Efficacy and Safety of Lucitanib + Nivolumab in Patients With Advanced Gynecologic Malignancies: Phase 2 Results From the LIO-1 Study (NCT04042116; ENGOT-GYN3/AGO/LIO)

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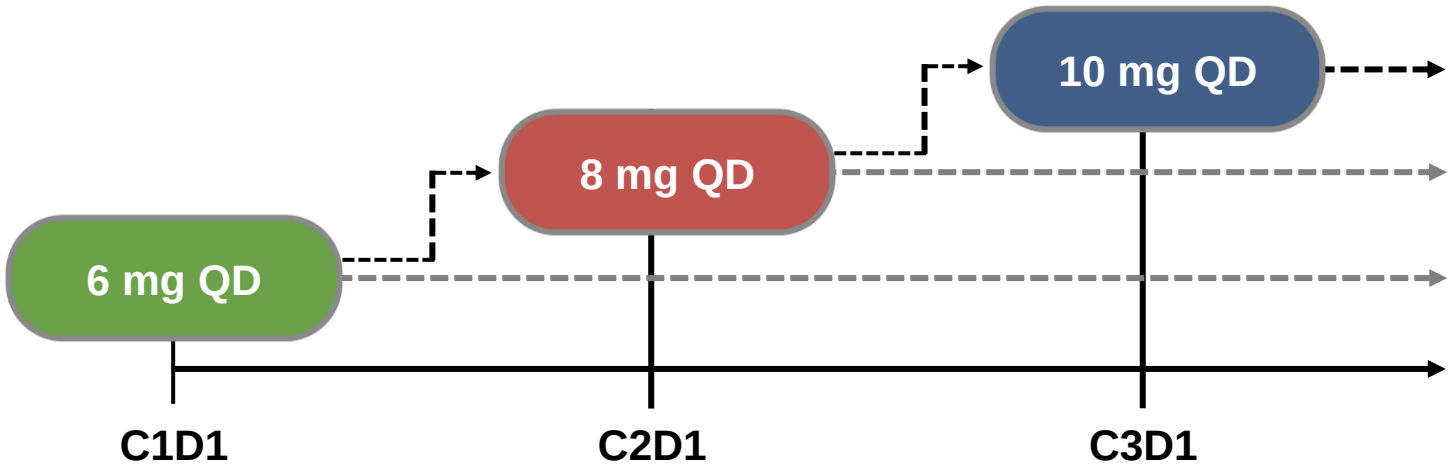
Supplementary Material

Clinical Criteria for Lucitanib Dose Escalation

- BP ≤150/90 mm Hg
- No treatment-related AEs grade >2
- No proteinuria >1+ (or urinary protein >1.0 g/24 h)
- No treatment-related diarrhea grade >1
- Not requiring any antihypertensive agents (or change to existing antihypertensive regimen if pre-existing stable, well-controlled BP at baseline)

Oral lucitanib safety-based dose titration[a]



+ nivolumab 480 mg IV every 28 days[b]

[a]Lucitanib treatment until PD, unacceptable toxicity, or other reason for discontinuation; [b]Nivolumab treatment for up to 24 months or until PD, unacceptable toxicity, or other reason for discontinuation.
AE, adverse event; BP, blood pressure; C, cycle; D, day; PD, progressive disease; QD, once daily

TEAEs Leading to Lucitanib Dose Reduction

TEAE, n (%)	Any causality	Lucitanib related
Patients with ≥1 TEAE leading to lucitanib dose reduction	21 (16.9)	21 (16.9%)
Hypertension	7 (5.6)	7 (5.6%)
Proteinuria	6 (4.8)	6 (4.8%)
Diarrhea	4 (3.2)	4 (3.2%)
Asthenia/fatigue	2 (1.6)	2 (1.6%)
Acute kidney injury	1 (0.8)	1 (0.8%)
Abdominal pain	1 (0.8)	1 (0.8%)
Decreased appetite	1 (0.8)	1 (0.8%)
Dehydration	1 (0.8)	1 (0.8%)
Hyponatremia	1 (0.8)	1 (0.8%)
Influenza-like illness	1 (0.8)	1 (0.8%)
Nausea	1 (0.8)	1 (0.8%)

TEAE, treatment-emergent adverse event.

TEAEs Leading to Study Drug Discontinuation

TEAE, n (%)	Lucitanib discontinuation		Nivolumab discontinuation	
	Any causality	Lucitanib related	Any causality	Nivolumab related
Patients with ≥1 TEAE leading to discontinuation	20 (16.1)	14 (11.3)	15 (12.1)	12 (9.7)
Hypertension[a]	6 (4.8)	6 (4.8)	3 (2.4)	2 (1.6)
Diarrhea	3 (2.4)	3 (2.4)	3 (2.4)	3 (2.4)
Large intestine perforation	2 (1.6)	2 (1.6)	2 (1.6)	2 (1.6)
Proteinuria	2 (1.6)	2 (1.6)	0	0
Alanine aminotransferase increase	1 (0.8)	0	1 (0.8)	1 (0.8)
Angina pectoris	1 (0.8)	1 (0.8)	0	0
Cerebrovascular accident	1 (0.8)	1 (0.8)	1 (0.8)	0
Esophageal varices hemorrhage	1 (0.8)	0	0	0
Female genital tract fistula	1 (0.8)	0	0	0
Hematuria	1 (0.8)	0	0	0
Myocarditis	1 (0.8)	0	1 (0.8)	1 (0.8)
Polycythemia vera	1 (0.8)	0	1 (0.8)	
Cardiac failure	0	0	1 (0.8)	1 (0.8)
Fatigue	0	0	1 (0.8)	1 (0.8)
Hyperglycemia	0	0	1 (0.8)	1 (0.8)
Thyroiditis	0	0	1 (0.8)	1 (0.8)

[a]Hypertension and/or hypertensive crisis.
TEAE, treatment-emergent adverse event.