PROTOCOL CODE: UMY0UF (teclistamab)

Cycle 1 (Outpatient)

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

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 #:**

Date of Previous Cycle:

☐ Delay treatment _____ week(s)
☐ **CBC & Diff, platelets** day of treatment

May proceed with doses as written if within 48 hours of Day 1, and within 24 hours of Day 3 and Day 5: **ANC greater than or equal to 0.5 x 10^9/L, platelets greater than or equal to 25 x 10^9/L** (without bleeding), and no signs or symptoms of CRS or ICANS.

Dose modification for: ☐ Other Toxicity: _____

Proceed with treatment based on blood work from _____

- Per physician's clinical judgement, physician to ensure prophylaxis with antiviral/antifungal/antibacterial

PREMEDICATIONS:

☐ **prochlorperazine** 10 mg PO or ☐ **metoclopramide** 10 mg PO 60 minutes prior to each dose of teclistamab

dexamethasone 20 mg ☐ PO or ☐ IV (select one) 60 minutes prior to each dose of teclistamab
acetaminophen 650 mg to 975 mg PO 60 minutes prior to each dose of teclistamab

Select one of the following:
☐ **loratadine 20 mg** PO 60 minutes prior to each dose of teclistamab
OR
☐ **diphenhydrAMINE 50 mg** ☐ PO or ☐ IV (select one) 60 minutes prior to each dose of teclistamab

☐ **Other:**

****Have Hypersensitivity Reaction Tray & Protocol Available****

TREATMENT:

Baseline ICANS assessment, including ICE score prior to Day 1.

Vital signs prior to each treatment and 15 minutes after treatment

teclistamab 0.06 mg/kg x _____ kg = _____mg subcutaneous injection on **Day 1** (**Round to one decimal place**)
THEN
teclistamab 0.3 mg/kg x _____ kg = _____mg subcutaneous injection on **Day 3*** (**Round to one decimal place**)
THEN
teclistamab 1.5 mg/kg x _____ kg = _____mg subcutaneous injection on **Day 5***

Administer doses greater than 2 mL as two syringes at two separate sites.
* Day 3 and Day 5 doses may be given 2 to 7 days after previous dose
Observe patient for 15 minutes after each treatment.

Continued on page 2

DOCTOR'S SIGNATURE:	**SIGNATURE:** **UC:**

PROTOCOL CODE: UMY0UF (teclistamab)

Cycle 1 (Outpatient)

DATE:

MONITORING: Patients must be admitted to hospital for monitoring for at least 48 hours after Cycle 1 Days 1, 3 and 5, unless there is a local plan in place for rapid assessment and intervention of suspected CRS and ICANS following outpatient administration. See protocol for more details.

Patients to be monitored daily for at least 48 hours after each treatment.

Cytokine Release Syndrome (CRS)
Clinical symptoms indicative of CRS are **fever, rigors, hypotension and hypoxemia.** Symptoms may also include but are not limited to: tachycardia, tachypnea, dyspnea, nausea, vomiting, diarrhea, mental status changes, transaminitis, fatigue, malaise, myalgias, headache, rash. Patients should be closely monitored for early signs and symptoms indicative of CRS – in particular fevers (temperature greater than 38 degrees Celsius), rigors, hypotension (systolic blood pressure less than 100 mmHg or drop of greater than 20 mmHg from baseline) and hypoxia. Refer to the separate SCCRS PPO for specific management of CRS.

Immune effector cell-associated neurotoxicity syndrome (ICANS)
Clinical symptoms indicative of ICANS are headache, confusion, disorientation, speech disturbances, altered levels of consciousness, seizures and motor weakness. Symptoms may also include, but are not limited to: lethargy, aphasia, difficulty concentrating, agitation, tremor, and rarely cerebral edema. Patients should be closely monitored for early signs and symptoms indicative of ICANS, depressed level of consciousness, ataxia, or any significant change in their clinical status. Refer to the separate SCICANS PPO for specific management of ICANS.

Patients must be counselled on the signs and symptoms of CRS and ICANS and to seek immediate medical attention should they occur. Patients must remain within the proximity of the treating facility for at least 48 hours following Step-up and the first full treatment doses (Cycle 1, Days 1, 3 and 5).

RETURN APPOINTMENT ORDERS

Return in **12 days** (12 days from Day 1 dose) for Doctor and Cycle 2
☐ Or Return in ____ days (minimum 7 days after Cycle 1, Day 5) for Doctor and Cycle 2

Prior to treatment on Day 3 and Day 5 of Cycle 1: **CBC & Diff, creatinine, sodium, potassium, calcium, magnesium, phosphate, ALT, alkaline phosphatase, total bilirubin, albumin, LDH**

Cycle 2, prior to Day 1: **CBC & Diff, creatinine, urea, sodium, potassium, total bilirubin, ALT, alkaline phosphatase, calcium, albumin, LDH, random glucose**

☐ If patient not admitted to hospital for monitoring, nurse telephone follow up for CRS and ICANS assessment on Cycle 1 Day 2, 4, 6 and 7

Cycle 2, if clinically indicated:
☐ **CBC & Diff** Days 8, 15, 22
☐ **Creatinine, sodium, potassium** Days 8, 15, 22
☐ **Total bilirubin, ALT, alkaline phosphatase** Days 8, 15, 22
☐ **Random glucose** Days 8, 15, 22
☐ **Calcium, albumin** Days 8, 15, 22
☐ **Phosphate** ☐ **Magnesium**
☐ **Other tests:** ☐ **Consults:**
☐ **See general orders sheet for additional requests**

DOCTOR'S SIGNATURE:

SIGNATURE:

UC: