LIO-1: Lucitanib + Nivolumab in Patients With Advanced Solid Tumors—Updated Phase 1b Results and Initial Experience in Phase 2 Ovarian Cancer Cohort (NCT04042116; ENGOT-GYN3/AGO/LIO)

Erika Hamilton,[1] Camille Gunderson Jackson,[2] Ramez N. Eskander,[3] Floor J. Backes,[4] Vicky Makker,[5] Fernanda Musa,[6] Alexander Olawaiye,[7] Jill Alldredge,[8] Bhavana Pothuri,[9] Angeles Alvarez Secord,[10] Nicole Concin,[11,12] Antonio González-Martín,[13] Jowell Go,[14] Kenton Wride,[14] Denise Lepley,[14] Terri Cameron,[15] Manish R. Patel[16]

[1]Sarah Cannon Research Institute/Tennessee Oncology, Nashville, TN, USA; [2]Stephenson Cancer Center, University of Oklahoma Health Sciences Center, Oklahoma City, OK, USA; [3]UC San Diego Moores Cancer Center, La Jolla, CA, USA; [4]Ohio State University Wexner Medical Center and James Cancer Hospital, Columbus, OH, USA; [5]Memorial Sloan Kettering Cancer Center, Weill Cornell Medical Center, New York, NY, USA; [6]Swedish Cancer Institute, Seattle, WA, USA; [7]Magee-Womens Hospital of UPMC, Pittsburgh, PA, USA; [8]Anschutz Cancer Pavilion, Aurora, CO, USA; [9]Laura and Isaac Perlmutter Cancer Center at NYU Langone, New York, NY, USA; [10]Duke Cancer Institute, Duke University School of Medicine, Durham, NC, USA; [11]Ev. Kliniken Essen Mitte, Germany; [12]Medizinische Universität Innsbruck, Austria; [13]Clínica Universidad de Navarra, Madrid, Spain; [14]Clovis Oncology, Inc., Boulder, CO, USA; [15]Clovis Oncology UK Ltd., Cambridge, UK; [18]Florida Cancer Specialists/Sarah Cannon Research Institute, Sarasota, FL, USA.

ASCO Congress | 4–8 June 2021 | Virtual Meeting

Abstract 5538

Supplementary Material

ENGOT
European Network of Gynaecological Oncological Trial groups

Phase 1b (n=17): TEAEs Occurring in ≥15% of Patients Receiving Lucitanib[a] + Nivolumab

TEAE, n (%)	Lucitanib 6 mg (n=7)		Lucitanib 8 mg (n=7)		Lucitanib 10 mg (n=3)	
	Any grade	Grade ≥3	Any grade	Grade ≥3	Any grade	Grade ≥3
Patients with ≥1 TEAE	7 (100)	5 (71.4)	7 (100)	3 (42.9)	3 (100)	1 (33.3)
Fatigue[b]	4 (57.1)	0	4 (57.1)	1 (14.3)	3 (100)	1 (33.3)
Hypertension[c]	3 (42.9)	2 (28.6)	4 (57.1)	2 (28.6)	2 (66.7)	0
Proteinuria	3 (42.9)	2 (28.6)	4 (57.1)	0	2 (66.7)	0
Nausea	2 (28.6)	0	3 (42.9)	1 (14.3)	1 (33.3)	0
Diarrhea	3 (42.9)	1 (14.3)	1 (14.3)	0	1 (33.3)	0
Vomiting	2 (28.6)	0	3 (42.9)	1 (14.3)	0	0
Cough	0	0	2 (28.6)	0	2 (66.7)	0
Dyspnea	1 (14.3)	0	2 (28.6)	0	1 (33.3)	0
Hypothyroidism[d]	2 (28.6)	0	1 (14.3)	0	1 (33.3)	0
Urinary tract infection	3 (42.9)	0	0	0	1 (33.3)	0
Abdominal pain	1 (14.3)	1 (14.3)	2 (28.6)	0	0	0
Constipation	1 (14.3)	0	2 (28.6)	0	0	0
Decreased appetite	1 (14.3)	0	1 (14.3)	0	1 (33.3)	0

- Two serious TEAEs were reported: kidney infection in 1 patient in the 6-mg cohort, and pneumonia in 1 patient in the 8-mg cohort. Neither were considered related to study treatment

[a]Across all doses. [b]Asthenia and/or fatigue. [c]Increased blood pressure and/or hypertension. [d]Increased blood thyroid stimulating hormone and/or hypothyroidism.
TEAE, treatment-emergent adverse event.

