

# HAEMATOLOGY ONCOLOGY RESEARCH TEAM

WELCOME!

SEPTEMBER 10 ISSUE 5

Welcome to the fifth edition of the Haematology Oncology research team newsletter! In this edition, which marks the 1 year anniversary of the newsletter, we will continue to update you on the latest haematology and lymphoma trial news.

## FOCUS ON: AML AND FOLLICULAR NON-HODGKIN LYMPHOMA

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### HODGKIN LYMPHOMA

- **PAIReD:** Reduced intensity transplantation using the BEAM-Alemtuzumab protocol for primary refractory/relapsed refractory Hodgkin's disease.
- **ReACH:** Reduced intensity sibling allogeneic transplantation for relapsed, chemosensitive, PET positive Hodgkin lymphoma.
- **RATHL:** PET-adapted dose-escalation of therapy in advanced stage HL.
- **AETHERA:** Randomisation of SGN-35 versus best supportive care post autograft in relapsed Hodgkin Lymphoma

### MANTLE CELL LYMPHOMA

- **MCP3:** Randomised phase 3 comparing FC Vs. FC-Rituximab 1st line.
- **SPRINT:** Randomised phase 3 comparing Lenalidomide to 'dealers choice' chemotherapy.
- **CD19:** As with follicular NHL.

### T-CELL LYMPHOMA

- **T-cell project:** Database registration for all T-cell NHL.
- **CHOP-Campath:** Phase 2 dose escalation study to find the MTD of Campath in conjunction with CHOP chemotherapy.

### FOLLICULAR LYMPHOMA

- **FORT:** Randomisation of high Vs. low dose radiotherapy for any radiotherapy indication in FL.
- **CD19:** Phase I study of adoptive transfer of autologous T Cells with pre-conditioning chemotherapy and IV IL2 in CD19 positive malignancy.
- **Halozyme:** Randomised s.c versus i.v. rituximab in patients receiving maintenance therapy.
- **PACIFICO:** Randomisation of R-CVP versus R-FC first line in patients over the age of 60.

### DLBCL

- **14 Vs 21 PET sub study:** prognostic value of early PET after 2 cycles of R-CHOP.
- **ORRCHARD:** Rituximab-DHAP Vs. Ofatumumab-DHAP in relapsed disease.
- **Inotuzumab Ozogamicin:** Phase 2 study of a novel antibody-drug conjugate in relapsed disease. Targets CD22.
- **CD19:** Phase I study of adoptive transfer of autologous T Cells with pre-conditioning chemotherapy and IV IL2 in CD19 positive malignancy.

## STUDIES...OPEN

### ROMIPILOSTIM

We would like to increase recruitment to the romiplostim study so please keep a look out for any potential patients. Please see the enclosed newsletter and refer any patients you think would be suitable.

### AML / MDS

- **AML16:** NCRN study for older AML/high risk MDS.
- **AML17:** NCRN study for adults with AML/high risk MDS.
- **AML Len 5 :** Lenalidomide as monotherapy & in combination with standard chemotherapy for AML/ high risk MDS with chromosome 5 abnormalities.
- **Romiplostim:** A study of Romiplostim for thrombocytopenia in low or INT-1 Risk MDS.
- **MDS Registry Study:** European registry for newly diagnosed MDS with low or INT-1 Risk.
- **MDS 005:** Lenalidomide vs placebo in transfusion-dependent anaemia due to IPSS Low or Int-1 risk MDS without deletion 5q[31].
- **Clavella:** Elacytarabine vs investigators choice in late stage AML.

### MYELOMA

- **Myeloma X:** Determine the role of a 2nd autologous transplant after high-dose chemotherapy.
- **Myeloma XI:** Thalidomide, Lenalidomide and Bortezomib combinations with maintenance Lenalidomide.
- **Vantage:** Open-label study of Vorinostat with Bortezomib in relapsed/refractory myeloma.
- **KW2478-INT-001:** Phase 2/3 study of KW-2478 with Bortezomib in relapsed/refractory myeloma.
- **Panorama:** HDAC inhibitor with bortezomib and dexamethasone.

### CML

- **Spirit 2:** Randomised comparison of imatinib and dasatinib in newly-diagnosed chronic phase CML.
- **CMML201:** Phase II study of azacitidine in CMML.

### TRANSPLANT

- **Ricaza:** Adjunctive azacitidine in patients undergoing RIC allogeneic transplantation for AML or MDS.
- **CMV impact:** Immunoprophylactic Adoptive Cellular Therapy Study.

### ALL

- **UKALL2003:** UK national randomised trial for children and young adults with ALL.

### CLL

- **Admire:** NCRN comparative study of FCR vs FCR plus mitoxantrone in previously untreated CLL.
- **Mable:** A Phase IIIb study of Rituximab with bendamustine or Chlorambucil.
- **CLL009:** Safety and efficacy of Lenalidomide dose regimens in relapsed/refractory B-Cell CLL.
- **Respect:** Use of Lenalidomide in early stage CLL with poor prognostic factors.

