ARTISTRY-7

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A Phase 3, Multicenter, Open-label, Randomized Study of Nemvaleukin Alfa in Combination with Pembrolizumab versus Investigator's Choice Chemotherapy in Patients with Platinum-Resistant Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Inclusion Criteria

- Female ≥18 years of age
- Histologically confirmed platinum-resistant/ -refractory epithelial ovarian, fallopian tube, or primary peritoneal cancer
  - PD ≤180 days after last dose of >1L of platinum therapy or
  - PD or no response during the most recent platinum therapy
- ≥1 L of systemic platinum therapy and ≤5 L of systemic therapy in the platinum-resistant setting
- Prior treatment with bevacizumab
- At least one measurable lesion by RECIST v1.1
- Pre-treatment tumor tissue biopsy or archival tumor tissue

Exclusion Criteria

- Primary platinum-refractory disease or primary platinum resistance
  - Defined as PD during 1L platinum-based therapy (refractory) or PD <3 months after completion of 1L platinum-based therapy (resistant)
- Histologically confirmed epithelial ovarian cancer with mucinous or carcinosarcoma subtype
- Recurrent fluid tapping >1/month or >500 ml fluid tapping within last 6 weeks
- Nonepithelial tumor or ovarian tumor with low malignant potential
- Prior anti–PD-(L)1 therapy or prior IL-2– or IL-15–based cytokine therapy or exposure to IL-12 (or analog)

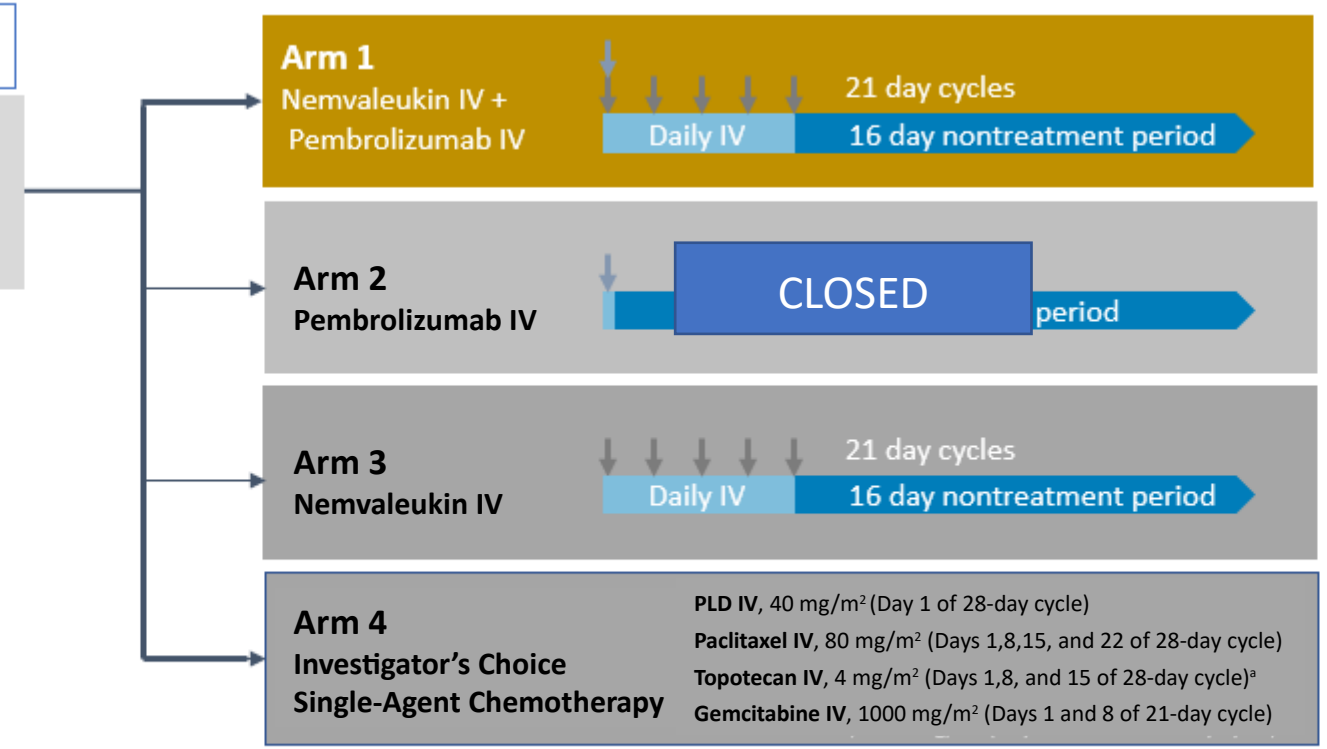
ARTISTRY-7; GOG-3063; ENGOT-OV68 Study Design

Global, phase 3, open-label, study of nemvaleukin alfa in combination with pembrolizumab in platinum-resistant epithelial ovarian cancer[1]

Nemvaleukin IV ± Pembrolizumab Vs Pembrolizumab Monotherapy or Chemotherapy

Estimated 376 participants

Randomization
3:1:1:3
Futility analysis planned for monotherapy arms[2]



NCT05092360

- **Testing of PD-L1 status is required prior to randomization[2]**

Conducted in collaboration with Merck, Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA; the Gynecologic Oncology Group (GO); and European Network of Gynaecological Oncological Trial Groups (ENGOT)[3]

Primary outcome measure:

- PFS[b]

Secondary outcome measures:

- ORR, DCR, DOR, and TTR[b]
- CA-125 response[c]
- OS and TEAEs

↓ Pembrolizumab dosing
↓ Nemvaleukin dosing

[a]Alternative topotecan regimen: 1.25 mg/m² on Days 1–5 of 21-day cycles. [b]Response per RECIST v1.1. [c]Response per GCIG. CA-125 = cancer antigen-125; DCR = disease control rate; DOR = duration of response; GCIG = Gynecologic Cancer InterGroup; IV = intravenous; ORR = objective response rate; OS = overall survival; PFS = progression-free survival; PLD = pegylated liposomal doxorubicin; RECIST = Response Evaluation Criteria in Solid Tumors; TEAE = treatment-emergent adverse event; TTR = time to response.

1. Clinicaltrials.gov identifier: NCT05092360. Accessed February 3, 2023. **2.** Herzog TJ, et al. Presentation at SGO Congress; May 18-21, 2022; Phoenix, AZ. **3.** Alkermes Press Release; October 26, 2021. https://investor.alkermes.com/news-releases/news-release-details/alkermes-initiates-artistry-7-phase-3-trial-nemvaleukin-alfa. Accessed Match 3, 2023.