PROTOCOL

The Clatterbridge Cancer Centre NHS Foundation Trust

Systemic Anti Cancer Therapy Protocol

MOGAMULIZUMAB

Mycosis Fungoides/ Sezary Syndrome

PROTOCOL REF: MPHAMMFSS
(Version No. 1.0)

Approved for use in:

- 3rd line systemic therapy or beyond 3rd line systemic therapy for patients with stage IIB to IVB mycosis fungoides
- 2nd line systemic therapy or beyond 2nd line systemic therapy for patients with stage IVA to IVB Sezary syndrome
- Blueteq registration is required – see Blueteq website for full criteria

Dosage:

Cycle 1:

Drug	Dose	Route	Frequency
Mogamulizumab	**1 mg/kg**	IV infusion	Day 1, 8, 15 and 22 of a 28 day cycle

Cycle 2 onwards:

Drug	Dose	Route	Frequency
Mogamulizumab	**1 mg/kg**	IV infusion	Day 1 and 15 of a 28 day cycle

To be continued until disease progression or unacceptable toxicities

Administration:

- Mogamulizumab should be administered within 2 days of the scheduled day. If a dose is missed by more than 2 days the next dose should be given as soon as possible,

after which dosing schedule should be resumed with doses given on the new scheduled days.

- Patients on mogamulizumab have experienced drug rashes, some of which have been serious
- A higher risk of transplant complications has been reported if mogamulizumab is given within a short time frame (approximately 50 days) before HSCT.
- Women of childbearing potential and males of reproductive potential should use effective contraception during treatment with mogamulizumab and for at least 6 months after treatment
- Mogamulizumab needs to go through a 0.22 micron filter

Emetogenic risk:

Mildly emetogenic.

Supportive treatments:

- Allopurinol PO 100mg OD or 300mg OD depending on renal function (first cycle only)
- Aciclovir PO 400mg BD
- Co-trimoxazole PO 480mg OD
- Metoclopramide PO 10mg TDS PRN

Extravasation risk:

Unknown

Refer to the CCC policy for the 'Prevention and Management of Extravasation Injuries'

Interactions:

No formal drug interaction studies have been performed with mogamulizumab.

Treatment schedule:

Cycle 1:

Day	Drug	Dose	Route	Diluent and rate
1	**Paracetamol**	**1000mg**	**PO**	Mandatory for first infusion only, only continue if infusion related reaction.
1	**Chlorphenamine**	**10mg**	**IV**	
1	**Mogamulizumab**	**1 mg/kg**	**IV**	Sodium Chloride 0.9% 250mL over 60 minutes via 0.22 micron filter

8	**Mogamulizumab**	**1 mg/kg**	**IV**	Sodium Chloride 0.9% 250mL over 60 minutes via 0.22 micron filter
15	**Mogamulizumab**	**1 mg/kg**	**IV**	Sodium Chloride 0.9% 250mL over 60 minutes via 0.22 micron filter
22	**Mogamulizumab**	**1 mg/kg**	**IV**	Sodium Chloride 0.9% 250mL over 60 minutes via 0.22 micron filter

Cycle 2 onwards:

Day	Drug	Dose	Route	Diluent and rate
1	**Mogamulizumab**	**1 mg/kg**	**IV**	Sodium Chloride 0.9% 250mL over 60 minutes via 0.22 micron filter
15	**Mogamulizumab**	**1 mg/kg**	**IV**	Sodium Chloride 0.9% 250mL over 60 minutes via 0.22 micron filter

Main toxicities:

Thrombocytopenia, neutropenia, anaemia, nausea, vomiting, diarrhoea, dermatological reactions and infusion related reactions

Investigations and treatment plan:

	Pre	Cycle 1 D1	Cycle 1 D8	Cycle 1 D15	Cycle 1 D22	Cycle 2+ D1	Cycle 2+ D15	Ongoing
Informed Consent	X							
Clinical Assessment	X	X				X		
SACT Assessment (to include PS and toxicities)	X	X	X	X	X	X	X	
FBC	X	X				X		
U&E, LFT, Ca profile	X	X				X		
CrCl (Cockcroft and Gault)	X							
Viral screen (EBV, CMV, Hepatitis B core antibody and surface antigens, Hep C & HIV 1+2)	X							
Blood pressure	X	X						Continuous monitoring for first dose. For subsequent doses only if previous infusion related reaction
Temperature, respiratory rate, pulse		X						
Weight	X	X				X		Every cycle
Height	X							
Pregnancy test	X							If indicated

Dose Modifications and Toxicity Management:

Non- Haematological toxicity:

Dosing in renal and hepatic impairment:

Renal	Based on population pharmacokinetic analysis, no dose modification is recommended in patients to mild to severe renal impairment

Hepatic	Based on population pharmacokinetic analysis, no dose modification is recommended in patients to mild to moderate hepatic impairment. Not studied in patients with severe hepatic impairment

Other toxicities:

Infusion-related reactions	Grade 1-3	Interrupt infusion and provide supportive treatment. Once symptoms resolve, resume at 50% of the previous rate
	Grade 4	Permanently discontinue

Dermatological reactions	Grade 2 or 3	Continue treatment when toxicity resolves to Grade 0-1
	Grade 4	Permanently discontinue

References:

1. https://www.medicines.org.uk/emc Mogamulizumab (accessed 14/9/21)

Circulation/Dissemination

Date added into Q-Pulse	27th May 2022
Date document posted on the Intranet	27th May 2022

Version History

Date	Version	Author name and designation	Summary of main changes
1.0	Nov 2021	**Aileen McCaughey HO Pharmacist**	Now available through CDF so mentions of compassionate use scheme removed and Blueteq criteria included. Also updated to current version of SACT protocol template.