UNIVERSITY HOSPTIALS DORSET HAEMATOLOGY TRIALS PORTFOLIO

Short Study Title	Treatment	Key Inclusion	Key Exclusion	UHD site & status
Acute Myeloid Leukaemia				
Optimise FLT3 (NIHR ID: 57535) Phase II/III First line AML Non-Commercial Optimise FLT3	**Randomisation** Control Arm • DA-Midostaurin Experimental Arm 1 • DA-GO-Midostaurin Experimental Arm 2 • FLAG-Ida-GO-Midostaurin	Diagnosis of AML. Age ⩾16yrs. Considered fit for intensive AML therapy. Confirmed FLT3 ITD or TKD mutation.	Receipt of any previous therapy for AML Other active malignancy requiring treatment Blast transformation of chronic myeloid leukaemia	OPEN Bournemouth Hospital Recruitment end date: 31/7/2029
Waldenstroms Macroglobulaemia				
BGB-11417-203 (NIHR ID: 57972) Phase II Relapsed/Refractory WM Commercial BeiGene	**BCL2 inhibitor (BGB-11417) Sonrotoclax** Cohort 1 R/R disease to both BTKi and anti-CD20 antibody Cohort 2 R/R disease to anti-CD20 antibody and were intolerant to BTKi Cohort 3 R/R disease to BTKi and are unsuitable for chemoimmunotherapy	Age ⩾ 18 years. Diagnosis of WM. Must have R/R disease at study entry unless had intolerance to the most recent therapy.	CNS involvement by WM. Transformation to aggressive lymphoma. Ongoing need for corticosteroid treatment. Prior BCL2 inhibitor.	OPEN Bournemouth Hospital (Travel and expenses reimbursed by sponsor) Recruitment end date: 30/09/2025
B-Cell Malignancies				
BGB-3111-LTE1 (NIHR ID: 46302) Phase III Extension study B-Cell	BTK inhibitor - Zanubrutinib	Patients with B-cell malignancies who are or were previously enrolled in a BeiGene parent study and who are still benefiting or may benefit from treatment with zanubrutinib	Permanently discontinued from zanubrutinib in Parent Study.	OPEN Bournemouth Hospital

Commercial BeiGene				Recruitment end date: 31/12/2027
Chronic Lymphocytic Leukaemia				
STATIC (NIHR ID: 52879) Phase III Non- Commercial STATIC Intermittent vs. continuous treatment strategies in CLL	**BTK inhibitor – Ibrutinib** **BTK inhibitor – Acalabrutinib (previously treated cohort only)** **Randomisation** front line and previously treated **Clinical need cohort** front line patients who have completed 6 years on FLAIR or IcICLLe trials.	Age ⩾ 18 years. Diagnosed with CLL or SLL **Randomisation** Front line Received 6 years of treatment on FLAIR or IcICLLe. In remission. Previously treated Currently receiving Ibrutinib or acalabrutinib for at least 3 years. In remission. **Clinical need cohort** Received 6 years of treatment on FLAIR or IcICLLe. Has signs of progressive or returning CLL after completing 6 years of treatment.	History or current evidence of Richters transformation. **Randomisation** Front line Disease progression. Treatment break for more than 28 days in last 12 months. Previously treated Disease progression. Treatment break for more than 28 days in last 12 months. Creatinine clearance <30ml/min **Clinical need cohort** Eligible for front line randomisation. Treatment other than Ibrutinib. Treatment break for more than 28 days in last 12 months.	OPEN Bournemouth Hospital Poole Hospital Recruitment end date: 01/11/2028
GLORA (NIHR ID: 59709) Phase III Previously treated CLL/SLL Commercial	**Randomisation** **Investigational Arm** BCL-2 selective inhibitor - Lisaftoclax (APG-2575) and BTKi - Acalabrutinib	Age ⩾ 18 years. Patients with CLL/SLL on Acalabrutnib monotherapy as 1st, 2nd or 3rd line for 1 year or more with at least one of the following: Stable disease Or Partial Response	Achieved complete response or disease progression whist on Acalabrutnib. Transformation to Richters. Prior venetoclax or BCL-2 inhibitors.	OPEN Bournemouth Hospital

