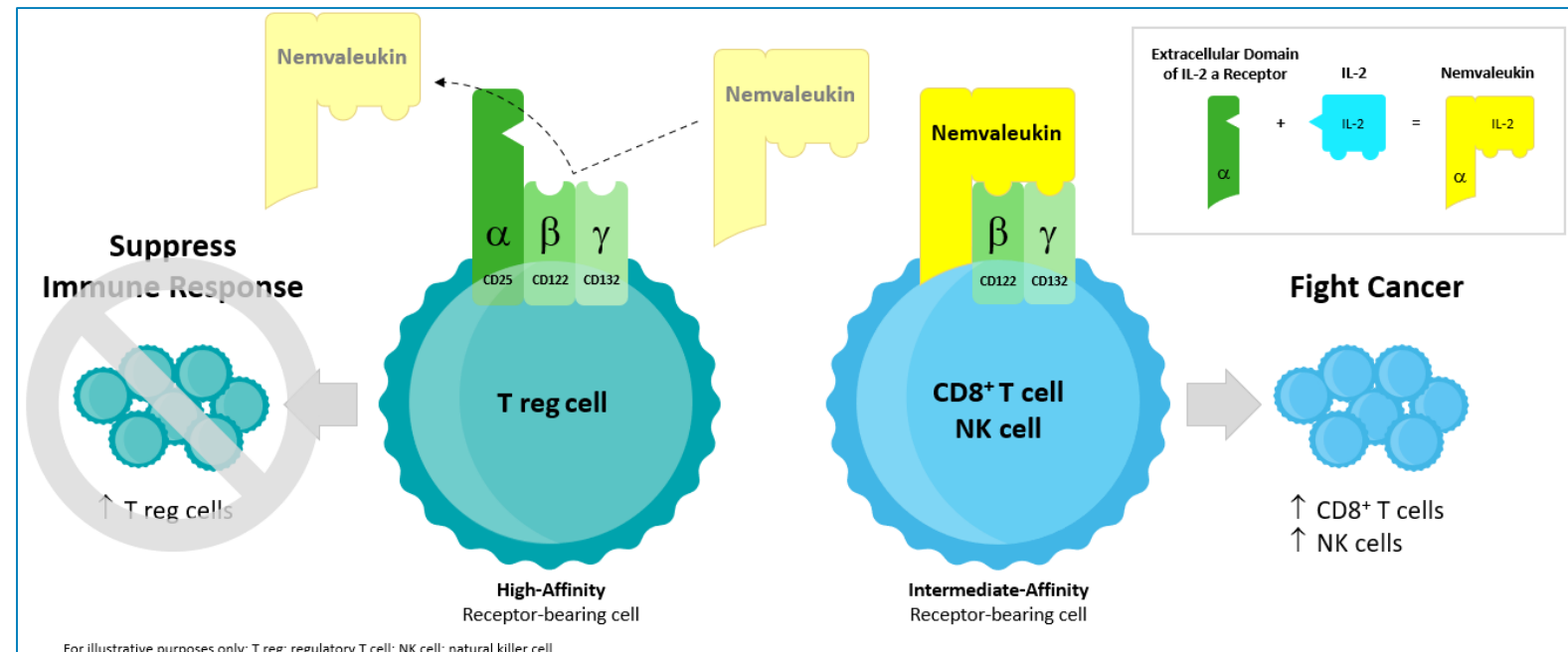
“Interleukin-2 (IL-2) was historically one of the few treatment for adults with stage IV solid tumors that could produce complete responses that were often durable for decades without further therapy. The majority of complete responses with metastatic renal cell carcinoma and metastatic melanoma could probably be classified as cures...The goal for IL-2 therapy is typically to administer the maximum number of doses of IL-2 without putting the patient at unacceptable risk for severe, irreversible toxicity.”

guidelines on pre-treatment screening, criteria for administration and withholding doses, and defines consensus criteria for safe administration and toxicity management. The somewhat heterogeneous best practices of 2014 will be compared and contrasted with the guidelines provided in 2001 and the package inserts from 1992 and 1998.

Nemvaleukin: Designed to Capture and Expand the Therapeutic Potential of High-Dose IL-2

Nemvaleukin's design intentions:

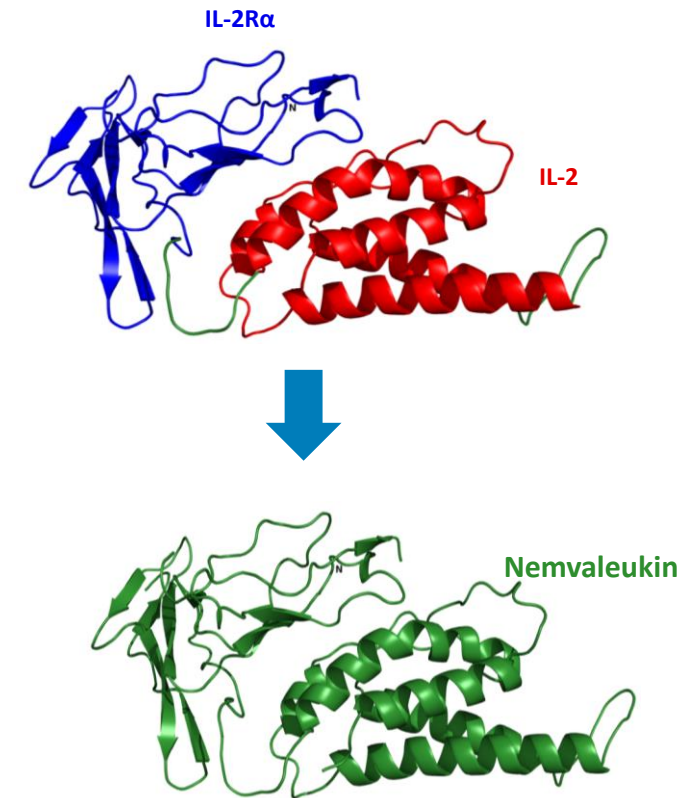
- Preferentially expand cancer-fighting CD8⁺ T cells and natural killer (NK) cells to potentially improve anti-tumor efficacy
- Prevent engagement with the high-affinity IL-2 receptor to mitigate:
 1. IL-2-derived expansion of immunosuppressive regulatory T cells (T regs)
 2. Activation of vascular endothelial cells, which has been associated with certain side effects of hdIL-2, including vascular leak syndrome