## STUDIES IN PLANNING

- **YM155:** Phase 1 study of a survivin inhibitor in conjunction with rituximab.
- **CHT25:** Radioimmunotherapy in refractory Hodgkin Lymphoma .
- **BELIEF:** Belinostat, a HDAC inhibitor in relapsed T-cell NHL.
- **MCL Mini Allo:** Low intensity allogeneic transplant in mantle cell lymphoma
- **PICLLe:** Olaparib in CLL patients with 11q deletion or ATM mutation , or T-Prolymphocytic Leukaemia and Mantle Cell Lymphoma
- **Reveal:** Velcade combination chemotherapy in relapsed or refractory patients with AML amyloidosis



**WE NEED  
YOUR  
HELP!**

As a tertiary referral centre we specialise in clinical trials that may not be available anywhere else in your catchment area. We ask you to review all your patients who may be eligible for our studies. We are relying on outside referrals to recruit to these studies, so please get in touch.

If you would like any more information about any of our studies, contact details for the research team are available on page 7.



## FOCUS ON... AML

### CLAVELA

**A randomised phase III study of elacytarabine vs. investigator's choice in patients with late stage acute myeloid leukaemia.**

Patients will be randomly assigned to treatment with either elacytarabine as a single agent (experimental treatment) or investigator's choice (control treatment).

The investigator will determine the control treatment prior to randomisation. Patients randomised to elacytarabine will receive 1-2 courses to induce remission and 1-2 courses as consolidation. Those who benefit may receive repeated courses of study drug even if remission is not attained.

**Primary Objective:** Compare the efficacy, measured as overall survival, response rate and duration of response, safety profile of elacytarabine and investigator's choice in patients with late stage AML.

#### Inclusion Criteria:

- ≥ 18 years of age
- Confirmed diagnosis of AML and received two or three previous induction/re-induction regimens. One of the (re-)induction regimens could be stem cell transplantation for achievement of remission. Maintenance and consolidation may have been given, but are not counted as previous regimens.
- Bone marrow aspirates and/or biopsies must contain > 5% leukaemic blast cells or the patient must have extramedullary AML or evidence of leukaemic blast cells in the peripheral blood.
- Must have:
  - never attained CR or CRi **OR**
  - failed initial induction therapy, and attained CR or CRi after salvage therapy and relapsed within <6 months **OR**
  - have attained CT or Cri after initial induction therapy and relapsed within <12 months, and failed to respond to salvage therapy **OR**
  - have relapsed after the latest CR or CRi within <6 months
- Must have received cytarabine if under the age of 65 years

#### Exclusion Criteria:

- History of allergic reaction to egg
- Persistent clinically significant toxicities from previous chemotherapy
- HIV positive, active heart disease or uncontrolled intercurrent illness
- Impairment of renal function which, in the opinion of the investigator, would limit compliance to the study

