

### Summary of CLL Trials Portfolio ~ May 2019:

	Currently Open or soon to Open Trials	Future Planned Trials
Patients considered fit for FCR (previously untreated)	CLL10 (FLAIR) – Phase III FCR vs Ibrutinib monotherapy vs Ibrutinib+venetoclax. (FCRvR+I arm closed in July 2018.) Recruitment scheduled to close late 2019	Acerta ACE-CL-007
Patients considered unfit for FCR (previously untreated)		Acerta ACE-CL-007
17p deleted CLL (previously untreated)	FLAIR I+V arm for 17p/P53mutated	
Consolidation/Maintenance	-	INTERRUPT Trial (Ibrutinib)
Stage A CLL	OXLORED Observational Study Planned to open for recruitment late 2019	
Richter's Transformation Frontline and relapsed	STELLAR: CHOP-R vs CHOP-R in combination with ACP-196 Bloodwise TAP Trial (First patient planned to be recruited Spring 2019)	
Relapsed/Refractory CLL	Beigene BGB-3111-305_CLL_Phase_3 Phase 3, Randomized Study of Zanubrutinib (BGB-3111) Compared with Ibrutinib in Patients with Relapsed/Refractory Chronic	

	Lymphocytic Leukemia or Small Lymphocytic Lymphoma	
Relapsed/Refractory CLL	Phase 1/Phase 2 ATRi + Acalabrutinib study (ACE-CL-110)	Sunesis Phase 1/Phase 2 dose escalation and cohort expansion study of SNS062 in patients with B cell malignancies  Zuma-8 CAR-T Cell Trial
Relapsed 17p del CLL	Phase 1/Phase 2 ATRi + Acalabrutinib study (ACE-CL-110)	Sunesis Phase 1/Phase 2 dose escalation and cohort expansion study of SNS062 in patients with B cell malignancies  Zuma-8 CAR-T Cell Trial
Relapsed 11q del CLL (T-PLL)	-	?HOVON T-PLL study

## **CLL10 FLAIR**

Phase III randomised trial to assess whether Ibrutinib+Rituximab or Ibrutinib + Venetoclax or Ibrutinib monotherapy is superior to Fludarabine, Cyclophosphamide and Rituximab (FCR) in terms of progression-free survival and secondary objectives overall survival, response, minimal residual disease negativity and relapse, toxicity, quality of life and health economics. Previously untreated patients are eligible if they are considered fit for FCR.

The FCR v Ibrutinib +Rituximab arm stopped in July 2018

The trial is sponsored by the Leeds Teaching Hospitals.

<http://medhealth.leeds.ac.uk/LICTR/flair>

<http://www.cancerresearchuk.org/about-cancer/trials/a-trial-ibrutinib-rituximab-chronic-lymphocytic-leukaemia-flair>

<https://beartofresearch.nihr.ac.uk/>

## **STELLAR**

A Phase II, randomised study of CHOP-R in combination with acalabrutinib compared to CHOP-R in patients with newly diagnosed Richter's Syndrome (RS) followed by an extension study to evaluate acalabrutinib and other novel therapies in relapsed/refractory RS

The trial is managed by the Cancer Research UK Clinical Trials Unit at the University of Birmingham.

This research is being funded by Bloodwise as part of the Trials Acceleration Program (TAP) and by Acerta Pharma.

Recruiting is scheduled to include:

Oxford Churchill Hospital  
St James Hospital Leeds  
Beatson WOSCC

Belfast City Hospital  
 Clatterbridge Cancer Centre  
 Kings College Hospital  
 Leicester Royal Infirmary  
 Nottingham City Hospital  
 Queen Elizabeth Birmingham  
 Royal Bournemouth Hospital  
 Sheffield Hallam Hospital  
 Southampton General  
 St Bartholomew's Hospital  
 The Christie  
 University Hospital of Wales  
 University College London

## **ACE-CL-110**

A Study Investigating AZD6738 Monotherapy (ATR Inhibitor) and Acalabrutinib in Combination With AZD6738 in Subjects With Relapsed or Refractory High-risk Chronic Lymphocytic Leukemia (CLL)

AZD6738 is an oral ATR kinase inhibitor.

Acalabrutinib is a new generation oral BTK inhibitor.

See: <https://clinicaltrials.gov/ct2/show/NCT03328273>

An International Trial sponsored by Acerta Pharma BV and currently recruiting in the UK at:

Leeds Teaching Hospitals NHS Trust  
 University of Oxford  
 Nottingham University Hospitals NHS Trust  
 Cardiff and Vale UHB Headquarters  
 Cambridge University Hospitals NHS Trust  
 The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust  
 King's College London  
 Barts Health NHS Trust  
 University College London (UCL) - Cancer Research UK & UCL Cancer Trials Centre  
 University of Southampton  
 University of Birmingham  
 University of Liverpool

## **OXLORED Study**

This is a study to identify the clinical, genomic and immunological predictive markers of progression to malignant disease.

It will be open to individuals diagnosed in the last 2 years with high count MBL, Binet Stage A CLL, IgG/ IgG/ IgM MGUS, asymptomatic WM not requiring treatment, and smouldering myeloma not requiring treatment.

The study is being undertaken by the University of Oxford and recruitment is planned to commence in 2019.

GWB

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