Nemvaleukin: A Novel, Differentiated Engineered Fusion Protein

Key Features of Nemvaleukin's Molecular Design

- Inherently selective, single polypeptide comprised of IL-2 and the high-affinity IL-2 alpha receptor chain
- Non-pegylated molecule; immediately active upon systemic entry; does not require metabolic or proteolytic activation
- Designed to selectively bind to the intermediate-affinity IL-2 receptor, thereby preferentially expanding tumor-killing CD8+ T and NK cells
- Designed to have negligible effects on T reg expansion and avoid activation of vascular endothelial cells



ARTISTRY-1: Designed to Characterize the Pharmacodynamic and Anti-Tumor Profile of IV Nemvaleukin

Establish pharmacokinetic/pharmacodynamic profile and determine RP2D

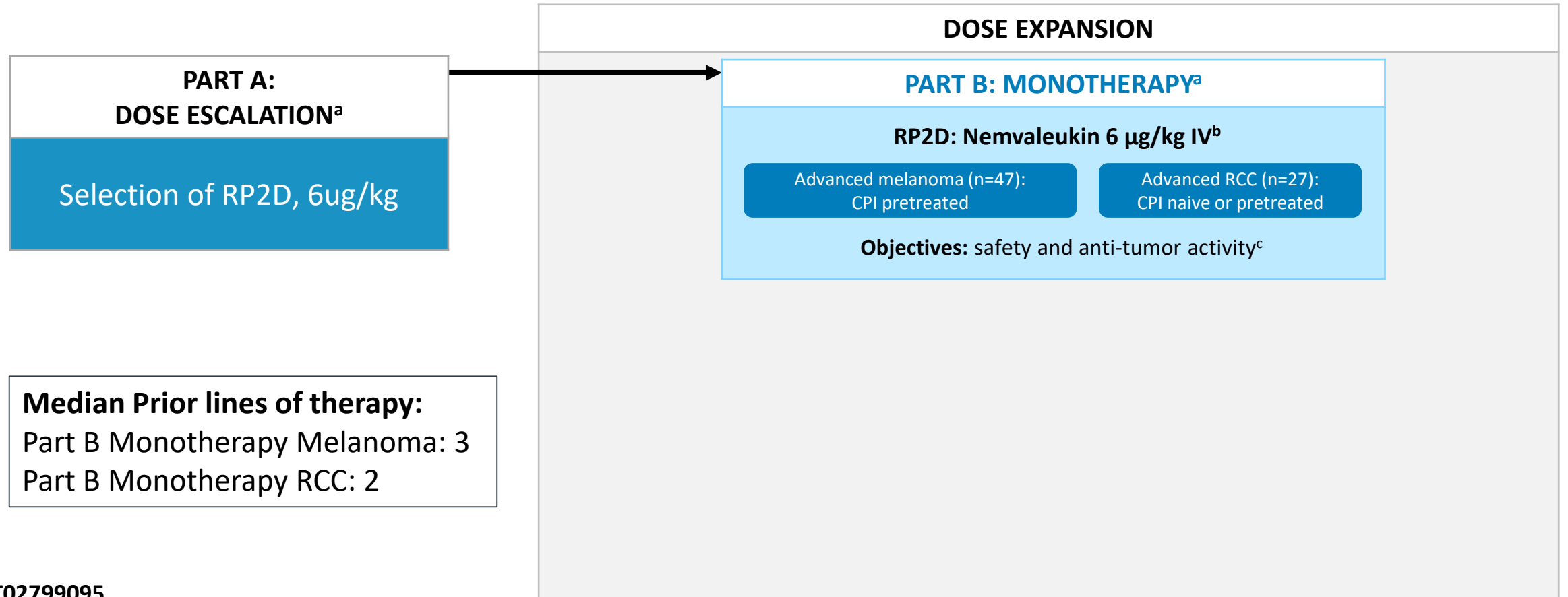
Demonstrate anti-tumor efficacy as monotherapy

