PROTOCOL CODE: ULYOGLOFIT

Cycle 1

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** of treatment

- Day 1: May proceed regardless of blood counts
- Days 8 and 15: May proceed with doses as written if within 48 hours **ANC greater than or equal to 0.5 x 10^9/L, platelets greater than or equal to 50 x 10^9/L**

Dose modification for: ☐ Other Toxicity: _____

Proceed with treatment based on blood work from _____

INPATIENT ORDERS:

valACYclovir 500 mg PO once daily

cotrimoxazole 1 DS tablet PO 3 times each week (Monday, Wednesday and Friday)

PREMEDICATIONS:

Patient to take own supply. RN/Pharmacist to confirm _____.

Day 1 (for oBInutuzumab):

60 minutes prior to treatment: **dexamethasone 20 mg** IV

30 minutes prior to treatment: **acetaminophen 650 to 975 mg** PO and **diphenhydrAMINE 50 mg** ☐ PO or ☐ IV (select one)

Days 8 and 15 (for glofitamab):

60 minutes prior to treatment: **dexamethasone 20 mg** IV

30 minutes prior to treatment: **acetaminophen 650 to 975 mg** PO and **diphenhydrAMINE 50 mg** ☐ PO or ☐ IV (select one)

☐ **Other:**

PREHYDRATION:

☐ 500 mL NS IV over 30 minutes prior to glofitamab on Days 8 and 15

MONITORING:

Cycle 1 Day 8: Patients must be admitted to hospital for monitoring during glofitamab Day 8 infusion (Step-up dose 1) and for at least 24 hours following completion of infusion.

Cycle 1 Day 15 may be given as inpatient or in ambulatory care setting:

- Inpatient treatment if *any grade* CRS with Cycle 1 Day 8. Monitoring per Cycle 1 Day 8 instructions.
- Ambulatory care treatment if no CRS and no treatment interruption with Cycle 1 Day 8. Patient to remain in proximity of treating facility for at least 24 hours after infusion completed.

Cytokine release syndrome (CRS)

Patients should be closely monitored for early signs and symptoms indicative of CRS – in particular fever (temperature greater than 38 degrees Celsius), chills, hypoxia, hypotension (systolic blood pressure less than 100 mmHg or drop of greater than 20 mmHg from baseline), dyspnea, and tachycardia. Refer to protocol and to the separate SCCRS PPO for specific management of CRS.

Immune effector cell-associated neurotoxicity syndrome (ICANS)

Clinical symptoms indicative of ICANS may include headache, confusion, disorientation, speech disturbances, altered levels of consciousness, seizures, muscle weakness, agitation, and tremor.

Patients should be closely monitored for early signs and symptoms indicative of ICANS- in particular ICE score 7 to 9, depressed level of consciousness, ataxia, or any significant change in their clinical status.

Refer to protocol and 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.

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

Date:

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

TREATMENT:

Day 1: ambulatory care treatment

Vital signs are not required for oBINutuzumab, unless symptomatic.

oBINutuzumab 1000 mg IV in 250 mL NS on **Day 1**. Start infusion at **50 mg/h**; after 30 minutes, increase by 50 mg/h every 30 minutes until rate = 400 mg/h unless toxicity occurs. Refer to protocol appendix for oBINutuzumab infusion rate titration table.

Due to the risk of infusion-related reactions, patients are to be under constant visual observation during all dose increases and for 30 minutes after infusion completed.

Day 8: inpatient treatment

Cycle 1 Day 8: In addition to IV for treatment, insert saline lock for emergency management.

Vital signs prior to glofitamab, every hour during infusion, at the end of the infusion, and as clinically indicated.

glofitamab 2.5 mg IV in 25 mL NS over 4 hours on **Day 8**

Concurrent infusion with glofitamab: Infuse NS IV at 20 mL/h via Y-site connector placed immediately before the injection site

Day 15:

☐ If no CRS with previous dose: **ambulatory care treatment**

Vital signs prior to glofitamab, at the end of the infusion, and as clinically indicated.

glofitamab 10 mg IV in 50 mL NS over 4 hours on **Day 15**

OR

☐ If any grade CRS with previous dose: **inpatient treatment**

In addition to IV for treatment, insert saline lock for emergency management.

Vital signs prior to glofitamab, every hour during infusion, at the end of the infusion, and as clinically indicated.

glofitamab 10 mg IV in 50 mL NS over 8 hours on **Day 15**

Concurrent infusion with glofitamab: Infuse NS IV at 20 mL/h via Y-site connector placed immediately before the injection site

Discharge Instructions- if patient admitted to hospital:

Responsible provider must assess patient and review labs (if ordered) drawn day after treatment prior to discharge.

RETURN APPOINTMENT ORDERS

Book ambulatory care treatment for Cycle 1 Day 1 (oBINutuzumab).
Admit for inpatient treatment in **one** week for Cycle 1 Day 8 (glofitamab Step-up dose 1), and
Book ambulatory care treatment in **two** weeks for Cycle 1 Day 15 (glofitamab Step-up dose 2) OR
☐ Readmit to hospital for Cycle 1 Day 15 (glofitamab Step-up dose 2)
Return in **three** weeks for Doctor and Cycle 2. Book ambulatory care treatment on Day 1 only.

Prior to Cycle 2: **CBC & Diff**
Cycle 1 Days 8 and 15: **CBC & Diff**
☐ Cycle 1 Day 9: **CBC & Diff, creatinine, sodium, potassium, calcium, magnesium, phosphate, ALT, alkaline phosphatase, total bilirubin, LDH** (prior to discharge)
If clinically indicated:
☐ **creatinine** ☐ **sodium** ☐ **potassium** ☐ **phosphate** ☐ **calcium**
☐ **magnesium** ☐ **uric acid** ☐ **albumin** ☐ **total bilirubin** ☐ **ALT**
☐ **alkaline phosphatase** ☐ **GGT** ☐ **LDH** ☐ **random glucose**
☐ **immunoglobulin panel (IgA, IgG, IgM)**
☐ **Other tests:** ☐ **Consults:**
☐ **See general orders sheet for additional requests.**

DOCTOR'S SIGNATURE:

SIGNATURE:

UC: