Obinutuzumab 1000 / Gemcitabine 1000 / Oxaliplatin 100 / Glofitamab (2.5/10), diffuse large B-Non-Hodgkin Lymphoma, cycle 1

Protocol-ID: 2808 V1.0 (Complete), OBIN1000/GEMC1000/OXAL100/GLOF(2,5/10), DLBCL, C1

Indication(s)

- NHL, B-Cell Type, Diffuse Large Cell; ICD-10 C83.3

Protocol classification

- Classification: current standard
- Intensity: Standard dose
- Therapy mode: Relapse therapy
- Therapy intention: palliative

Cycles

Cycle length 21 days, recommended cycles: 1

Protocol sequences

- STARGLO: OBIN1000/GEMC1000/OXAL100/GLOF(2,5/10), DLBCL, C1 (PID2808) -|- C2-8 (PID2809) -|- C9-12 (PID2810)

Risks

- Emetogenicity (MASCC/ESMO): moderate (30-90%)
- Neutropenia: high (21-40%)
- Febrile Neutropenia: high (>20%)
- Upper Respiratory Tract Infection: CTC AE °1-4: 9%
- Neurotoxicity: CTC AE °1-4: 31%
- Pneumonia: CTC AE °1-4: 13%
- Cytokine Release Syndrome: CTC AE °1-2: 42%; °3: 2%
- COVID-19 infection: CTC AE °1-4: 14%

Therapy

Hydration: Balanced Crystalloid Solution **HYD**

Access: peripheral venous

Hydration before, during, or after antitumor therapy

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	**Balanced Crystalloid Solution**	500 ml		i.v.	60 min	60 min before Obinutuzumab (d1)
2	**Balanced Crystalloid Solution**	500 ml		i.v.	60 min	60 min before Gemcitabine (d2)
8	**Balanced Crystalloid Solution**	500 ml		i.v.	60 min	60 min before Glofitamab (d8)
15	**Balanced Crystalloid Solution**	500 ml		i.v.	60 min	60 min before Glofitamab (d15)

Antiemesis: Emetogenicity moderate, GRAN i.v., DEXA i.v. **AE**

Access: peripheral venous

ASCO 2015, DGHO 2016, DKG 2016, MASCC/ESMO 2016, if palonosetron not available

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
2	**Dexamethasone**	8 mg	NaCl 0.9% 50 ml	i.v.	5 min	30 min before Gemcitabine (d2)
2	**Granisetron**	1 mg	NaCl 0.9% 50 ml	i.v.	5 min	15 min before Gemcitabine (d2)
or other 5-HT3 receptor antagonist						
3-4	**Dexamethasone**	8 mg		p.o.		1-0-0-0

Allergy prophylaxis: Allergy prophylaxis Obinutuzumab and Glofitamab **AP**

Access: peripheral venous

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	**Prednisolone**	100 mg	NaCl 0.9% 100 ml	i.v.	15 min	90 min before Obinutuzumab (d1)
1	**Paracetamol**	1000 mg		p.o.		60 min before Obinutuzumab (d1)
1	**Dimetinden**	4 mg	NaCl 0.9% 50 ml	i.v.	5 min	60 min before Obinutuzumab (d1)
8	**Prednisolone**	100 mg	NaCl 0.9% 50 ml	i.v.	15 min	90 min before Glofitamab (d8)
8	**Paracetamol**	1000 mg		p.o.		60 min before Glofitamab (d8)
8	**Dimetinden**	4 mg	NaCl 0.9% 50 ml	i.v.	5 min	60 min before Glofitamab (d8)
15	**Prednisolone**	100 mg	NaCl 0.9% 50 ml	i.v.	15 min	90 min before Glofitamab (d15)
15	**Paracetamol**	1000 mg		p.o.		60 min before Glofitamab (d15)
15	**Dimetinden**	4 mg	NaCl 0.9% 50 ml	i.v.	5 min	60 min before Glofitamab (d15)

Antineoplastic therapy: OBIN1000/GEMC1000/OXAL100/GLOF(2.5/10) **ANTX**

Access: peripheral venous

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
1	**Obinutuzumab**	1000 mg	NaCl 0.9% 250 ml	i.v.	4 h	Sequence
The infusion can be started at a rate of 50 mg/hr and increased in increments of 50mg/hr every 30 minutes to a maximum of 400 mg/hr.						
2	**Gemcitabine**	1000 mg/m² BSA	NaCl 0.9% 250 ml	i.v.	30 min	Sequence
2	**Oxaliplatin**	100 mg/m² BSA	Dextrose 5% 500 ml	i.v.	2 h	Sequence
8	**Glofitamab**	2.5 mg	NaCl 0.9% 100 ml	i.v.	4 h	Sequence
15	**Glofitamab**	10 mg	NaCl 0.9% 100 ml	i.v.	4 h	Sequence
In patients who have experienced Cytokine Release Syndrome at previous doses of glofitamab, the infusion duration may be extended up to 8 h.						

Hematopoietic growth factors: FN risk above 20%, G-CSF long-acting, pegylated **HW**

Access: - none -

Risk of febrile neutropenia (FN) >20%, ASCO 2015, DKG 2016

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
3	**Pegfilgrastim**	6 mg		subc	Bolus	24 h after Oxaliplatin (d2)
or other long-acting G-CSF						

Infection prophylaxis: Pneumocystis jirovecii pneumonia **IP**

Access: - none -

Day	Substance	Dosage	Solution	Appl.	Inf. time	Procedure
(1,3,5) x 3	**Cotrimoxazole**	960 mg		p.o.		1-0-0-0

Substance links

Links to substances are found here.

Concomitant therapy supplements

Antihypertensive therapy should be interrupted at least 12 hours before Obinutuzumab administration and should not be restarted until at least one hour after administration, as hypotension may occur as a sign of an infusion-related reaction during the infusion.
Occurrence of Cytokine Release Syndrome possible. Consider administration of Tocilizumab from grade 2 (see corresponding protocol).
Observe tumor lysis syndrome risk classification according to Cairo 2010, use "Tumor lysis syndrome prophylaxis, medium risk" protocol for LDH elevation without tumor bulk. In case of LDH elevation above twice the upper limit and tumor bulk protocol use "Tumor Lysis Syndrome Prophylaxis, High Risk".
CMV reactivation should be treated preventively.

Cycle diagram

Hydration: Balanced Crystalloid Solution

	Week 1 / d							Week 2 / d							Week 3 / d						
Substance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Balanced Crystalloid Solution (i.v.)	■																				
Balanced Crystalloid Solution (i.v.)		■																			
Balanced Crystalloid Solution (i.v.)								■													
Balanced Crystalloid Solution (i.v.)															■						

Antiemesis: Emetogenicity moderate, GRAN i.v., DEXA i.v.

	Week 1 / d							Week 2 / d							Week 3 / d						
Substance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Dexamethasone (i.v.)		■																			
Granisetron (i.v.)		■																			
Dexamethasone (p.o.)			■	■																	

Allergy prophylaxis: Allergy prophylaxis Obinutuzumab and Glofitamab

	Week 1 / d							Week 2 / d							Week 3 / d						
Substance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Prednisolone (i.v.)	■																				
Paracetamol (p.o.)	■																				
Dimetinden (i.v.)	■																				
Prednisolone (i.v.)								■													
Paracetamol (p.o.)								■													
Dimetinden (i.v.)								■													
Prednisolone (i.v.)															■						
Paracetamol (p.o.)															■						
Dimetinden (i.v.)															■						

Antineoplastic therapy: OBIN1000/GEMC1000/OXAL100/GLOF(2.5/10)

	Week 1 / d							Week 2 / d							Week 3 / d						
Substance	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**
Obinutuzumab (i.v.)	■																				
Gemcitabine (i.v.)		■																			
Oxaliplatin (i.v.)		■																			
Glofitamab (i.v.)								■													
Glofitamab (i.v.)															■						

Hematopoietic growth factors: FN risk above 20%, G-CSF long-acting, pegylated

	Week 1 / d							Week 2 / d							Week 3 / d						
Substance	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**
Pegfilgrastim (subc)			■																		

Infection prophylaxis: Pneumocystis jirovecii pneumonia

	Week 1 / d							Week 2 / d							Week 3 / d						
Substance	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	**21**
Cotrimoxazole (p.o.)	■		■		■			■		■		■			■		■		■		

Cycles

Cycle length 21 days, recommended cycles: 1

Controls:

- Blood count: on day 1 and subsequently weekly
- HIV-1, Herpes simplex, Varicella zoster, Cytomegalovirus, EBV, Hepatitis B (HBV) Test: HBsAg, anti-HBc; Hepatitis C (HCV) CMV-IgG and IgM
- Vaccination status COVID-19, influenza, pneumococci (CAVE: exclusion of failure of specific antibody formation, PSAF), herpes zoster
- IgG regularly under therapy
- Echocardiography, ECG especially in patients with mediastinal involvement. Tumor flare possible.
- Day 1: CMV (cytomegalovirus) PCR-quantitative: in case of seropositivity before therapy, during the course in case of suspected risk of infection and closely when CMV replication is detected
- Day 1,8,15: Uric acid, Crea, GFR, LDH, Na^+, K^+, Ca^{2+}, Mg^{2+}, $PO4^{2-}$.
- Day 1,8,15: GOT, GPT, GGT, Bilirubin, AP, Cholinesterase
- Day 8,9,15,16: Pulse
- Day 8,9,15,16: Blood pressure Every 8 hours
- Day 8,9,15,16: Body temperature Every 8 hours
- Day 8,9,15,16: Oxygen saturation Every 8 hours
- Day 8,9,15,16: Neurostatus according to ICE scoring system

Original indication

Relapsed and refractory DLBCL, not suitable for transplantation ECOG 0-1

Original author

Abramson JS (2024)

Origin

Massachusetts General Hospital Cancer Center, Boston, MA, USA, STARGLO trial

References

- Abramson JS, Glofitamab plus gemcitabine and oxaliplatin (GemOx) versus rituximab-GemOx for relapsed or refractory diffuse large B-cell lymphoma (STARGLO): a global phase 3, randomised, open-label trial. Lancet 2024 Nov 16;404(10466):1940-1954. doi: 10.1016/S0140-6736(24)01774-4. PMID: 39550172. [PMID]

Recommendations

- 12/2024: National Comprehensive Cancer Network

Status

Valid since 2025-02-03, Version 1.0, last updated 2025-12-02

Last modification: V1.0: Dosing and durations according to the summary of product characteristics.

Important notice