Demonstrate anti-tumor efficacy in combination with pembrolizumab

Confirm differentiated safety and tolerability profile

ARTISTRY-1: First-In-Human Study of IV Nemvaleukin

Global, Multicenter, Open-Label Phase 1/2 Study



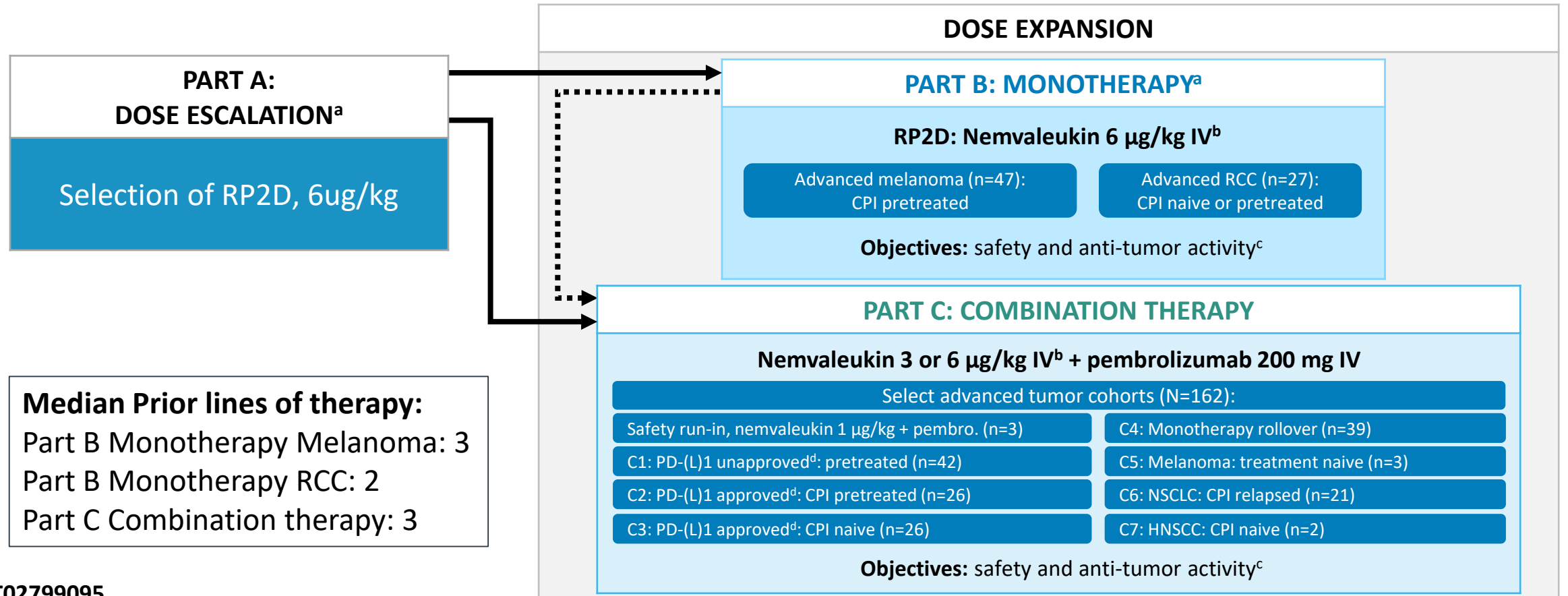
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^aPatients from Parts A and B could roll over to Part C upon progression or stable disease (after ≥4 cycles) on monotherapy. ^bNemvaleukin daily Q5D, then off treatment for 9 days (cycle 1) or 16 days (cycle 2+). ^cORR assessed by investigator (RECIST v1.1). IV, intravenous; ORR, overall response rate.

CPI, checkpoint inhibitor; RCC, renal cell carcinoma; RECIST, Response Evaluation Criteria In Solid Tumors; RP2D, recommended phase 2 dose.

ARTISTRY-1: First-In-Human Study of IV Nemvaleukin

Global, Multicenter, Open-Label Phase 1/2 Study



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^aPatients from Parts A and B could roll over to Part C upon progression or stable disease (after ≥ 4 cycles) on monotherapy. ^bNemvaleukin daily Q5D, then off treatment for 9 days (cycle 1) or 16 days (cycle 2+). ^cORR assessed by investigator (RECIST v1.1). ^dNemvaleukin 3 μ g/kg/d in C1-C4, 6 μ g/kg/d in C5-C7. ^ePD-(L)1 approved/unapproved indication based on US FDA prescribing information and may have changed over time.

C1-7, Cohort 1-7; CPI, checkpoint inhibitor; HNSCC, head & neck squamous cell carcinoma; IV, intravenous; NSCLC, non-small cell lung cancer; ORR, overall response rate; PD-(L)1, programmed death (ligand) 1; RCC, renal cell carcinoma; RECIST, Response Evaluation Criteria In Solid Tumors; RP2D, recommended phase 2 dose.

