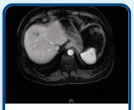
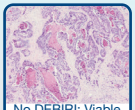
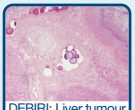
Trials for Hepatic Metastases

	Design	Endpoint	Regimen	Status	n	Location
Colorectal	**Drug-Eluting Bead, Irinotecan (DEBIRI) Therapy of Liver Metastases from Colon Cancer with Concomitant Systemic Oxaliplatin, Fluorouracil and Leucovorin Chemotherapy, and Anti-Angiogenic Therapy**					
	Feasibility phase: 10 patients Randomised phase: 60 patients	Safety Efficacy	FOLFOX + Avastin (IV) vs FOLFOX + Avastin + DEBIRI	Recruiting	70	USA
	Schema **Week 1** FOLFOX + Avastin **Week 2** LC Bead 100mg Irinotecan **Week 3** FOLFOX +Avastin **Week 4** LC Bead 100mg Irinotecan **Week 5** FOLFOX + Avastin **Week 6** Break **Week 7** FOLFOX + Avastin • Then repeat CT to evaluate initial response					
	Response Rates and Pharmacokinetics to Date* • 3 and 6-month response rate: 100% (2 CR, 8 PR) **Surgical Downstaging** • 5 (50%) patients downstaged to resection • All tolerated surgical resection • Pathologic response rates >90%					
	Chemoembolisation with Irinotecan-Loaded DC Bead® (DEBIRI) in Combination with Cetuximab in the First-line Treatment of Patients with KRAS Wild-type Metastatic Colorectal Cancer (mCRC)					
	Feasibility study	Feasibility Safety Efficacy	FOLF + Cetuximab + DEBIRI	Protocol in development	10	Belgium
	A Single-arm Phase II Study of Neoadjuvant Therapy Using Irinotecan Bead in Patients with Resectable Liver Metastases from Colorectal Cancer					
	Single-arm, multicentre	Rate of R0 at Resection	DEBIRI Prior to Resection	Recruiting	20	UK, Spain France
	 Before DEBIRI  No DEBIRI: Viable liver tumour cells  4 weeks after DEBIRI  DEBIRI: Liver tumour cell death					
	Response Rates to Date* • 19 patients recruited and embolised • 17 now operated • 50% demonstrate 90-100% tumour necrosis • 30% demonstrate 50-90% tumour necrosis • 20% demonstrate <50% tumour necrosis					
	A Randomised Phase II Trial of Irinotecan Drug-Eluting Beads Administered by Hepatic Chemoembolisation with Cetuximab (IV) vs Systemic Treatment with Cetuximab (IV) in Patients with Refractory Metastatic Colorectal Cancer and KRAS Wild-type Tumours					
	Multicentre Randomised controlled trial	Safety Efficacy	Cetuximab + DEBIRI vs Cetuximab + irinotecan	Recruiting	74	Germany
	DC Bead®/LC Bead™ International Registry					
	Registry	Safety Efficacy	DEBIRI in current clinical practice	Recruiting	550	Global
Melanoma	**Transcatheter Arterial Chemoembolisation (TACE) with Doxorubicin-Loaded LC Bead in the Treatment of Liver Metastases in Patients with Stage IV Metastatic Melanoma: A Multicenter Pilot, Non-Randomised Feasibility Trial**					
	Multicentre pilot study	Feasibility Safety Efficacy	LC Bead + Doxorubicin	Recruiting	40	USA +Germany
Neuroendocrine	**Transarterial Chemoembolisation of Liver Metastases from Well Differentiated Gastroenteropancreatic Endocrine Tumours with Doxorubicin-Eluting Beads**					
	Single-arm, prospective study	Feasibility Safety Efficacy	DC Bead + Doxorubicin	Published JVIR 19 (6) 2008	30	France