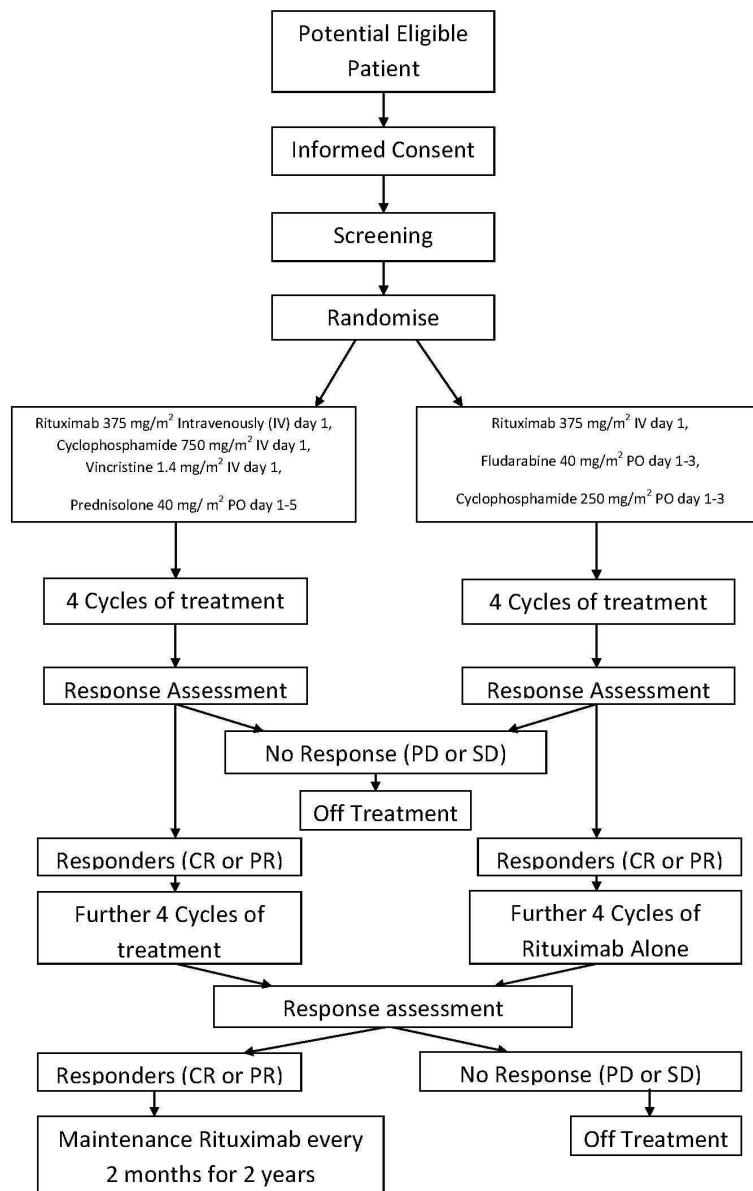
# FOCUS ON... FOLLICULAR NHL

## PACIFICO

A randomised comparison of R-FC vs R-CVP in elderly (>60 y.o.) patients with Follicular Lymphoma.

**Objective:** FL predominantly affects the elderly, yet the optimum treatment for older patients with the disease has not been defined. This study aims to address this question by comparing the drug combination that is currently considered the gold-standard (R-CVP) with a newer combination (R-FC) that might be more effective without being significantly more toxic. In order to take into account the balance between efficacy and toxicity, a dual primary endpoint has been employed: progression-free survival and toxicity in the form of grade 3-4 infection.

### Study Design:



Every issue we will be focusing on a specific study or disease area in order to increase recruitment. Please see our 'focus on pages' this month featuring studies which will be suitable for your AML and follicular NHL patients.



## FOCUS ON... FOLLICULAR NHL

### Inclusion Criteria:

- Ann Arbor stage II-IV
- Aged 60 years or over, or aged less than 60 but anthracycline-based therapy contra-indicated
- Requires initiation of treatment
- CrCl >30 ml/min

### Exclusion Criteria:

- Prior anti-lymphoma treatment
- Overt transformation to diffuse large B-cell lymphoma
- Grade 3b follicular lymphoma
- WHO performance status 3 or 4
- Creatinine clearance < 30 mL/min
- Pre-existing neuropathy

**Contact:** Professor John Radford, Dr. Kim Linton or Dr. Adam Gibb

## HALOYZME

**A two-stage phase Ib study to investigate the pharmacokinetics, safety and tolerability of rituximab subcutaneous (SC) formulation in patients with follicular lymphoma (FL) as part of maintenance treatment.**

**Objective:** To determine a SC rituximab dose that yields comparable serum trough concentrations to IV rituximab.

**Study Design:** Subjects will be randomized between a s.c or i.v dose for one (any) dose of their 2 year maintenance

### Inclusion Criteria

- A lymph node biopsy must have been performed prior to commencement of induction treatment to histologically confirmed CD20-positive, follicular NHL grade 1, 2 or 3a
- Patients treated with, and responded to rituximab (375 mg/m<sup>2</sup>); i.e. patients must have achieved a documented PR or CR at the end of induction treatment
- Patients must have completed induction therapy and must have received at least one dose of IV rituximab maintenance treatment. The minimum induction therapy required is 4 cycles of rituximab with any number of chemotherapy cycles.
- Patients must commence maintenance within 12 weeks of completing induction

### Exclusion Criteria

- History of severe allergic or anaphylactic reactions to humanized or murine monoclonal antibodies, other than rituximab. Known sensitivity or allergy to murine products.



**TEAM NEWS**

**ARE YOU  
GCP  
TRAINED?**

If not, please see below for details on how to book on to a course at The Christie ....

**HAEMATOLOGY AND TRANSPLANT WEBSITE LAUNCH**

We are pleased to announce the launch of our new website which contains the latest information on our clinical trial portfolio and research team members.

To visit the site please [click here](#).

**ADVANCES IN HAEMATOLOGY RESEARCH 2010  
STUDY DAY**

Thanks to everyone who attended the study day in June 2010, the day was a great success with a fantastic turnout!

**OUR TEAM HAS GROWN!**

We would like to wish Justine Parkin a big warm welcome back to the team, she will be returning in October after being on maternity leave.



The haematology team has also recruited an additional member!

Stephanie Manning has joined our team in September as a Senior Clinical Trials Assistant. We would like to welcome Stephanie to the team!



**DATES TO KEEP IN MIND!**

**IS YOUR GCP TRAINING UP TO DATE?**

If you are working in clinical trials, it is essential that you complete GCP training every 2 years.

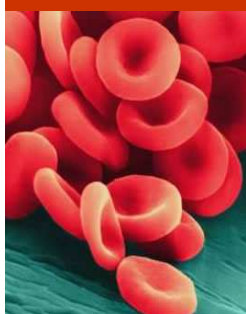
The following dates for Christie GCP training are available:

**Tuesday 30th November 2010**

Update sessions are being held on:

**Monday 29th November 2010 (am or pm session)**

To book on please contact Rachael Baxter in R&D (Rachael.Baxter@christie.nhs.uk).



## CONTACT DETAILS

**NEXT  
ISSUE**  
Dec 10

In our next issue we will be focusing on...

Transplant and Hodgkins.

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