

## Regimen Reference Order – GAST – ramucirumab + PACLitaxel

ARIA: GAST – [ramucirumab + PACLitaxel]

Planned Course: Every 28 days until disease progression or unacceptable toxicity

Indication 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  $1.5 \times 10^9/L$  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

Establish primary solution 500 mL of: normal saline

| Drug                                                                                      | Dose    | CCMB Administration Guideline                                                                                                                                        |
|-------------------------------------------------------------------------------------------|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Day 1</b>                                                                              |         |                                                                                                                                                                      |
| famotidine                                                                                | 40 mg   | Orally 1 hour prior to ramucirumab                                                                                                                                   |
| acetaminophen                                                                             | 650 mg  | <b>ONLY</b> to be given if patient experienced a Grade 1 or 2 infusion-related reaction with any previous ramucirumab infusion<br>Orally 1 hour prior to ramucirumab |
| dexamethasone                                                                             | 20 mg   | IV in normal saline 50 mL over 15 minutes                                                                                                                            |
| diphenhydramine                                                                           | 50 mg   | IV in normal saline 50 mL over 15 minutes                                                                                                                            |
| <b>Wait 30 minutes after completion of IV pre-medications before starting ramucirumab</b> |         |                                                                                                                                                                      |
| ramucirumab                                                                               | 8 mg/kg | IV in normal saline 250 mL over 1 hour<br>(Maximum rate 25 mg/minute)<br>Use 0.2 or 0.22 micron filter                                                               |

|                                                                                                                                                 |                      |                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                 |                      | <p><i>*Alert: Pharmacy to ensure final volume in bag = 250 mL</i></p> <p><i>*Nursing Alert: PACLitaxel infusion starts after observation period is complete (if required)</i></p>                                                                                                                                     |
| PACLitaxel                                                                                                                                      | 80 mg/m <sup>2</sup> | <p>IV in normal saline 250 mL over 1 hour</p> <p><i>Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron filter</i></p> <p><i>Concentration dependent drug: Pharmacy will adjust diluent volume to ensure drug stability</i></p>                                                                |
| <b>Day 8</b>                                                                                                                                    |                      |                                                                                                                                                                                                                                                                                                                       |
| famotidine                                                                                                                                      | 40 mg                | Orally 1 hour prior to PACLitaxel                                                                                                                                                                                                                                                                                     |
| cetirizine                                                                                                                                      | 10 mg                | Orally 1 hour prior to PACLitaxel                                                                                                                                                                                                                                                                                     |
| dexamethasone                                                                                                                                   | 20 mg                | IV in normal saline 50 mL over 15 minutes                                                                                                                                                                                                                                                                             |
| <b>Wait 30 minutes after completion of IV pre-medications before starting PACLitaxel</b>                                                        |                      |                                                                                                                                                                                                                                                                                                                       |
| PACLitaxel                                                                                                                                      | 80 mg/m <sup>2</sup> | <p>IV in normal saline 250 mL over 1 hour</p> <p><i>Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron filter</i></p> <p><i>Concentration dependent drug: Pharmacy will adjust diluent volume to ensure drug stability</i></p>                                                                |
| <b>Day 15</b>                                                                                                                                   |                      |                                                                                                                                                                                                                                                                                                                       |
| famotidine                                                                                                                                      | 40 mg                | Orally 1 hour prior to ramucirumab                                                                                                                                                                                                                                                                                    |
| acetaminophen                                                                                                                                   | 650 mg               | <p><b><u>ONLY</u></b> to be given if patient experienced a Grade 1 or 2 infusion-related reaction with any previous ramucirumab infusion</p> <p>Orally 1 hour prior to ramucirumab</p>                                                                                                                                |
| dexamethasone                                                                                                                                   | 20 mg                | IV in normal saline 50 mL over 15 minutes                                                                                                                                                                                                                                                                             |
| diphenhydramine                                                                                                                                 | 50 mg                | IV in normal saline 50 mL over 15 minutes                                                                                                                                                                                                                                                                             |
| <b>Wait 30 minutes after completion of IV pre-medications before starting ramucirumab</b>                                                       |                      |                                                                                                                                                                                                                                                                                                                       |
| ramucirumab                                                                                                                                     | 8 mg/kg              | <p>IV in normal saline 250 mL over 1 hour</p> <p><i>(Maximum rate 25 mg/minute)</i></p> <p><i>Use 0.2 or 0.22 micron filter</i></p> <p><i>*Alert: Pharmacy to ensure final volume in bag = 250 mL</i></p> <p><i>*Nursing Alert: PACLitaxel infusion starts after observation period is complete (if required)</i></p> |
| PACLitaxel                                                                                                                                      | 80 mg/m <sup>2</sup> | <p>IV in normal saline 250 mL over 1 hour</p> <p><i>Use non-DEHP bags and non-DEHP administration sets with 0.2 or 0.22 micron filter</i></p> <p><i>Concentration dependent drug: Pharmacy will adjust diluent volume to ensure drug stability</i></p>                                                                |
| All doses will be automatically rounded that fall within the DSG Approved Dose Bands. See GAST DSG – Dose Banding document for 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 O<sub>2</sub> 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 O<sub>2</sub> 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 |

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## DISCHARGE INSTRUCTIONS

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- 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

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## ADDITIONAL INFORMATION

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