

HAEMATOLOGY & TRANSPLANT RESEARCH TEAM

SEPTEMBER 09 ISSUE 1

WELCOME!

Welcome to the first edition of the Haematology and Transplant research team newsletter!

Every 3 months we will keep you fully informed of the team's activities. In addition to this, in each issue we will be looking at specific studies which are new or are facing recruitment difficulties....

STUDY STATUS UPDATES...OPEN

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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 randomized 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.

ALL

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

MYELOMA

- **Myeloma X:** NCRN study to determine the role of a 2nd autologous transplant following prior high-dose chemotherapy and autologous transplant.
- **Velcade:** Randomized study of subcutaneous and intravenous VELCADE in previously treated myeloma.
- **KW2478:** A Phase I study of KW2478 in patients with relapsed/refractory myeloma.
- **MERCK 095:** Open-label study of Vorinostat in combination with Bortezomib in relapsed and refractory multiple myeloma.
- **Myeloma IX:** Myelomatosis therapy trial for patients of all age groups. Relapsed sub protocol.

TRANSPLANT

- **Ricaza:** Adjunctive azacitidine in patients undergoing RIC allogeneic transplantation for AML or MDS.

SUPPORTIVE CARE

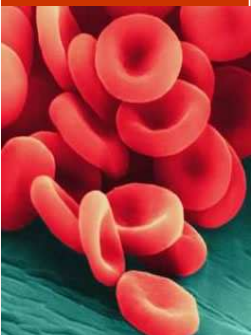
- **Anidulafungin:** Comparative study of anidulafungin and voriconazole vs voriconazole alone for primary therapy of proven or probable invasive aspergillosis.

CML

- **Spirit 2:** Randomised comparison of imatinib and dasatinib in newly-diagnosed chronic phase CML.

CLL

- **Lucid:** Lumiliximab with FCR vs FCR alone in relapsed CLL.
- **The Continuum Trial:** Lenalidomide as maintenance therapy for B-cell CLL following second-line therapy.



STUDIES IN PLANNING

FOCUS ON...

Every issue we will be focusing on a specific study or disease area in order to increase recruitment. Please see our focus on MDS pages this month featuring two studies which will be suitable for many of your MDS patients. See pages 2 and 3 for more details.

We will be closely monitoring outside referrals to studies and presenting a league table so make sure you're top of the league for recruitment!

- **AZD1152 C14 Mass Balance:** A phase I study to assess the metabolism, excretion and pharmacokinetics of AZD1152 and AZD1152 hQPA following intravenous administration of [¹⁴C]-AZD1152 in patients with AML.
- **Admire:** NCRN comparative study of FCR vs FCR plus mitoxantrone in previously untreated CLL.
- **ReACH:** A study of reduced intensity sibling allogeneic transplantation for relapsed, chemosensitive, PET positive Hodgkin lymphoma.
- **PAIRed:** Reduced intensity transplantation using the BEAM-Alemtuzumab protocol for primary refractory/relapsed refractory Hodgkin's disease.

FOCUS ON... MDS

MDS REGISTRY

A prospective, multicenter European Registry for newly diagnosed patients with Myelodysplastic Syndromes of IPSS low and intermediate-1 subtypes.

Study Objectives: To describe the demographics and the disease-management of IPSS low and intermediate-1 MDS patients who are newly diagnosed and classified according to the WHO criteria. To collect and to present data on clinical characteristics, disease-management and relevant outcomes.

Inclusion criteria:

- Male or female.
- Age > 18 years.
- Newly diagnosed patient (within 3 months from the date of the diagnostic bone marrow aspirate).
- MDS classified according to WHO criteria.
- IPSS Risk group Low or Intermediate-1.

Exclusion criteria:

- Age <18 years.
- Intermediate-2 or high risk MDS.
- Secondary/therapy-related MDS.

Treatment schedule

The registry is designed to collect information from a large cohort of newly diagnosed MDS patients and is not a treatment study. Patients will be required to complete a reported outcomes questionnaire and blood and urine samples will be collected for biological correlative studies. These will be performed at the start of study then every 6 months. Enrolment time will be 18 months with a follow-up period of 5 years.



**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 MDS patients who may be eligible for our MDS 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 4.



FOCUS ON... MDS

ROMIPILOSTIM

A Randomized, Double Blind, Placebo Controlled Study Evaluating the Efficacy and Safety of Romiplostim Treatment of Thrombocytopenia in Subjects with Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS)

Primary Objective: To evaluate the efficacy of romiplostim for the treatment of thrombocytopenia in subjects with international prognostic scoring system (IPSS) low or intermediate-1 risk MDS as measured by the number of clinically significant bleeding events.

Inclusion Criteria:

- Diagnosis of MDS (WHO classification), IPSS low or intermediate-1
- The mean of the two platelet counts taken within 4 weeks prior to randomization must be:
 - $\leq 20 \times 10^9/L$, with no individual count $>30 \times 10^9/L$, with or without a history of bleeding, OR
 - $\leq 50 \times 10^9/L$, with no individual count $>60 \times 10^9/L$ with a history of bleeding
- Subjects must be ≥ 18 and ≤ 90 years of age at the time of informed consent. Subjects between 85 and 90 years of age must have been diagnosed with MDS ≤ 5 years from study start
- ECOG status of 0-2
- Bone marrow biopsy and aspirate with cytogenetics within 3 months of starting first dose of investigational product

Exclusion criteria:

- Have ever received any disease-modifying treatment for MDS
- Previously diagnosed with intermediate-2 or high risk MDS using the IPSS
- Prior history of leukemia, aplastic anemia, or other non-MDS related bone marrow stem cell disorder, hematopoietic stem cell transplantation
- Persistent peripheral blood monocytosis (≥ 3 months with an absolute monocyte count $>1,000/\mu L$)
- Active or uncontrolled infections
- Unstable angina, congestive heart failure, uncontrolled hypertension or cardiac arrhythmia, or recent MI (1yr)
- History of arterial thrombosis within the past year
- History of venous thrombosis that currently requires anti-coagulation therapy
- Received IL-11 within 4 weeks of the first dose of investigational product
- Have previously received any thrombopoietic growth factor
- Receipt or planned receipt of G-CSF, peg-G-CSF, or GM-CSF within 4 weeks of the first dose
- Known hypersensitivity to any recombinant *E coli*-derived product

Treatment schedule

Patients will receive S/C romiplostim/placebo weekly for 26 weeks followed by a 2-4 week washout period then a further 24 weeks of weekly treatment. During the interim washout period a bone marrow biopsy will assess changes in the marrow. Subjects will be followed for survival for an additional 60 months following end of study.

DATES TO KEEP IN MIND!

NEXT ISSUE

December 09

Focus on... CLL studies.

Remember to look out for our first study referral league table so start looking out for patients !!

IS YOUR GCP TRAINING UP TO DATE?

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

The following dates for Christie GCP training are available:

Monday 9th November 2009

Thursday 3rd December 2009

To book on please contact Kate Carr-Deed in R&D (Kate.Carr-Deed@christie.nhs.uk), if these dates are not suitable and your training is due please contact Antonia Veale for some alternative external courses (Antonia.Veale@christie.nhs.uk).

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STAFF NEWS

One of our longstanding members of staff Justine Parkin is going on maternity leave in the near future. We wish her all the best and look forward to her return next October.