NMDSG07A

A multicentre phase II study of the efficacy and safety of lenalidomide in high-risk myeloid disease (high-risk MDS and AML) with a karyotype including del(5q) or monosomy 5

NMDSG07A

- An investigator initiated study with financial support from Celgene
- Sponsor: Nordic MDS Group
- Sweden, Denmark, Norway, Finland and Iceland
- 20 centers
- 50 patients
- Inclusion 2007-2009

NMDSG07A

- 16 weeks
- Oral drug

Study endpoints

- Primary endpoint
  - Major cytogenetic response at 16 weeks (FISH)

Celgene

- Financial support according to budget
- Contract written with NMDSG chair Eva HL as employed at division of HemOnc Karolinska
- Safety management (SUSAR decision)
- Drug including supply to one central pharmacy per country
- Administrative support during application to MPAs

Budget

Nordic MDS group

- Application costs
- Transport costs for biobank samples
- FISH analysis
- NMDSG Secretary/database
- Study coordinator Dr Lars Möllgård

137.500 Euro

Celgene

- Application support
- Pharmacy
- 1200€ / pt to participating center (
  - CRF, study nurse time
  - Extra laboratory costs
- Monitoring

74.500 Euro

NMDSG support

- Nordic Cancer Union for secretariat / database / shipment of samples (DHL)
- Swedish Cancer Foundation Group grant (meetings)
- Research grants EHL including
  - Study coordinator Dr Lars Möllgård 2 months for preparation + 1 month / year
  - FISH
  - Initial applications

2006

MAY	Idea
SEP	Discussing study with Celgene in London
OCT	The NMDSG work group starts designing the protocol. Discussing budget with Celgene
NOV	Preliminary protocol presented at the NMDSG meeting

2007

JAN	Final Budget
FEB	Protocol version 1.0
	Celgene safety review of protocol
	Ethics Committee application
MAR	Ethics Committee approval
APR	MPA application prepared. Cross reference letter from Celgene
MAY	Protocol version 2.0
	MPA application submitted

2007

JUN	MPA approval
JUL	Ethics Committee application in Denmark
	MPA application in Denmark
AUG	Ethics Committee approval in Denmark
	MPA approval in Denmark
SEP	Start up meeting
OCT	Swedish centers ready for inclusion
	First patient is included
DEC	Subcontract NMDSG / Danish centra signed (transfer of sponsor duties)

2008

JAN 3 patients included in Sweden

Danish centers ready for inclusion

Norway, Iceland and Finland are working on their applications

FEB Amendment to MPA (minor changes)

SUSAR

- SAE are reported to sponsor and Celgene.
- Celgene decide if the SAE should be classified SUSAR
- If SUSAR the sponsor report to all investigators and the Eudravigilance database

Monitoring

- Inclusion criteria checked by NMDSG secretariat before start of patient.
- Inclusion criteria, endpoints, results according to the assessment schedule, and AE will be monitored / source verified at the end of treatment for each patients
- Monitoring will take place when the patient has completed the study
- Special monitoring structure for FISH
- No monitoring of concomittant drugs

Monitoring and SAE

- Different solutions in the different countries
- Denmark: first 80 h / study is financed by university
- Sweden; use local monitoring facility, usually licensed study nurses at other departments
- Approx 1 h / patient = 50€
- A new organisation; Clinical Trial Alliance at Karolinska will manage SAE database
- CTA can also support application proceedure

Study report and conclusion

- Database will be arranged to support final report, which should be delivered within 6 months from end of study
- Final report = manuscript
- NMDSG look forward to submitting the next phase II protocol
  - "copy and paste"