AML 18

A Programme of Development for Older Patients with Acute Myeloid Leukaemia and High-Risk Myelodysplasia Syndrome

PATIENT RANDOMISATION NOTEPAD 2B

For patients who have residual disease detected or unassessable and received DA (+/- mylotarg) in course 1

Trials Office tel: 02922 510 530 Trials Office fax: 02920 687 501

AML 18 Trial Number: ☐☐☐☐

[1]Patient's Initials: …… [2]DoB: DD / MMM / YYYY [3]Sex: Male / Female

[4]Hospital: …… [5]NHS/CHI No.: ……

[6]Responsible Consultant: …… [7]Consent Form 3a– version number signed: ……

[8]Person entering patient: …… [9]Consent Form 4– version number signed: ……

ELIGIBILITY CHECKLIST

Inclusion Criteria:

	YES	NO
[10.1] Has the patient's disease status been confirmed as residual disease detected or unassessable?	☐	■
[10.2] Has the patient completed the first course of treatment?	☐	■
[10.3] Has the patient provided written informed consent for this randomisation?	☐	■

Note: if the patient has a FLT3 mutation confirmed by the trials office please complete the cardiac condition section below. If the patient does not have a FLT3 mutation confirmed by the trials office they are not eligible to enter the AC220 randomisation and will be randomised between the chemotherapy options. Please skip to question 13.1.

	YES	NO
[11.1] Is the patient entering the AC220 randomisation?	☐	☐

If yes, please complete the cardiac condition section below. If no, please skip to question 13.1

Does the patient suffer from any of the following cardiac conditions? If YES, they are excluded from the small molecule randomisation

Known serious cardiac illness or medical conditions, including but not limited to:

	YES	NO
[12.1] Clinically unstable cardiac disease, including unstable atrial fibrillation, symptomatic bradycardia, unstable congestive heart failure, active myocardial ischemia, or indwelling temporary pacemaker	■	☐
[12.2] Ventricular tachycardia or a supraventricular tachycardia that requires treatment with a Class Ia antiarrhythmic drug (e.g., quinidine, procainamide, disopyramide) or Class III antiarrhythmic drug (e.g., sotalol, amiodarone, dofetilide). Use of other antiarrhythmic drugs is permitted	■	☐
[12.3] Use of medications that have been linked to the occurrence of torsades de pointes (see Protocol for the list of such medications)	■	☐
[12.4] Second- or third-degree atrioventricular (AV) block unless treated with a permanent pacemaker	■	☐

[12.5] Complete left bundle branch block (LBBB)	■	☐
[12.6] History of long QT Syndrome or a family member with this condition	■	☐
[12.7] QTc >450 ms (average of triplicate ECG recordings); a consistent method of QTc calculation must be used for each patient's QTc measurements. QTcF (Fridericia's formula) is preferred	■	☐
[12.8] Serum potassium, magnesium, and calcium levels outside the laboratory's reference range	■	☐

Cladribine Exclusion Criteria:	**YES**	**NO**
[13.1] Is the patient's serum creatinine within the local ULN?	☐	■

If no, the patient will not be allocated cladribine and will be randomised between the other options.

Information to be obtained from the trials office

☐ **Flag IDA** ☐ **DA (50mg)**

☐ **DA + Cladribine**

Small molecule (if eligible) ☐ **Short AC220** ☐ **None**

☐ **Long AC220**

Date of entry: Signature: _____ Date: