Academic Haematology
The Medical School
Framlington Place
Newcastle NE2 4HH

Email: c.a.hedgley@ncl.ac.uk

20 April 2009

Dear Sir/Madam,

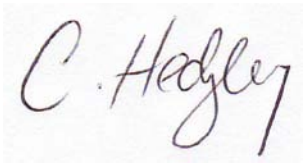
SPIRIT 2 - A phase III, prospective randomised comparison of imatinib (STI571, Glivec/Gleevec) 400mg daily versus dasatinib (Sprycel) 100mg daily in patients with newly-diagnosed chronic phase chronic myeloid leukaemia.

EUDRACT number: 2007-006185-15

Please find on the enclosed CD the Annual Safety Report for the above study.

If you have any queries regarding the report please don't hesitate to contact the Chief Investigator (Dr S G O'Brien) or myself.

Yours sincerely,



Corinne Hedgley
Senior Trial Project Manager.

cc Amanda Tortice
R&D Manager, Newcastle-upon-Tyne Hospitals Trust

Annual Safety Report

Study Title	SPIRIT 2 - A phase III, prospective randomised comparison of imatinib (STI571, Glivec/Gleevec) 400mg daily versus dasatinib (Sprycel) 100mg daily in patients with newly-diagnosed chronic phase chronic myeloid leukaemia.
EUDRACT Number	2007-006185-15
ISRCTN Number	ISRCTN54923521
MREC Reference	07/H0718/90
Chief Investigator	Dr S. G. O'Brien
SPONSOR	Newcastle upon Tyne Hospitals Trust
Reporting Period	April 2008 – April 2009

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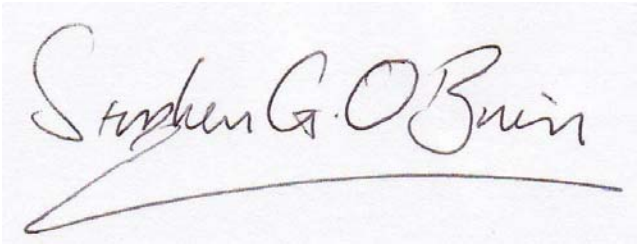

21 May 2009

Dr S. G. O'Brien (Chief Investigator) Date

1 Report on the subjects' safety

The first patient enrolled into the study was randomised in August 2008. 22 patients have been randomised up to April 2009 as follows;
11 patients on 400mg imatinib daily
11 patients on 100mg dasatinib daily

For the period April 2008 to April 2009 there were no SUSARs and no SARs reported to the sponsor.
During this period we received 3 SAE reports (unrelated to trial medication).

There have been no other major safety issues to report with the trial.

2 Line listing of all suspected SARs (including all SUSARs)

IDENTIFIERS				SAE DETAILS			CAUSALITY		STUDY DRUG DETAILS					
Patient Number	CASE ID	AGE	SEX	ONSET DATE	DIAGNOSIS	OUTCOME	IMATINIB	PEGASYS	DRUG NAME	DOSE/UNITS/FREQUENCY/ ROUTE				DRUG START
None to report														

Indicates a SAR reported in a previous safety report

3 Aggregate summary tabulation of suspected SARs

Not applicable