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 **Cohort 1 and 3 closed to recruitment**	**BCL2 inhibitor (BGB-11417) Sonrotoclax** Cohort 1 R/R disease to both BTKi and anti-CD20 antibody (CLOSED) 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 (CLOSED)	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 expenses reimbursed by sponsor) Recruitment end date: 30/09/2025
B-Cell Malignancies				
BGB-3111-LTE1 (NIHR ID: 46302)	BTK inhibitor - Zanubrutinib	Patients with B-cell malignancies who are or were previously enrolled in a BeiGene	Permanently discontinued from zanubrutinib in Parent Study.	OPEN

Phase III Extension study B-Cell Commercial BeiGene		parent study and who are still benefiting or may benefit from treatment with zanubrutinib		Bournemouth Hospital 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	**Randomisation**	Age ⩾ 18 years. Patients with CLL/SLL on Acalabrutnib monotherapy as 1st, 2nd or 3rd line for 1	Achieved complete response or disease progression whist on Acalabrutnib.	OPEN

Previously treated CLL/SLL Commercial 亞盛醫藥 Ascentage Pharma	**Investigational Arm** BCL-2 selective inhibitor - Lisaftoclax (APG-2575) and BTKi (Ibrutinib, Acalabrutinib and Zanubrutinib) **Control Arm** BTKi monotherapy (continue on same BTKi the patient is on)	year or more with at least one of the following: Stable disease Or Partial Response 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.	Transformation to Richters. Prior venetoclax or BCL-2 inhibitors.	Bournemouth Hospital (Travel expenses reimbursed by sponsor) Recruitment end date: 31/10/2025
BGB-16673-302 (NIHR ID: 66043) Phase III CLL previously exposed to both BTK and BCL2 inhibitors BeiGene **Coming October 2025**	**Randomisation 3:2 Ratio** **Investigational Arm (Arm A)** BGB-16673 (oral) **Control Arm (Arm B)** Investigators' choice of: • Idelalisib plus Rituximab • Bendamustine plus Rituximab (patients can not have del(17p) or TP53 mutation) • Venetoclax plus Rituximab (patients must have best response of last BCL2i regimen, of PR or better. Last BCL2i should have been at least 1 year prior to most recent progression) Patients that progress on Arm B can cross over to Arm A upon sponsor approval.	Age ⩾ 18 years. Prior exposure to both BTK and BCL2 inhibitors (at least 80 patients with prior exposure to ncBTKi). Measurable disease by CT - at least 1 lymph node, 1.5cm in the longest diameter. ECOG Performance Status of 0 to 2. Patients must have adequate organ function.	Known prolymphocytic Leukemia or history of, or currently suspected, Richter's transformation. Prior autologous stem cell transplant or chimeric antigen receptor-T cell therapy in the last 3 months. Patients with any malignancy ⩽ 3 years before randomization except for CLL and any locally recurring cancer that has been treated curatively. Prior exposure to any BTK protein degraders. Patients with clinically significant cardiovascular disease.	IN SET UP Bournemouth Hospital (Travel expenses reimbursed by sponsor) Recruitment end date: 15/05/2028

BGB-11417-303 (NIHR ID: 67252) Phase III Relapsed/refractory CLL/SLL BeiGene **NOW OPEN**	**Randomisation - Ratio 2:2:1:2** **Arm A** Sonrotoclax plus Obinutuzumab (SO) **Arm B** Sonrotoclax plus Rituximab (SR) **Arm C** Sonrotoclax plus Obinutuzumab with MRD-guided therapy (MRD-SO) **Arm D** Venetoclax plus Rituximab (VR)	Age ⩾ 18 years. Patients must have ⩾ 1 prior therapy for CLL/SLL. For each line of therapy, patients must have received at least 2 cycles of this therapy. Adequate marrow function. Life expectancy > 6 months. Indication for CLL/SLL treatment is met as per IWCLL 2018 criteria. Adequate renal function.	Known active prolymphocytic leukaemia or currently suspected Richter's transformation. Patients who have active symptomatic COVID-19 infection. Prior autologous stem cell transplant < 3 months after transplant; or prior CAR-T therapy < 3 months after cell infusion. History of prior or active malignancy within the past 18 months. Clinically significant cardiovascular disease.	Bournemouth Hospital (Travel expenses reimbursed by sponsor) Recruitment end date: 01/06/2026
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 expenses reimbursed by sponsor) Recruitment end date: 07/10/2025 (to be extended)

MagnetisMM-32 (C1071032) (NIHR ID: 59789) Phase III Relapsed/Refractory MM Commercial  	**Randomisation** **Arm A** Elranatamab monotherapy **Arm B** Investigators choice Elotuzumab-Pomalidomide-Dex (EPd) or Carfilzomib-Dex (Kd) or Pomalidomide-Bortezomib-Dex (PVd)	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 (Travel 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)	**Randomised Cohort**	Age ⩾ 16 years. **Randomised Cohort**	**Randomised Cohort**	OPEN

Phase II Newly diagnosed and relapsed/refractory RS Non-Commercial 	*Must not have developed RS within 4 weeks of last dose of Ibrutinib. R-CHOP V R-CHOP + acalabrutinib **Single arm platform** 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 CLL and newly diagnosed biopsy proven DLBCL-type RS. Suitable for anthracycline-containing immunochemotherapy **Cohort 1** 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.	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. Known central nervous system (CNS) involvement of CLL or DLBCL. Chronic or ongoing active infectious disease.	Bournemouth Hospital Recruitment end date: 31/12/2025
Follicular Lymphoma				
PETReA (NIHR ID: 34767) Phase III Previously untreated FL Non-commercial 	**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	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

	PET +ve = Rituximab/Obinutuzumab alone or Rituximab/Obinutuzumab and Lenalidomide			
OLYMPIA 5 (R1979-ONC-22102) (NIHR ID: 56593) Phase III Relapsed/Refractory FL/MZL Commercial REGENERON science to medicine®	**** R/R for FL and MZL** **Randomisation** **Arm A** Odronextamab (anti-CD20 x anti-CD3 bispecific antibody) plus Lenalidomide **Arm B** Rituximab in combination with Lenalidomide	Age ⩾ 18 years. 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.	Primary CNS lymphoma or known involvement. 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.	OPEN 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: closing soon
BGB-11417-302	**Double blind study**	Age ⩾ 18 years.	Prior therapy with BCL2i.	OPEN

(NIHR: 65142) Phase III Relapsed/refractory Commercial BeiGene	**Experimental arm:** Zanubrutnib plus Sonrotoclax **Control arm:** Zanubrutnib plus placebo	Received 1 to 5 prior line of treatment including an anti-CD20 mAb-based immunotherapy or chemoimmunotherapy and requiring treatment. 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.	Prior therapy with covalent or non-covalent BTKi. Prior ASCT or chimeric antigen receptor T-cell therapy within 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.	Poole Hospital (Travel expenses reimbursed by sponsor) Recruitment end date: 30/08/2027
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

Olympia 1 – first line follicular lymphoma

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