Roundtable Discussion: ARTISTRY-1 Clinical Trial



Ulka N. Vaishampayan, M.D.
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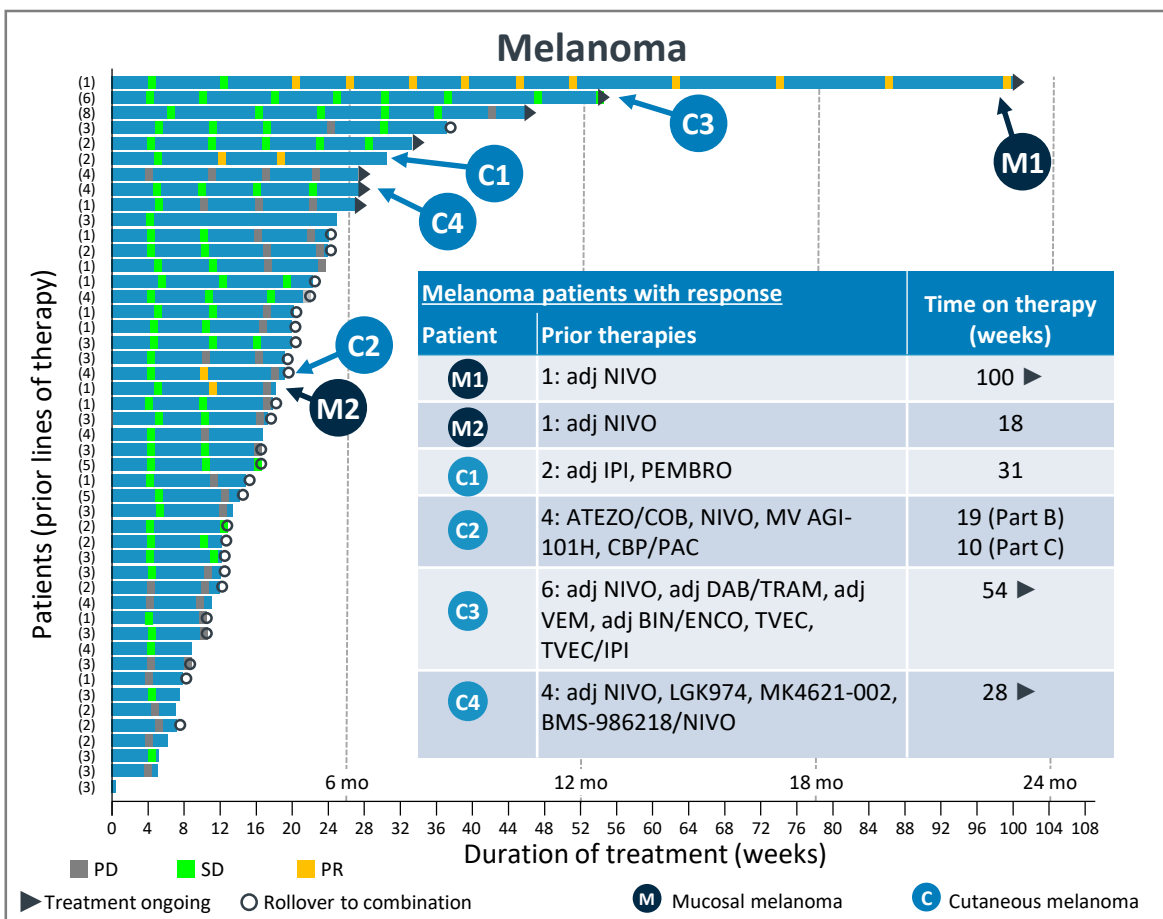
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GOG Partners*



Single-Agent Activity of Nemvaleukin: Monotherapy Responses

Melanoma: Duration of Treatment and Summary of Responses

Dose Expansion (Part B, Monotherapy)



Responses per RECIST v1.1.

adj, adjuvant; ATEZO, atezolizumab; BIN, binimetinib; CBP, carboplatin; CI, confidence interval; COB, cobimetinib; CPI, checkpoint inhibitor; CR, complete response; DAB, dabrafenib; DCR, disease control rate (CR+PR+SD); DOR, duration of response; ENCO, encorafenib; FDA, US Food and Drug Administration; IPI, ipilimumab; MV, melanoma vaccine; NA, not applicable; NIVO, nivolumab; ORR, overall response rate; PAC, paclitaxel; PD, progressive disease; PEMBRO, pembrolizumab; PR, partial response; SD, stable disease; TRAM, trametinib; TVEC, talimogene laherparepvec; VEM, vemurafenib. Data cut off Oct 29, 2021

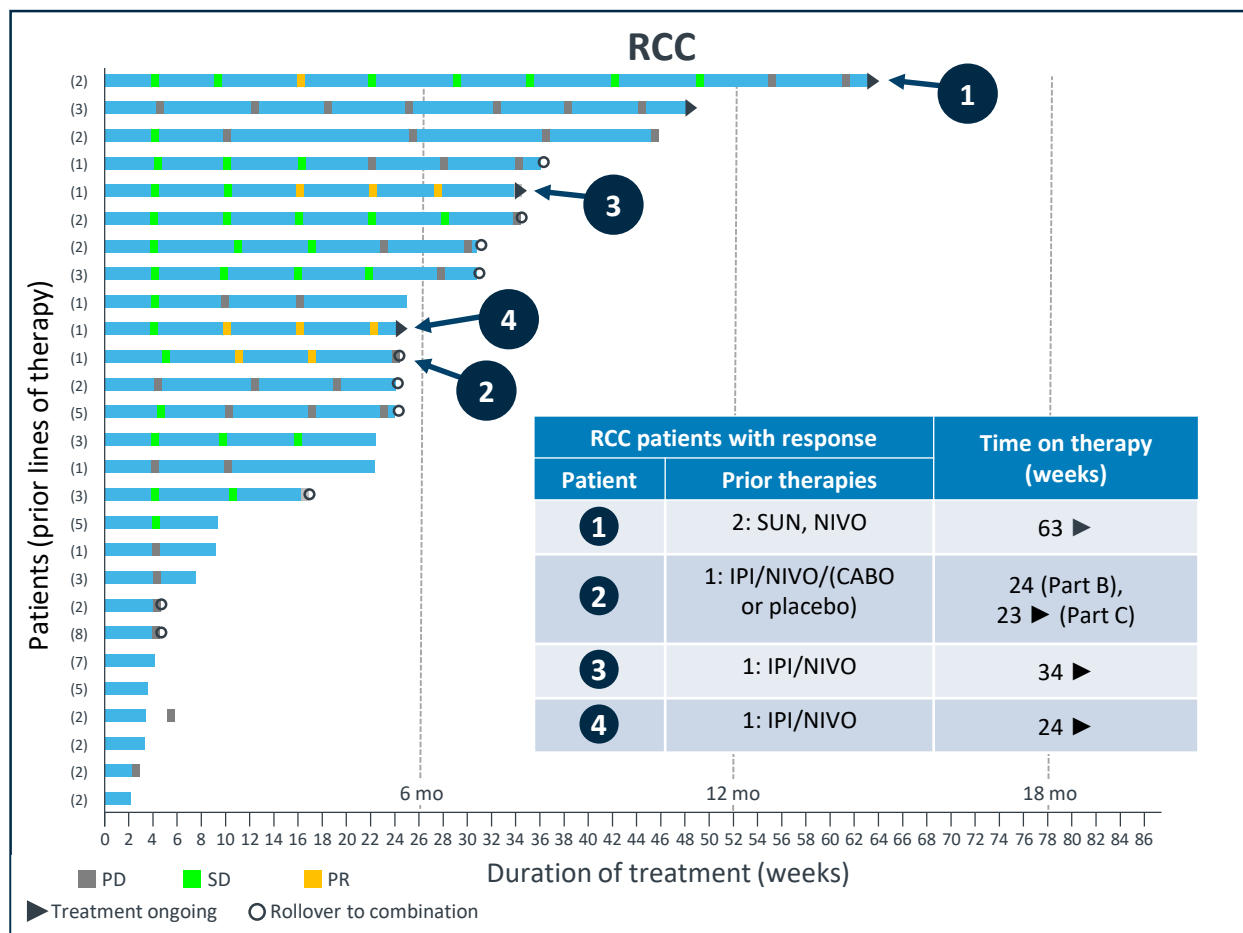
	All ^{a,b} (n=46)	Mucosal (n=6)
Best overall response, n (%)	Best overall response, n (%)	
CR	0	0
PR	6 (13.0) ^c	2 (33.3) ^d
SD	31 (67.4)	2 (33.3)
PD	9 (19.6)	2 (33.3)
ORR, n (%) [95% CI]	6 (13.0) [4.9-26.3]	2 (33.3) [4.3-77.8]
DCR, n (%) [95% CI]	37 (80.4) [66.1-90.6]	4 (66.7) [22.3-95.7]
Median DOR, ^e weeks (range)	8.1 (6.1-79.0)	NA (6.1-79.0)

