

PROTOCOL CODE: UMYDARLD (IV Cycle 1)

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A BC Cancer "Compassionate Access Program" request form must be completed and approved prior to treatment.

Patient RevAid # _____

DOCTOR'S ORDERS		Ht _____ cm Wt _____ kg BSA _____ m ²
REMINDER: Please ensure drug allergies and previous bleomycin are documented on the Allergy & Alert Form		
DATE:	To be given:	Cycle #: 1
Date of Previous Cycle: _____		
Risk Category: <input type="checkbox"/> Female of Childbearing Potential (FCBP) Rx valid for 7 days		
Risk Category: <input type="checkbox"/> Male or Female of non-Childbearing Potential (NCBP)		
**** <u>Ensure Red Blood Cell Phenotype and Group and Screen</u> for all patients prior to Cycle 1****		
<input type="checkbox"/> Delay treatment _____ week(s) <input type="checkbox"/> CBC & Diff, Platelets day of treatment <ul style="list-style-type: none"> May proceed with daratumumab day 1 doses as written, if within 96 hours (or within 48h for days 8,15,22) ANC greater than or equal to 1 x 10⁹/L, Platelets greater than or equal to 50 x 10⁹/L May proceed with lenalidomide doses as written, if within 96 hours ANC greater than or equal to 1 x 10⁹/L, Platelets greater than or equal to 30 x 10⁹/L, eGFR as per protocol 		
Dose modification for: <input type="checkbox"/> Hematology: _____ <input type="checkbox"/> Other Toxicity: _____		
Proceed with treatment based on blood work from _____		
CHEMOTHERAPY: LENALIDOMIDE <input type="checkbox"/> lenalidomide* _____ mg PO daily, in the evening, on days 1 to 21 and off for 7 days <input type="checkbox"/> lenalidomide* _____ mg PO _____ MITTE: (*available as 25 mg, 20mg, 15 mg, 10 mg, 5 mg and 2.5 mg capsules) *Note: Use one capsule strength for the total dose; there are cost implications as costing is per capsule and not weight based <input type="checkbox"/> FCBP dispense 21 capsules (1 cycle) <input type="checkbox"/> For Male and Female NCBP: Mitte: 21 capsules (1 cycle). Physician to assure DVT prophylaxis in place: ASA, Warfarin, low molecular weight heparin or direct oral anticoagulant or none	<u>Pharmacy Use for Lenalidomide:</u> RevAid confirmation number: _____ Lenalidomide lot number: _____ Pharmacist counsel (initial): _____	
DOCTOR'S SIGNATURE:	SIGNATURE:	
Physician RevaId ID:	UC:	

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DATE:

STERIOD: RN to use patient's therapeutic steroid as pre-med for daratumumab - refer to protocol.

Standard Regimen: daratumumab full dose administered on Cycle 1 Day 1

dexamethasone 40 mg or 20 mg PO before daratumumab on days 1, 8, 15 and 22

OR

predniSONE 100 mg PO before daratumumab on days 1, 8, 15, and 22

OR

Alternative Regimen: daratumumab split dose administered on Cycle 1 Day 1 and Day 2

dexamethasone 20 mg PO before daratumumab on days 1 and 2, and 40mg before daratumumb on days 8, 15, 22

OR

dexamethasone 20 mg PO before daratumumab on days 1 and 2 and 20mg before daratumumb on days 8, 15, 22

OR

predniSONE 50 mg PO before daratumumab on days 1 and 2, and prednisone 100mg before daratumumb on days 8, 15, 22

****Have Hypersensitivity Reaction Tray and Protocol Available****

DARATUMUMAB

If patient is VZV seropositive and/or at physician's clinical judgement, physician to ensure prophylaxis with valACYclovir 500 mg daily while on daratumumab and for 4 weeks after discontinuation

DARATUMUMAB PREMEDICATIONS: Patient to take own supply. RN/Pharmacist to confirm.

dexamethasone as ordered in steroid section

montelukast 10 mg PO prior to daratumumab on Day 1 (and Day 2 if on alternative regimen)

montelukast 10 mg PO prior to daratumumab on Days 8, 15 and 22

acetaminophen 650 mg PO prior to each daratumumab. Repeat acetaminophen 650 mg PO every 4 hours x 1 dose during infusion on day 1 of cycle 1 only, then every 4 hours when needed

Select one of the following:

loratadine 10 mg PO prior to each daratumumab, then diphenhydrAMINE 50 mg IV every 4 hours when needed

OR

diphenhydramine 50 mg PO or IV prior to each daratumumab.

