

Research Ethics  
Committee for Wales

Chairman/Cardeirydd :  
Dr Gordon Taylor

# REC for WALES

Ymchwil Ethegau  
Aml-Ganolfan  
yng Nghymru

Administrator/Gweinyddes:  
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Fax No. 029 2037 6824

17 July 2009

Professor Alan Burnett  
Professor of Haematology  
Department of Haematology  
School of Medicine,  
Heath Park,  
Cardiff CF14 4XN

Dear Professor Burnett

**Study title:** AML 17: A Programme of Development for the Treatment of Younger Patients with Acute Myeloid Leukaemia and High Risk Myelodysplastic Syndrome  
**REC reference:** 08/MRE09/29  
**Protocol number:** 2, dated May 2008  
**EudraCT number:** 2007-003788-16  
**Amendment number:** Amendment 1 modified  
**Amendment date:**

Thank you for submitting the above amendment, which was received on 03 July 2009. It is noted that this is a modification of an amendment previously rejected by the Committee.

The modified amendment was reviewed by the Sub-Committee in correspondence. A list of the members who took part in the review is attached.

#### Ethical opinion

Members noted that it is still not clear from the documentation provided as to what will happen to those patients who would have received AC220 having failed CEP-701. It is suggested that these patients who would have received AC220 will instead receive an infusion of Danarubicin. Subject to receiving a written confirmation of this, the members of the Sub Committee would be content to give a favourable opinion of the amendment.

I am pleased to confirm that the Committee has given a favourable ethical opinion of the modified amendment on the basis described in the notice of amendment form and supporting documentation.

The documents reviewed and approved are:

| Document | Version            | Date |
|----------|--------------------|------|
| Protocol | 3.2 dated May 2009 |      |

|   |                          |  |
|---|--------------------------|--|
| Participant Information Sheet: 8 - and consent form | 5 dated May 2009         |  |
| Modified Amendment                                  | Amendment 1 modified     |  |
| Covering Letter                                     | signed Professor Burnett |  |

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

|                     |   |
|---------------------|---|
| <b>08/MRE09/29:</b> | <b>Please quote this number on all correspondence</b> |
|---------------------|---|

Yours sincerely



**Dr. Corinne Scott**  
Committee Co-ordinator

Enclosures: List of names and professions of members who took part in the review

Copy to: Dr Kathryn Pittard-Davies

**REC for Wales**

**Attendance at Sub-Committee of the REC meeting on 15 July 2009**

| Name                 | Profession   | Capacity |
|----------------------|--|----------|
| Dr Maurice Buchalter | Alternate Vice Chairman / Hospital Consultant (Cardiologist) | Expert   |
| Dr Gordon Taylor     | Chairman / Statistician                                      | Expert   |
| Dr Pete Wall         | Vice Chairman / Clinical Physiologist                        | Expert   |

**Written comments received from:**

| Name                 | Profession   | Capacity |
|----------------------|--|----------|
| Dr Maurice Buchalter | Alternate Vice Chairman / Hospital Consultant (Cardiologist) | Expert   |
| Dr Gordon Taylor     | Chairman / Statistician                                      | Expert   |
| Dr Pete Wall         | Vice Chairman / Clinical Physiologist                        | Expert   |