^aExcludes 1 patient who did not meet tumor-evaluable criteria. ^bPatients with mucosal, cutaneous, uveal, acral included in 'All'. ^cIncludes 3 confirmed PRs (1 occurred after data cutoff date), 2 unconfirmed PRs, and 1 PR awaiting confirmation (occurred after data cutoff date). ^d1 confirmed PR. ^eDOR for Part B only and does not include patients who rolled over to Part C; some patients may still be on treatment.

All responders had been on prior CPI therapy and progressed
 FDA Orphan Drug and Fast Track designations granted in mucosal melanoma
 Data supported design of ARTISTRY-6 study
 (see Weber et al. poster # TPS9609 at this congress)

RCC: Duration of Treatment and Summary of Responses

Dose Expansion (Part B, Monotherapy)



Responses per RECIST v1.1.

CABO, cabozantinib; CPI, checkpoint inhibitor; CR, complete response; DCR, disease control rate (CR+PR+SD); DOR, duration of response; IPI, ipilimumab; mo, months; NIVO, nivolumab; ORR, overall response rate (CR+PR); PD, progressive disease; PR, partial response; RCC, renal cell carcinoma; SD, stable disease; SUN, sunitinib.

	RCC (n=22) ^a
Best overall response, n (%)	
CR	0
PR	4 (18.2) ^b
SD	10 (45.5)
PD	8 (36.4)
ORR, n (%) [95% CI]	4 (18.2) [5.2-40.3]
DCR, n (%) [95% CI]	14 (63.6) [40.7-82.8]
Median DOR, ^c weeks (range)	15.6 (12.3-39.0)

^aExcludes 5 patients who did not meet tumor-evaluable criteria ^bIncludes 3 confirmed PRs and 1 unconfirmed PR. ^cDOR is for Part B only and does not include rollover to Part C; some patients may still be on treatment.

Clinically meaningful responses observed
All responders had been on prior CPI therapy and progressed

Responses in Combination With Pembrolizumab



ARTISTRY-1: IV Nemvaleukin in Combination With Pembrolizumab

PD-1/L1 Unapproved Tumor Types

Tumor Type	Number of Prior Therapies*	Best Overall Response	Max Decrease in Target Lesions	Time on Therapy (Weeks)	Continued on Therapy?	
Nemvaleukin (3 µg/kg) + pembrolizumab (200 mg)						
PD-1/L1 Unapproved Tumor Types	Platinum-resistant ovarian	5	CR	70%	146	Yes
	Platinum-resistant ovarian	2	CR	100%	90	Yes
	Platinum-resistant ovarian	6	uPR	45%	36	No
	Platinum-resistant ovarian	6	PR	41%	75	No
	Pancreatic	3	PR	63%	20	No
	Esophageal SCC	1	PR	48%	58	No

- Out of the **14 patients with platinum-resistant ovarian cancer (PROC)**:
 - 2 complete responses (CR), 2 PRs (1 unconfirmed)
 - 3 of these 4 PROC patients with objective responses had been on treatment >1 year
 - Median duration of response: 53.4 weeks
 - 6 had stable disease
 - **Objective response rate: 28.6%; Disease control rate: 71.4%**
- Partial responses were also observed in patients with esophageal and pancreatic cancers

* For full list of prior therapies, please see ASCO 2022 presentation “Nemvaleukin Alfa Monotherapy and in Combination With Pembrolizumab in Patients With Advanced Solid Tumors: ARTISTRY-1”; iPR, Immune partial response; PR, Partial response; uPR, Unconfirmed partial response; SCC, Squamous cell carcinoma; SD, Stable disease