Repeat diphenhydramine 50 mg PO or IV every 4 hours x 1 dose during the infusion on day 1 of cycle 1 only, then diphenhydrAMINE 50 mg IV every 4 hours when needed

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SIGNATURE:

UC:

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DATE:	
Have Hypersensitivity Reaction Tray and Protocol Available	
Standard regimen: daratumumab full dose administered on Cycle 1 Day 1	
<input type="checkbox"/> CYCLE 1, Day 1:	
daratumumab (First dose) 16mg/kg x _____ kg = _____ mg IV in 1000mL NS (use 0.2 micron in-line filter)	
OR	
Alternative regimen: daratumumab split dose administered on Cycle 1 Day 1 and Day 2	
<input type="checkbox"/> CYCLE 1, Days 1 and 2	
daratumumab 8mg/kg x _____ kg = _____ mg IV in 500mL NS (use 0.2 micron in-line filter)	
Infusion rate for Day 1, (and Day 2, if Alternative regimen):	
Start at 50 mL/h. If no infusion-related reactions after 60 minutes, increase by 50 mL/h every 60 minutes to a maximum rate of 200 mL/h	
If BP falls to less than 80/50 mmHg or pulse increases to greater than 120 or if flushing, dyspnea, chills, rash, pruritis, vomiting, chest pain, throat tightness, cough, wheezing, or any other new acute discomfort occurs, stop daratumumab infusion and page physician.	
Vitals monitoring:	
Vital signs immediately before the start of infusion, then every 30 minutes x 4, then every 1-2 hours until the end of infusion and at 30 minutes post infusion. Observe patient for 30 minutes after each daratumumab infusion	
<input type="checkbox"/> CYCLE 1, Day 8:	
daratumumab 16mg/kg x _____ kg = _____ mg IV in 500mL NS (use 0.2 micron in-line filter)	
Infusion rate: Physician to determine rate of infusion	
<i>If no reaction in the previous infusion or reaction is Grade 2 or less:</i>	
<input type="checkbox"/> Start at 200 mL/h. If no infusion-related reactions after 30 minutes, infuse the remainder at 450 mL/h (Rapid infusion)	
OR	
<i>If reaction in the previous infusion is Grade 3:</i>	
<input type="checkbox"/> Start at 50 mL/h. If no infusion-related reactions after 60 minutes, increase by 50 mL/h every 60 minutes to a maximum rate of 200 mL/h (Slow infusion)	
Vitals monitoring:	
Vital signs immediately before the start, at the end of the infusion and as needed. Observe patient for 30 minutes after infusion.	
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	UC:

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DATE:	
Have Hypersensitivity Reaction Tray and Protocol Available	
<p>CYCLE 1, Days 15 and 22: daratumumab 16mg/kg x _____ kg = _____ mg IV in 500mL NS (use 0.2 micron in-line filter)</p> <p><u>Infusion rate for Days 15 and 22: Physician to determine rate of infusion</u> <i>If no reaction in the previous infusion or reaction is Grade 2 or less:</i></p> <p><input type="checkbox"/> Start at 200 mL/h. If no infusion-related _____ after 30 minutes, infuse the remainder at 450 mL/h (Rapid infusion)</p> <p>OR</p> <p><i>If reaction in the previous infusion is Grade 3:</i></p> <p><input type="checkbox"/> Start at 100 mL/h. If no infusion-related reactions after 60 minutes, increase by 50 mL/h every 60 minutes to a maximum rate of 200 mL/h. Refer to protocol for modified starting rate if previous infusion reactions were experienced during infusion rate of greater than or equal to 100 mL/h (Slow infusion)</p> <p>Vitals monitoring: Vital signs immediately before the start, at the end of the infusion and as needed. Observe patient for 30 minutes after infusion (vitals and observation not required after 3 treatments with no reaction).</p>	
RETURN APPOINTMENT ORDERS	
<p><input type="checkbox"/> STANDARD REGIMEN: For Cycle 1, book chemo on days 1, 8, 15 and 22</p> <p><input type="checkbox"/> ALTERNATIVE REGIMEN: For Cycle 1, book chemo on days 1, 2, 8, 15 and 22</p> <p>For Cycle 2 book chemo on days 1, 8, 15, 22</p> <p>Return in four weeks for Doctor and Cycle 2</p>	
<p>Laboratory: Blood work done prior to next cycle must be done less than or equal to 4 days prior to the start date</p> <p>Red Blood Cell phenotype and Group and Screen prior to cycle 1</p> <p>TSH every three months</p> <p>Cycles 1-2:</p> <p>Day 1: CBC & Diff, platelets, sodium, potassium, creatinine, calcium, ALT, bilirubin, Serum Protein Electrophoresis and Serum Free Light Chain Levels</p> <p><input type="checkbox"/> Day 1: urine protein electrophoresis</p> <p><input type="checkbox"/> Day 1: immunoglobulin panel</p> <p>Day 8, 15, 22: CBC & Diff, platelets</p> <p><input type="checkbox"/> CBC & Diff, Platelets, Creatinine, Calcium every two weeks</p> <p><input type="checkbox"/> Sodium, Potassium <input type="checkbox"/> ALT <input type="checkbox"/> bilirubin <input type="checkbox"/> Creatinine</p> <p><input type="checkbox"/> Quantitative β-hCG blood test for FCBP 7-14 days and 24 h prior to cycle 1 and every week for 4 weeks during cycle 1</p> <p><input type="checkbox"/> Quantitative β-hCG blood test for FCBP less than or equal to 7 days prior to cycle 2</p> <p><input type="checkbox"/> See general orders sheet for additional requests</p> <p><input type="checkbox"/> Other tests: _____ <input type="checkbox"/> Consults: _____</p>	
DOCTOR'S SIGNATURE:	SIGNATURE:
	UC: