2022-RA-588-ESGO NEMVALEUKIN ALFA MONOTHERAPY AND IN COMBINATION WITH PEMBROLIZUMAB IN PATIENTS WITH ADVANCED SOLID TUMOURS: ARTISTRY-1

[1]Ulka Vaishampayan, [2]Piotr Tomczak, [3]Jameel Muzaffar, [4]Ira Winer, [5]Seth D Rosen, [6,7]Christopher J Hoimes, [8]Aman Chauhan, [9]Anna Spreafico, [10]Karl D Lewis, [11]Debora S Bruno, [12]Olivier Dumas, [13]David F McDermott, [14]James F Strauss, [15]Quincy Siu-Chung Chu, [16]Lucy Gilbert, [17]Arvind Chaudhry, [18]Jessicca Rege, [19]Valentina Boni, [20]Marc S Ernstoff, [21]Vamsidhar Velcheti. *[1]University of Michigan Rogel Cancer Center, Ann Arbor, MI; [2]Klinika Onkologii Oddzial Chemioterapii, Poznan, Poland; [3]Moffitt Cancer Center, Tampa, FL; [4]Barbara Ann Karmanos Cancer Institute, Wayne State University, Detroit, MI; [5]Hematology Oncology Association of the Treasure Coast, Port St. Lucie, FL; [6]Duke University Medical Center, Durham, NC; [7]University Hospitals, Phase I Oncology Program, Case Comprehensive Cancer Center, Cleveland, OH; [8]University of Kentucky, Lexington, KY; [9]Princess Margaret Cancer Centre, Toronto, ON, Canada; [10]University of Colorado School of Medicine, Aurora, CO; [11]University Hospitals, Thoracic Oncology Program, Case Comprehensive Cancer Center, Cleveland, OH; [12]CHU de Québec-Université Laval, Québec City, QC, Canada; [13]Beth Israel Deaconess Medical Center, Boston, MD; [14]Mary Crowley Cancer Research, Dallas, TX; [15]14Cross Cancer Institute, University of Alberta/Alberta Health Services, Edmonton, AB, Canada; [16]Division of Gynecologic Oncology, McGill University Health Centre, Montreal, QC, Canada; [17]Summit Cancer Centers, Spokane, WA; [18]Alkermes, Inc., Waltham, MA; [19]NEXT Oncology Madridc, Hospital Universitario, Quironsalud, Spain; [20]Department of Medicine, Roswell Park Comprehensive Cancer Center, Buffalo, NY; [21]Laura and Isaac Perlmutter Cancer Center, New York University, New York, NY*

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Introduction/Background Nemvaleukin alfa (nemvaleukin, ALKS 4230) is an engineered cytokine that selectively binds to the intermediate-affinity interleukin-2 (IL-2) receptor to preferentially activate anti-tumour $CD8^+$ T and natural killer cells with minimal expansion of immunosuppressive regulatory T cells. Nemvaleukin was designed to leverage anti-tumour effects of the IL-2 pathway while mitigating toxicities associated with activation of the high-affinity IL-2 receptor.

Methodology ARTISTRY-1 (NCT02799095) is a 3-part, first-in-human, phase 1/2 study of intravenous nemvaleukin +/- pembrolizumab in patients with advanced solid tumours. Parts A (monotherapy dose escalation to 10 µg/kg/day ×5/cycle), B (monotherapy in patients with melanoma or renal cell carcinoma [RCC]), and C (combination with nemvaleukin 3 or 6 µg/kg/day ×5/cycle and pembrolizumab every 21 days) were included. Investigator-assessed anti-tumour activity (RECIST v1.1) and safety are reported as of 29 October 2021.

