Chemosat®

PATIENT REFERRAL FORM FOR HEALTHCARE PROFESSIONAL USE ONLY

This document should be used by Healthcare Professionals (HCPs) only. Completing the form below will help determine your patient's suitability for CHEMOSAT. Once completed, this document should be sent to the lead contact at the referring site (**www.chemosat.com/HCPs/treatment-centres.html**). Information contained on this form should not be shared with any other third party.

CHEMOSAT PATIENT SELECTION CRITERIA

For patients with unresectable metastatic uveal melanoma

- Histologically confirmed metastatic uveal melanoma with liver dominant metastases (50% or less) not amenable to curative (R0) liver surgical resection, which must be agreed at local multi-disciplinary team (MDT) meeting with hepatic surgery & radiology representation
- Life expectancy >3 months
- ECOG performance status of 0 to 1 at screening

Date

Chemosat®

ELIGIBILITY CRITERIA

Presence of one of the following criteria excludes a CHEMOSAT referral	Yes (exclude)	No
Child-Pugh Class B or cirrhosis	○	○
Evidence of portal hypertension	○	○
Cardiac conditions precluding use of general anaesthesia	○	○
Pulmonary disease precluding use of general anaesthesia	○	○
Prior Whipple's procedure and/or patient's normal hepatic biliary/vascular anatomy has been deranged	○	○
Taking immunosuppressive drugs or patients who are unable to be temporarily removed from chronic anti-coagulation therapy	○	○

REFERRING CLINICIAN INFORMATION

Clinician Name

Clinical Nurse Specialist (if applicable)

Clinician Secretary/ Site Co-ordinator

Address

Phone

E-mail (clinician)

PATIENT INFORMATION

Name	
Address	
Phone	
E-mail	
Date of Birth	
Patient number	
Sex	

Extrahepatic disease

1
2.
3.
4.

Allergies:

PREVIOUS SURGERY AND OR ABLATION

	Dates	Response	Notes
Surgery/ablation 1			
Surgery/ablation 2			
Surgery/ablation 3			
Surgery/ablation 4			

PREVIOUS SYSTEMIC THERAPY

Prior to receiving Chemosat patients must have:

- Recovered from all side effects of prior therapeutic and diagnostic interventions
  - Patients receiving anti-PD-1 immunotherapy such as pembrolizumab or nivolumab, or anti- CTLA-4 immunotherapy such as ipilimumab, should wait 8 weeks before being treated with CHEMOSAT
  - Adequate hepatic, hematological and renal function
  - Negative serum pregnancy test, if applicable

	Therapy/Agent	Dates (from/to)	Response	Progression (date)
Line 1				
Line 2				
Line 3				
Line 4				

BLOOD TESTS

Test	Bilirubin	ANC (neutrophils)	Platelets	Albumin
Date				
Actual value				

IMAGING

	CT	MRI	PET
Liver			
Chest			
Abdomen			
Brain			
Pelvis			

Further information e.g., insurance provider if relevant.

INDICATIONS FOR USE: The Delcath CHEMOSAT® Hepatic Delivery System is used for percutaneous intra-arterial administration of chemotherapeutic agent (melphalan hydrochloride) for perfusion of the liver with subsequent extracorporeal filtration of the regional (hepatic) venous blood, lowering the concentration of chemotherapeutic agent in the blood before returning it to the systemic venous circulation. Please refer to the Instructions for Use for full warnings and precautions. **NAME AND ADDRESS OF LEGAL MANUFACTURER:** Delcath Systems, Inc. 566 Queensbury Avenue, Queensbury, NY 12804, USA. **NAME AND ADDRESS OF EU AUTHORISED REP:** Delcath Systems Limited, Unit 19 Mervue Industrial Estate, Mervue, Galway, IRELAND, H91 EP89. **CE MARK AND NOTIFIED BODY NUMBER:** 2797. **CHEMOSAT®** is a registered trademark of Delcath Systems Inc. **WEBSITES:** www.delcath.com, www.chemosat.com, www.againsttheodds.com. **EMEA-P-1026-v1 (v1.0) © 2023 Delcath Systems Ltd.**