DC Bead®

Clinical Trials for Hepatocellular Carcinoma

	Study Design	Endpoint	Status	n	Location
Bridge to Liver Transplant	**Prospective Randomised Study of Transarterial Doxorubicin-Eluting Bead Embolisation vs Conventional TACE in the Treatment of Patients with Hepatocellular Carcinoma on the Liver**				
	Multicentre, Randomised, Phase II	Histological Response and Transplantability	Recruiting	88	Germany
	Assessment of Chemoembolisation using Doxorubicin-Eluting Beads in Patients Listed for Orthotopic Liver Transplantation with Hepatocellular Carcinoma with Explant Correlation				
	Single-Centre, Phase II	Histological Response and Transplantability	Recruiting	20	New Zealand
Downstage to Resection or Transplant	**LC Drug-Eluting Bead for Treatment of Liver Cancer Which Cannot be Surgically Removed (HCC)**				
	Single-Centre, Phase II	Histological Response and Resectability	Recruiting	18	USA
	A Pilot Study of Neoadjuvant Therapy for Hepatocellular Carcinoma using Doxorubicin-Eluting Embolic Beads				
	Single-Centre, Phase II	Downstage to Transplant	Recruiting	20	USA
Unsuitable for Liver Transplant or Resection	**Chemoembolization of Hepatocellular Carcinoma with Drug-Eluting Beads: Efficacy and Doxorubicin Pharmacokinetics (PRECISION I)**				
	Single-Centre, Phase II	Safety, Efficacy and Pharmacokinetics (Dose Escalation)	Published: Varela M, Real MI, Burrel M et al: Journal of Hepatology 46 (2007) 474-481	27	Spain
	A Phase I/II Trial of Chemoembolization for Hepatocellular Carcinoma using a Novel Intra-arterial Drug-Eluting Bead (PRECISION II)				
	Prospective, Single-Arm, Phase I/II	Phase I: Dose Escalation Phase II: Safety and Efficacy	Published: Poon R, Tso W, Pang R et al: Journal Clinical Gastroenterology and Hepatology 5 (2007) 1100-1108	35	Hong Kong
	Prospective Randomised Study of Doxorubicin in the Treatment of Hepatocellular Carcinoma by Drug-Eluting Bead Embolisation (PRECISION V)				
	International Multicentre, Prospective, Randomised, Single-Blind, Phase II	Safety and Efficacy	Published: Lammer J, Malagari K, Vogl T et al: Cardiovasc Intervent Radiol 33 (2010) 41-52[1]	212	International Multicentre
	Doxorubicin-eluting Bead-enhanced Radiofrequency Ablation of Hepatocellular Carcinoma: a Pilot Clinical Study				
	Prospective, Single-Arm, Pilot	Safety and Efficacy	Published: Lencioni R, Crocetti L, Petruzzi P et al: Journal of Hepatology 49 (2008) 217-222	20	Italy
	Prospective Randomized Comparison of Chemoembolization with Doxorubicin-Eluting Beads and Bland Embolization with BeadBlock for Hepatocellular Carcinoma				
	Prospective, Randomised, Single-Centre	Efficacy, Safety, Time to Progression and Survival	Published: Malagari K, Pomoni M, Kelekis et al: Cardiovasc Intervent Radiol 33 (2010) 541-551	41	Greece
	Single Centre Phase II Trial of Transarterial Chemoembolization with Drug-Eluting Beads for Patients with Unresectable Hepatocellular Carcinoma				
	Prospective, Single-Arm, Phase II, Pilot	Efficacy, Safety, Feasibility, Progression-Free Survival and Overall Survival	Published: Reyes D, Vossen J, Geschwind J et al: The Cancer Journal 15 (2009) 526-532	20	USA
	A Phase II Randomized, Double-blind, Placebo-controlled Study of Sorafenib or Placebo in Combination With Transarterial Chemoembolization (TACE) Performed With DC Bead and Doxorubicin for Intermediate Stage Hepatocellular Carcinoma (HCC)				
	International Multicentre, Randomised, Double-Blind, Phase II	Time to Untreatable Progression	Recruiting	300	International Multicentre

Bridge to Liver Transplant
Downstage to Resection or Transplant
Unsuitable for Liver Transplant or Resection

Reference: 1 Data accepted by Biocompatibles DC Bead product brochures

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Biocompatibles UK Ltd
Chapman House
Farnham Business Park
Weydon Lane, Farnham
Surrey, GU9 8QL, UK

Tel: +44 (0) 1252 732 732
Fax: +44 (0) 1252 732 777
email: marketing@biocompatibles.com
www.biocompatibles.com

Label Colour	Nominal Bead Size	Volume of Beads	Product Code
Yellow	100 - 300 µm	2ml	DC2V103
Blue	300 - 500 µm	2ml	DC2V305
Red	500 - 700 µm	2ml	DC2V507

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