Data cut off Oct 29, 2021

ARTISTRY-1: IV Nemvaleukin in Combination With Pembrolizumab

PD-1/L1 Approved Tumor Cohort and Tumor-Specific Cohorts

	Tumor Type	Number of Prior Therapies*	Best Overall Response	Max Decrease in Target Lesions	Weeks on Therapy	Continued on Therapy?
Nemvaleukin (3 µg/kg) + pembrolizumab (200 mg)						
PD-1/L1 Approved Tumor Types	Esophageal adenocarcinoma	4 (PD-1/L1 treatment naïve)	PR	52%	93	Yes
	Cervical	2 (PD-1/L1 treatment naïve)	PR	39%	45	No
	Cervical	1 (PD-1/L1 treatment naïve)	uPR	39%	29	No
	Bladder	1 (PD-1/L1 treatment naïve)	PR	74%	55	Yes
	Hodgkin's lymphoma	1 (PD-1/L1 treatment naïve)	CR	100%	56	Yes
	ER+/HER2- breast	3 (PD-1/L1 pretreated)	uPR	32%	16	No
	SCLC	2 (PD-1/L1 treatment naïve)	PR	70%	45	Yes
	Colorectal	2 (PD-1/L1 treatment naïve)	PR	46%	51	Yes
	RCC (rollover)	2 (PD-1/L1 treatment naïve)	PR	74%	4 (mono) + 61 (combo)	Yes
	RCC (rollover)	1 (PD-1/L1 pretreated)	PR	38%	24 (mono) + 23 (combo)	Yes
	Acral melanoma (rollover)	3 (PD-1/L1 pretreated)	PR	36%	12 (mono) + 37 (combo)	Yes
Nemvaleukin (6 µg/kg) + pembrolizumab (200 mg)						
Tumor-Specific Cohorts	Mucosal melanoma	Treatment naïve	PR	100%	64	Yes
	Cutaneous melanoma	Treatment naïve	CR	100%	31	Yes
	NSCLC	3	PR	63%	41	No
	NSCLC	1	PR	53%	32	Yes
	Head & neck SCC	1	PR	60%	51	Yes

* For full list of prior therapies, please see ASCO 2022 presentation "Nemvaleukin Alfa Monotherapy and in Combination With Pembrolizumab in Patients With Advanced Solid Tumors: ARTISTRY-1"; ER+/HER2-, Estrogen Receptor+ Human Epidermal Growth Factor Receptor 2-; NSCLC, Non-small-cell lung cancer; SCLC, Small cell lung cancer; GEJ, Esophagogastric junction; RCC, Renal cell carcinoma; SCC, Squamous cell carcinoma; PR, Partial response; uPR, Unconfirmed partial response

Data cut off Oct 29, 2021

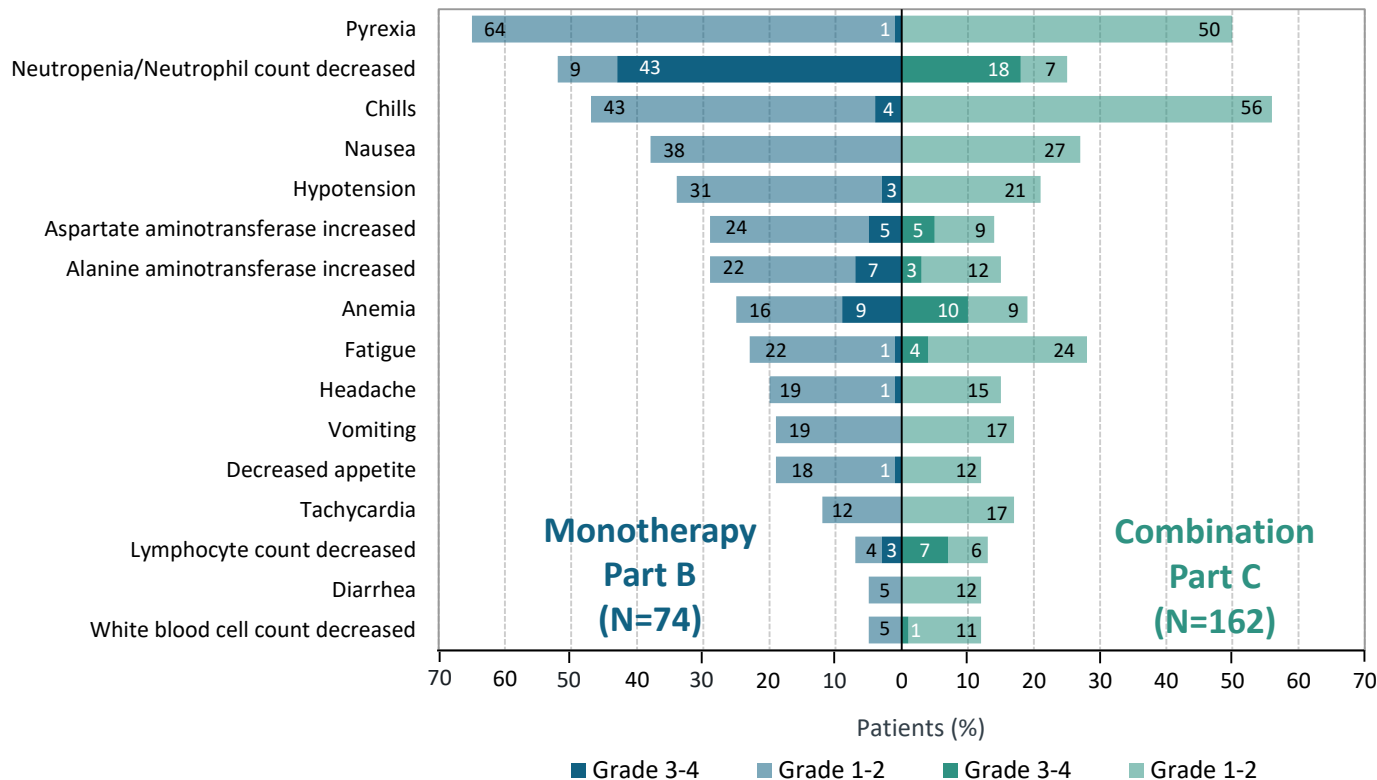


ARTISTRY-1 Safety Summary

ARTISTRY-1: Overall Safety Summary

Dose Expansion: Monotherapy and Combination Therapy

Summary of most frequent TRAEs (≥10% in either cohort)



- AE profile consistent with nemvaleukin mechanism of action
- Monotherapy safety profile was similar to combination safety profile with no additive toxicity observed
- Most frequently observed grade 3/4 TRAE: neutropenia^a
 - Median duration 4 days; was not associated with risk of serious infections or febrile neutropenia
- TRAEs leading to discontinuation: 3% (monotherapy), 4% (combination)
- No event of capillary leak syndrome reported to date in ARTISTRY-1

Part C includes patients who received nemvaleukin at 1, 3, or 6 µg/kg IV in combination with pembrolizumab 200 mg IV.