亞盛醫藥 Ascentage Pharma	**Control Arm** BTKi - Acalabrutinib monotherapy (amendment coming to include BTKi Ibrutinib and Zanubrutinib)	with LN ⩾ 2.5 cm Or Partial response with ALC of 25 x 109/L Or Partial response with at least one of the following high-risk factors: Del 17p and/or p53mut, Complex karyotype with ⩾ 5 abnormal, factors Unmutated IGHV.		(Travel and expenses reimbursed by sponsor) Recruitment end date: 31/10/2025
Myeloma				
EXCALIBER-Maintenance (BMS-IM048-022) (NIHR ID: 54560) Phase III Post transplant – newly diagnosed MM Commercial EXCALIBER Post SCT MAINTENANCE	**Randomisation** **Arm A** Iberdomide (potent CELMoD) **Arm B** Lenalidomide (Noval CELMoD)	Age ⩾ 18 years. Participant has received 3 to 6 cycles of an induction therapy that includes a PI and IMiD with or without a CD38 monoclonal antibody, or VCd, and followed by a single or tandem ASCT. Post-stem cell transplant consolidation is permitted. Participants within 12 months from initiation of induction who achieved at least a PR after ASCT with or without consolidation.	Participant has progressive disease or clinical relapse. Participant has known central nervous system/meningeal involvement of MM. Peripheral neuropathy of Grade ⩾ 2. Participant has any concurrent severe and/or uncontrolled medical condition or psychiatric disease. Participant has gastrointestinal disease that may significantly alter the absorption of either drug.	OPEN Bournemouth Hospital (Travel and expenses reimbursed by sponsor) Recruitment end date: 07/10/2025
MagnetisMM-32 (C1071032) (NIHR ID: 59789) Phase III Relapsed/Refractory MM	**Randomisation** **Arm A** Elranatamab monotherapy **Arm B** Investigators choice	Age ⩾ 18 years. Prior diagnosis of multiple myeloma and previously received at least 1 but no more than 4 prior lines of therapy. At least 2 consecutive cycles of an anti-CD38 antibody and at least 2 consecutive cycles of a lenalidomide-containing regimen.	Plasma cell leukaemia. Stem cell transplant within 12 weeks prior to enrollment. Known CNS involvement. Active graft versus host disease. Previous treatment with a BCMA-directed or CD3 redirecting therapy.	OPEN Bournemouth Hospital Poole Hospital

Commercial 	Elotuzumab-Pomalidomide-Dex (EPd) or Carfilzomib-Dex (Kd) or Pomalidomide-Bortezomib-Dex (PVd)			(Travel and expenses reimbursed by sponsor) Recruitment end date: 31/08/2025 (to be extended)
Myeloproliferative Disorders				
Mithridate High risk Polycythemia Vera (NIHR ID: 39201) Phase III First line PV Non-Commercial 	**Randomisation** Investigational Arm Ruxolitinib Best available therapy Arm Interferon (any formulation) Hydroxycarbamide	Age ⩾ 18 years. Diagnosis of PV within the last 10 years. Meets criteria for high-risk PV. Patients may have received antiplatelet agents and venesection. Patients may have received ONE cytoreductive therapy for PV less than 5 years (BUT they should not be resistant or intolerant to that therapy).	Diagnosis of PV > 10 years previously. Absence of any JAK-2 mutation. Active infection. Patients who have transformed to myelofibrosis.	OPEN Bournemouth Hospital Recruitment end date: 01/07/2027
Richters Syndrome				
STELLAR (NIHR ID: 38923) Phase II Newly diagnosed and relapsed/refractory RS Non-Commercial	**Randomised Cohort** *Must not have developed RS within 4 weeks of last dose of Ibrutinib. R-CHOP V R-CHOP + acalabrutinib **Single arm platform**	Age ⩾ 16 years. **Randomised Cohort** Patients with CLL and newly diagnosed biopsy proven DLBCL-type RS. Suitable for anthracycline-containing immunochemotherapy **Cohort 1**	**Randomised Cohort** Ibrutinib-exposed CLL patients who have been newly diagnosed with RS within four weeks of their last dose of ibrutinib. **All Cohorts** Previous acalabrutinib exposure.	OPEN Bournemouth Hospital Recruitment end date: TBC

STELLAR	Cohort 1 - R/R to CHOP + anti CD20 Acalabrutnib monotherapy Cohort 2 - anthracycline-naïve and who have developed RS within 4 weeks of last dose of ibrutinib R-CHOP + acalabrutinib	Patients with relapsed/refractory RS who received anthracycline based chemotherapy with anti-CD20 monoclonal antibody. **Cohort 2** Ibrutinib-exposed CLL patients who have developed biopsy-proven DLBCL-type RS within four weeks of last dose of ibrutinib. No previous anthracycline treatment and suitable for anthracycline-containing chemoimmunotherapy.	Known central nervous system (CNS) involvement of CLL or DLBCL. Chronic or ongoing active infectious disease.	
Follicular Lymphoma				
PETReA (NIHR ID: 34767) Phase III Previously untreated FL Non-commercial PETReA	**Initial treatment as per standard of care:** Rituximab or Obinutuzumab with either: Bendamustine, CHOP, CVP **Maintenance Randomisation** **PET -ve** = Stop drug or Rituximab/Obinutuzumab alone **PET +ve** = Rituximab/Obinutuzumab alone or Rituximab/Obinutuzumab and Lenalidomide	Age ⩾ 18 years. FL diagnosis – grade 1,2 or 3a. Non-contiguous stage II, stage III or stage IV. Must be in need of systemic therapy in accordance with GELF criteria. Must not have received prior systemic therapy for lymphoma. Must have a WHO performance status score of less than or equal to 2.	History of active malignancy during the past 3 years. Laboratory abnormalities unless due to lymphoma. Central nervous system involvement. Ongoing need for medication that is not permitted in the trial.	OPEN Poole Hospital Recruitment end date: 31/10/2025
OLYMPIA 5 (R1979-ONC-22102) (NIHR ID: 56593)	**** R/R for FL and MZL Randomisation**	Age ⩾ 18 years.	Primary CNS lymphoma or known involvement.	OPEN