Results In Part A (N=46), nemvaleukin recommended phase 2 dose was 6 µg/kg/day intravenously ×5/cycle. The maximum tolerated dose was not reached. Nemvaleukin monotherapy demonstrated durable anti-tumour activity in RCC (objective response rate [ORR], 18.2% [4/22]) and melanoma (ORR, 8.7% [4/46]), with 2 partial responses (PRs; 1 unconfirmed) in 30 patients with cutaneous melanoma (ORR, 6.7%) and 2 PRs (1 unconfirmed) in 6 patients with mucosal melanoma (ORR, 33.3%). Durable anti-tumour activity was also observed for combination therapy (ORR, 16.1% [22/137]; disease control rate [DCR], 59.9%), including in platinum-resistant ovarian cancer, with 2 complete responses and 2 PRs (1 unconfirmed) in 14 patients (ORR, 28.6% [4/14]; DCR, 71.4%). 43 patients remain on therapy. Most common grade 3/4 treatment-related adverse events in Parts B and C, respectively, were anaemia (9%, 10%), neutropaenia (34%, 9%), and decreased neutrophil count (12%, 9%).

Conclusion Nemvaleukin was generally well tolerated.

Durable responses were observed with monotherapy and combination therapy in heavily pre-treated patients across a range of tumours, warranting further investigation.

2022-RA-589-ESGO THE EFFECT OF MAJOR POSTOPERATIVE COMPLICATIONS ON RECURRENCE AND LONG-TERM SURVIVAL AFTER CYTOREDUCTIVE SURGERY FOR OVARIAN CANCER

[1]Martina Aida Angeles, [2]Alicia Hernández, [3]Asunción Pérez-Benavente, [4]Bastien Cabarrou, [2]Emanuela Spagnolo, [5]Agnieszka Rychlik, [6]Amel Daboussi, [7]Federico Migliorelli, [8]Sarah Bétrian, [1]Gwénaël Ferron, [3]Antonio Gil-Moreno, [9]Frédéric Guyon, [1]Alejandra Martinez. *[1]Department of Surgical Oncology, Institut Universitaire du Cancer de Toulouse – Oncopole, Toulouse, France; [2]Hospital La Paz, Madrid, Spain; [3]Hospital Vall d'Hebron, Barcelona, Spain; [4]Biostatistics Unit, Institut Universitaire du Cancer de Toulouse – Oncopole, Toulouse, Spain; [5]Maria Skłodowska-Curie National Research Institute of Oncology, Warsaw, Poland; [6]Department of Anesthesiology, Institut Universitaire du Cancer de Toulouse – Oncopole, Toulouse, France; [7]Paule de Viguier Hospital, Toulouse University Hospital, Toulouse, France; [8]Department of Oncology, Institut Universitaire du Cancer de Toulouse – Oncopole, Toulouse, France; [9]Institut Bergonié, Bordeaux, France*

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Introduction/Background To assess the impact on survival of major postoperative complications and to identify the factors associated with these complications in patients with advanced ovarian cancer after cytoreductive surgery.

Methodology We designed a retrospective multicenter study collecting data from patients with IIIC-IV FIGO Stage ovarian cancer who had undergone either primary debulking surgery (PDS), early interval debulking surgery (IDS) after 3–4 cycles of neoadjuvant chemotherapy, or delayed debulking surgery (DDS) after 6 cycles, with minimal or no residual disease, from January 2008 to December 2015. Univariable and multivariable analyses were conducted to identify factors associated with major surgical complications (≥Grade 3). We assessed disease-free survival (DFS) and overall survival (OS) rates according to the occurrence of major postoperative complications.

Results 549 women were included. The overall rate of major surgical complications was 22.4%. Patients who underwent PDS had a higher rate of major complications (28.6%) than patients who underwent either early IDS (23.2%) or DDS (14.0%). Multivariable analysis revealed that extensive peritonectomy and surgical timing were associated with the occurrence of major complications. Median DFS and OS were 16.9 months (95%CI=[13.7–18.4]) and 48.0 months (95%CI=[37.2–73.1]) for the group of patients with major complications, and 20.1 months (95%CI=[18.6–22.4]) and 56.7 months (95%CI=[51.2–70.4]) for the group without major complications. Multivariable analysis revealed that major surgical complications were significantly associated with DFS, but not with OS.

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