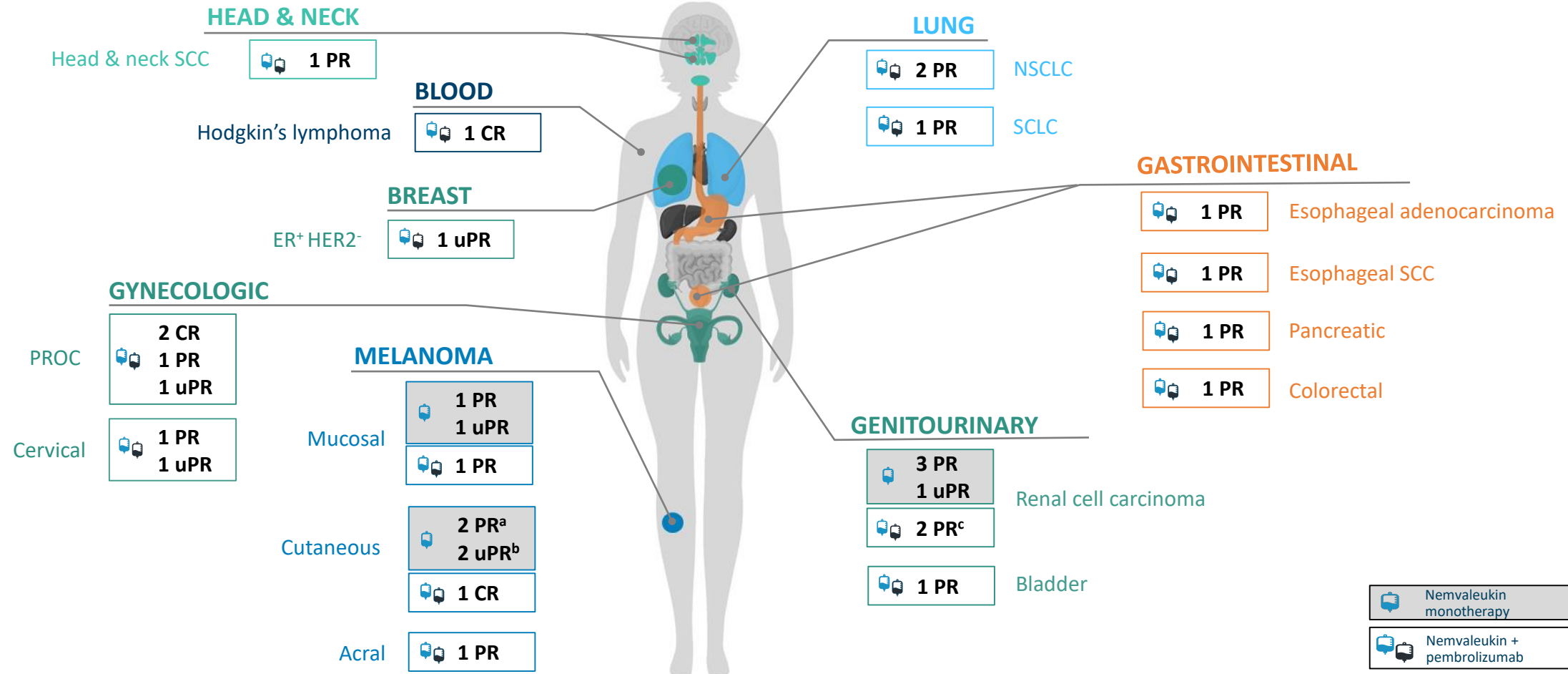
^aIncludes neutropenia and decreased neutrophil count.

AE, adverse event; TRAEs, treatment-related AEs.

Data cut off Oct 29, 2021


ARTISTRY-1: Summary of Individual Responses

Dose Expansion Monotherapy (Part B) and Combination Therapy (Part C)



^a1 PR occurred after the data cutoff date. ^bIncludes 1 PR awaiting confirmation (occurred after the data cutoff date). ^cIncludes 1 patient (marked as RCC 2 in slide 14) who had a PR on nemvaleukin monotherapy (shown as one of the 3 monotherapy PRs) and rolled over to combination. Responses per RECIST v1.1.
 CR, complete response; ER, estrogen receptor; HER, human epidermal growth factor; NSCLC, non-small cell lung cancer; PR, partial response; PROC, platinum-resistant ovarian cancer; SCC, squamous cell carcinoma; SCLC, small-cell lung cancer; uPR, unconfirmed PR.

