Regimen Reference Order – GAST – ramucirumab + PACLitaxel

ARIA: GAST - [ramucirumab + PACLitaxel]

Planned Course:Every 28 days until disease progression or unacceptable toxicityIndication for Use:Gastric/Gastroesophageal Junction Cancer; Locally Advanced or Metastatic

CVAD: At Provider's Discretion

Proceed with treatment if:

Day 1

- ANC equal to or greater than 1.5 x $10^9/L$ AND Platelets equal to or greater than $100 \times 10^9/L$
- Total bilirubin equal to or less than 1.5 times upper limit of normal
- AST and ALT equal to or less than 3 times upper limit of normal if no liver metastases
- AST and ALT equal to or less than 5 times upper limit of normal if liver metastases

Days 8 and 15

- ANC equal to or greater than $1 \times 10^9/L$ AND Platelets equal to or greater than 75 $\times 10^9/L$
- Total bilirubin equal to or less than 1.5 times upper limit of normal
- AST and ALT equal to or less than 3 times upper limit of normal if no liver metastases
- AST and ALT equal to or less than 5 times upper limit of normal if liver metastases
 - Contact Physician if parameters not met

SEQUENCE OF MEDICATION ADMINISTRATION

Pre-treatment Requirements		
Drug	Dose	CCMB Administration Guideline
Not Applicable		

Treatment Regimen – GAST – ramucirumab + PACLitaxel

Drug	Dose	CCMB Administration Guideline
Day 1		
acetaminophen	650 mg	ONLY to be given if patient experienced a Grade 1 or 2 infusion- related reaction with any previous ramucirumab infusion Orally 1 hour prior to ramucirumab
dexamethasone	20 mg	IV in normal saline 50 mL over 15 minutes at least <u>30 minutes</u> prior to ramucirumab and at least <u>1 hour</u> prior to PACLitaxel *Nursing Alert: PACLitaxel starts at least 1 hour after completion of dexamethasone infusion
diphenhydrAMINE	50 mg	IV in normal saline 50 mL over 15 minutes <u>30 minutes</u> prior to ramucirumab and at least 1 hour prior to PACLitaxel



(Maximum rate 25 mg/minute) Use 0.2 or 0.22 micron filter *Alert: Pharmacy to ensure final volume in bag = 250 mL *Nursing Alert: PACLitaxel infusion starts ofter observation period is complete (if required) PACLitaxel 80 mg/m² IV in normal saline 250 mL over 1 hour, following the administration rates below: • Administer at 100 mL/hour for 15 minutes, then • Administer at 100 mL/hour for 15 minutes with 0.2 or 0.22 micron filter *Nursing Alert: PacLitaxel invest bags and non-DEHP doministration sets with 0.2 or 0.22 micron filter *Nursing Alert: Senty invert bag 8 to 10 times immediately prior to administration of PACLitaxel to evenly distribute the drug Day 8 cetirizine 20 mg V in normal saline 50 mL over 15 minutes <u>1 hour</u> prior to PACLitaxel dexamethasone 20 mg V in normal saline 250 mL over 1 hour, following the administration rates below: • Administer anting volume over 45 minutes Wait 1 hour after completion of IV pre-medication(s) before starting PACLitaxel PACLitaxel 80 mg/m² V in normal saline 250 mL over 1 hour, following the administration rates below: • Administer remaining volume over 45 minutes Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron filter • Nursing Ale			
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(Maximum rate 25 mg/minute)	Wait 30 minutes after	completion of IV pr	e-medication(s) before starting ramucirumab
(Maximum rate 25 mg/minute)	ramucirumab	8 mg/kg	IV in normal saline 250 mL over 1 hour
			(Maximum rate 25 mg/minute)
USE U.Z UI U.ZZ IIIICIUII JIILEI			Use 0.2 or 0.22 micron filter



		*Alert: Pharmacy to ensure final volume in bag = 250 mL *Nursing Alert: PACLitaxel infusion starts after observation period is complete (if required)
PACLitaxel	80 mg/m ²	IV in normal saline 250 mL over 1 hour, following the administration rates below:
		Administer at 100 mL/hour for 15 minutes, then
		Administer remaining volume over 45 minutes
		Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron filter
		*Nursing Alert: Gently invert bag 8 to 10 times immediately prior to administration of PACLitaxel to evenly distribute the drug

All doses will be automatically rounded that fall within CCMB Approved Dose Bands. See Dose Banding docu more information

In the event of an infusion-related hypersensitivity reaction, refer to the 'Hypersensitivity Reaction Standing Order'

REQUIRED MONITORING

All Cycles

Day 1

- CBC, serum creatinine, urea, AST, ALT, total bilirubin, urine protein and blood pressure as per Physician Orders
 - Urinalysis for protein: Where urinalysis is not possible, use dipstick. If lab urinalysis for protein is greater than or equal to 1 g/L or dipstick proteinuria shows 2+ or 3+, notify medical oncologist
- TSH as per Physician Orders

Day 8

• CBC, serum creatinine, urea, AST, ALT and total bilirubin as per Physician Orders

Day 15

- CBC, serum creatinine, urea, AST, ALT, total bilirubin, urine protein and blood pressure as per Physician Orders
 - Urinalysis for protein: Where urinalysis is not possible, use dipstick. If lab urinalysis for protein is greater than or equal to 1 g/L or dipstick proteinuria shows 2+ or 3+, notify medical oncologist

ramucirumab and PACLitaxel monitoring

Cycle 1

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O₂ saturation) at baseline and as clinically indicated
- Observe patient for 1 hour after first and second ramucirumab infusions. Full vital signs after observation period is complete. PACLitaxel infusion begins after observation period is complete
- No observation period is required after PACLitaxel administration. Patient can be discharged from treatment room if stable whether they had a reaction or not

Cycle 2 and Onwards

- Full vital signs (temperature, heart rate, respiratory rate, blood pressure and O₂ saturation) at baseline and as clinically indicated
- For patients with no prior infusion-related reaction to ramucirumab, no observation period is required
- For patients who have had a previous infusion-related reaction to ramucirumab, observe patient for 1 hour after ramucirumab infusion. Full vital signs after observation period is complete. PACLitaxel infusion begins after observation period is complete
- No observation period is required after PACLitaxel administration. Patient can be discharged from treatment room if stable whether they had a reaction or not



Recommended Support Medications		
Drug	Dose	CCMB Administration Guideline
metoclopramide	10 – 20 mg	Orally every 4 hours as needed for nausea and vomiting

DISCHARGE INSTRUCTIONS

- Patients should be instructed to contact their cancer team immediately if symptoms of hypersensitivity reactions occur after discharge
- Instruct patient to continue taking anti-emetic(s) at home
- Inform patient of possibility of delayed infusion type reactions: chills, flushing, hypotension, bronchospasm, dyspnea and hypoxia
- Reinforce applicable safe handling precautions of medications, blood and body fluids for 48 hours after completion of chemotherapy

ADDITIONAL INFORMATION

- ramucirumab can cause increased risk of hypertension, post-operative bleeding, wound healing complications and thromboembolic events
- PACLitaxel may cause progressive, irreversible neuropathy