Phase 2 OC Cohort (n=24): TEAEs Occurring in ≥15% of Patients Receiving Lucitanib + Nivolumab

TEAE, n (%)	Any grade		Grade ≥3		Serious	
	Any	Treatment related	Any	Treatment related	Any	Treatment related
Patients with ≥1 TEAE	24 (100)	23 (95.8)	10 (41.7)	7 (29.2)	7 (29.2)	5 (20.8)
Fatigue[a]	13 (54.2)	11 (45.8)	1 (4.2)	1 (4.2)	1 (4.2)	1 (4.2)
Hypertension[b]	12 (50.0)	11 (45.8)	5 (20.8)	4 (16.7)	2 (8.3)	2 (8.3)
Nausea	8 (33.3)	7 (29.2)	0	0	0	0
Diarrhea	7 (29.2)	6 (25.0)	0	0	1 (4.2)	1 (4.2)
Headache	7 (29.2)	4 (16.7)	0	0	0	0
Proteinuria	7 (29.2)	6 (25.0)	0	0	0	0
Hypothyroidism[c]	6 (25.0)	6 (25.0)	0	0	0	0
Constipation	5 (20.8)	3 (12.5)	0	0	0	0
Decreased appetite	5 (20.8)	5 (20.8)	0	0	0	0
Vomiting	5 (20.8)	4 (16.7)	0	0	0	0
Abdominal distension	4 (16.7)	1 (4.2)	0	0	0	0
Dyspnea	4 (16.7)	2 (8.3)	1 (4.2)	1 (4.2)	1 (4.2)	1 (4.2)

[a]Asthenia and/or fatigue. [b]Increased blood pressure and/or hypertension. [c]Increased blood thyroid stimulating hormone and/or hypothyroidism.
OC, ovarian cancer; TEAE, treatment-emergent adverse event.

Phase 2 OC Cohort (n=24): TEAEs Leading to Treatment Interruption in Patients Receiving Lucitanib + Nivolumab

TEAE, n (%)	Lucitanib interruption		Nivolumab interruption	
	Any	Lucitanib related	Any	Nivolumab related
Patients with ≥1 TEAE leading to treatment interruption	10 (41.7)	8 (33.3)	4 (16.7)	3 (12.5)
Hypertension[a]	3 (12.5)	3 (12.5)	0	0
Decreased appetite	2 (8.3)	2 (8.3)	0	0
Nausea	2 (8.3)	2 (8.3)	0	0
Abdominal distension	1 (4.2)	0	0	0
Constipation	1 (4.2)	1 (4.2)	0	0
Diverticulitis	1 (4.2)	1 (4.2)	0	0
Dyspnea	1 (4.2)	0	0	0
Embolism	1 (4.2)	0	0	0
Fatigue[b]	1 (4.2)	1 (4.2)	1 (4.2)	1 (4.2)
Muscular weakness	1 (4.2)	1 (4.2)	0	0
Proteinuria	1 (4.2)	1 (4.2)	0	0
Small intestinal obstruction	1 (4.2)	0	1 (4.2)	0
Syncope	1 (4.2)	0	0	0
Vomiting	1 (4.2)	1 (4.2)	0	0
Diarrhea	0	0	1 (4.2)	1 (4.2)
Dehydration	0	0	1 (4.2)	1 (4.2)
Hypertriglyceridemia	0	0	1 (4.2)	1 (4.2)
Infusion-related reaction	0	0	1 (4.2)	1 (4.2)

Data are sorted based on decreasing rates of TEAEs leading to interruption of lucitanib treatment. TEAEs assessed as being related to one study treatment may also have been assessed as being related to the other study treatment. [a]Increased blood pressure and/or hypertension. [b]Asthenia and/or fatigue. OC, ovarian cancer; TEAE, treatment-emergent adverse event.

Phase 2 OC Cohort (n=24): TEAEs Leading to Lucitanib Dose Reduction in Patients Receiving Lucitanib + Nivolumab

TEAE, n (%)	Any	Lucitanib related
Patients with ≥1 TEAE leading to lucitanib dose reduction	3 (12.5)	3 (12.5)
Dehydration	1 (4.2)	1 (4.2)
Diarrhea	1 (4.2)	1 (4.2)
Fatigue[a]	1 (4.2)	1 (4.2)
Hypertension[b]	1 (4.2)	1 (4.2)
Nausea	1 (4.2)	1 (4.2)

TEAEs assessed as being related to one study treatment may also have been assessed as being related to the other study treatment.
[a]Asthenia and/or fatigue. [b]Increased blood pressure and/or hypertension.
OC, ovarian cancer; TEAE, treatment-emergent adverse event.