Data cut off Oct 29, 2021



Advancing a Differentiated IL-2 Towards Potential Registration

Richard Pops, CEO, Alkermes

ARTISTRY-1: Designed to Characterize the Pharmacodynamic and Anti-Tumor Profile of IV Nemvaleukin



Establish pharmacokinetic/pharmacodynamic profile and determine RP2D

- Dose-dependent, selective expansion of NK and CD8⁺ T cells
- Negligible expansion of regulatory T cells in the periphery
- PK/PD profile of nemvaleukin remained consistent when used in combination with pembrolizumab



Demonstrate anti-tumor efficacy as monotherapy

- Single-agent activity as monotherapy observed in melanoma and RCC
- All responders to nemvaleukin monotherapy had progressed on prior checkpoint inhibitor treatment



Demonstrate anti-tumor efficacy in combination with pembrolizumab

- Durable responses observed in combination with pembrolizumab in multiple tumor types, including PROC
- PD-1/L1 unapproved and post CPI failure



Confirm differentiated safety and tolerability profile

- Differentiated safety profile, with no major safety signals observed with monotherapy or in combination with pembrolizumab
- No CLS Reported

RP2D, Recommended Phase 2 Dose; NK, natural killer; PK/PD, Pharmacokinetic/Pharmacodynamic; RCC, Renal Cell Carcinoma; PROC, Platinum Resistant Ovarian Cancer; PD1/L1, Programmed Death1/Ligand 1;cCPI, Checkpoint Inhibitor; CLS, Capillary Leak Syndrome

Nemvaleukin: Potential First-in-Class, Differentiated IL-2 Variant Immunotherapy

	Nemvaleukin (Alkermes)	Proleukin ^{®1,7}	Bempeg ^{2,7}	THOR-707/SAR245 ^{3,7}	MDNA-11 ^{4,7}	RG6279/RO7284755 ^{5,7}	WTX-124 ^{6,7}
Molecular design does not include non-natural/synthetic sequences or additional functionality	✓	✓	✗	✗	✗	✗	✗
No binding to IL-2R alpha	✓	✗	✗	✓	✓	✓	✗
Observed expansion of CD8/NK cells with minimal effect on regulatory T cells in humans	✓	✗	✗	✓	✓	✓	○
Observed monotherapy responses in multiple tumor types	✓	✓	✗	○	○	○	○
Demonstrated clinical activity post-CPI progression and in CPI-unapproved tumor types	✓	○	✗	○	○	○	○
Clinically testing subcutaneous dosing	✓	✗	✗	○	○	○	○
Development status	Phase 3/Potential Registrational Studies	Approved	Discontinued	Phase 2	Phase 1/2	Phase 1	Preclinical

1. Proleukin PI: <https://proleukin.com/PI/Proleukin%20Prescribing%20Information.pdf>, Lotze M T et al, J Immunol 1985; Meyers FJ, et al Clin PharmacolTher. 1991; Foureau et al, Cancer ImmunolImmunother2014; Schantz et al, Arch Otolaryngol Head Neck Surg 1990
 2. Nektar Analyst Call at ESMO 2021; Nektar JPM 2022 presentation; Bentebibel et al, Cancer discovery, 2019; Charych et al, PLOS One 2017
 3. AACR 2021: Cancer Res (2021) 81 (13_Supplement): LB041; Ptacin, J.L., et al. Nat Commun 12, 4785 (2021)

4. [Frontiers in Cancer Immunotherapy 2022 Presentation](#); [Next-Gen Cytokine Therapeutics Summit 2021 presentation](#); [AACR-NCI-EORTC](#)
 5. Melero et al, ESMO2018; Immune Netw. 2022 Feb; 22(1): e5 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8901704/>
 6. [Werewolf AACR 2022 Poster](#); Cancer Immunol Res 2022 May 3;10(5):581-596.
 7. Nature Reviews Drug Discovery. 18 Feb 2021. "Restoring IL-2 to its cancer immunotherapy glory"

○ Data not presented / available as of June 1, 2022; For illustrative purposes only. Not based on head-to-head studies. Limited conclusions should be derived from this indirect comparison given the variability of study designs, molecular design and patient populations studied. Clinical relevance of these differences is still under investigation.

Nemvaleukin: Ongoing Studies to Support Broad Potential Use

Potential Registration Supporting

ARTISTRY-6



Evaluating efficacy, safety and tolerability as monotherapy

Tumor Type: Advanced cutaneous and mucosal melanoma: previously treated with checkpoint inhibitor

FDA granted nemvaleukin both Orphan Drug Designation and Fast Track Designation for treatment of mucosal melanoma.

ARTISTRY-7



Evaluating efficacy, safety and tolerability; as monotherapy and in combination with pembrolizumab, compared to investigator choice chemotherapy

Tumor Type: Platinum-resistant ovarian cancer

FDA granted nemvaleukin in combination with pembrolizumab Fast Track Designation for treatment of platinum-resistant ovarian cancer

Dose Options

ARTISTRY-2



Evaluating safety, SC RP2D, and ORR; as monotherapy and in combination with pembrolizumab

Tumor Type: Advanced solid tumors that have progressed after at least one line of treatment

ARTISTRY-3



Evaluating efficacy, safety and tolerability of less frequent IV dosing, and PK/PD in TME, as monotherapy and in combination with pembrolizumab

Tumor Type: Advanced solid tumors that progressed after treatment or intolerant to at least one established, indication-specific therapy


Potential Strategic Collaboration

Next phase of development


Scientific rationale for combinations with multiple targeted treatment approaches

Tumor Type: Opportunity to enable broad utility across a number of solid tumor types

Administration:

 Subcutaneous injection

 Intravenous infusion

 In collaboration with MSD. Partnership with the GOG Foundation and ENGOT to conduct the study

Region:

 Global

 USA

IV, Intravenous; SC, Subcutaneous; RP2D, Recommended phase 2 dose; ORR, Overall response rate; TME, Tumor microenvironment; MSD, A tradename of Merck & Co., Inc. Kenilworth, NJ, USA; GOG, Gynecologic Oncology Group, USA; ENGOT, European Network of Gynaecological Oncological Trial Groups

Q&A



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