Phase III Relapsed/Refractory FL/MZL Commercial REGENERON science to medicine®	**Arm A** Odronextamab (anti-CD20 x anti-CD3 bispecific antibody) plus Lenalidomide **Arm B** Rituximab in combination with Lenalidomide	Local histologic confirmation of FL grade 1-3a or MZL (nodal, splenic, or extra nodal MZL). Must have refractory disease or relapsed after at least 1 prior line (with a duration of at least 2 cycles), should include an anti-CD20. Have measurable disease, nodal lesion of >1.5cm, extranodal >1cm.	Participants with histological evidence of transformation to a high-grade or diffuse large B-cell lymphoma. A malignancy other than NHL, must be cancer free for at least 3 years. Active infection.	Bournemouth Hospital (Travel and expenses reimbursed by sponsor) Recruitment end date: 31/01/2027
Mantle Cell Lymphoma				
CARAMEL (NIHR ID: 51359) Phase II Previously untreated elderly or frail MCL patients Non-Commercial CARAMEL	Acalabrutnib (BTKi) Rituximab 6 cycles Followed by: Acalabrutnib monotherapy maintenance	⩾60 years of age. Stage II-IV MCL and requiring treatment. ECOG performance status 0-3. One or more of the following: – ⩾ 80 years – CIRS-G score ⩾ 6 – Left ventricular ejection fraction (LVEF) ⩽50% – Significant co-morbidities or cardiac risk factors – Heart failure – Impaired respiratory function – Significant respiratory illness	Prior therapy for MCL. Fit enough to receive standard, full dose cytotoxic immunochemotherapy. Clinically significant cardiovascular disease. Uncontrolled AIHA or ITP. Requires treatment with proton pump inhibitors. Calculated creatinine clearance <30 mL/min.	OPEN Bournemouth Hospital Poole Hospital Recruitment end date: 31/08/2025.
BGB-11417-302 (NIHR: 65142) Phase III Relapsed/refractory Commercial	**Double blind study** **Experimental arm:** Zanubrutnib plus Sonrotoclax **Control arm:** Zanubrutnib plus placebo	Age ⩾ 18 years. Received 1 to 5 prior line of treatment including an anti-CD20 mAb-based immunotherapy or chemoimmunotherapy and requiring treatment.	Prior therapy with BCL2i. Prior therapy with covalent or non-covalent BTKi. Prior ASCT or chimeric antigen receptor T-cell therapy within	OPEN Poole Hospital Recruitment end date: 30/08/2027

BeiGene		Measurable disease defined as ⩾ 1 nodal lesion, that is > 1.5 cm in longest diameter, or ⩾ 1 extranodal lesion that is > 1 cm in longest diameter.	3 months before the first dose of study drug. Prior allogeneic stem cell transplant within 6 months of the first dose of the study treatment. Prior malignancy (other than the disease under study) within the past 2 years.	(Travel and expenses reimbursed by sponsor)
Marginal Zone Lymphoma				
RITZ (IELSG48) (NIHR ID: 63793) Phase III Previously untreated splenic MZL Non-Commercial IELSG	**Randomisation** **Arm A** Rituximab plus Zanubrutnib **Arm B** Rituximab Monotherapy	Age ⩾ 18 years. Confirmed diagnosis of SMZL. Measurable lesions. Treatment needs according to ESMO guideline criteria. Adequate liver, kidney, and coagulation function. Able to swallow whole tablets.	Central nervous system involvement. Prior (other) malignancy within 2 years. Significant cardiovascular disease. Active systemic infection requiring iv antimicrobial treatment. Active, uncontrolled autoimmune condition requiring steroid therapy prednisone equivalent >20 mg/day.	OPEN Bournemouth Hospital Recruitment end date: 01/05/2026

Recently closed to recruitment studies

Olympia 1 – first line follicular lymphoma

Remodl-A – previously untreated Diffuse Large B-Cell Lymphoma (DLBCL)