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AGENDA: Randomised, double-blind trial of dacarbazine with or without Genasense® (oblimersen, G3139) in advanced melanoma

Submission date 14/04/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/06/2008	**Overall study status** Completed	
Last Edited 11/04/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00518895

Protocol serial number
GM307

Study information

Scientific Title
A multicentre, randomised, double-blind study of dacarbazine with or without Genasense® in chemotherapy-naïve subjects with advanced melanoma and low lactate dehydrogenase (LDH) (The AGENDA Trial)

Acronym
AGENDA

Study objectives
This study is being performed to prospectively determine whether dacarbazine plus Genasense® is significantly better than dacarbazine plus placebo in chemotherapy-naïve subjects with advanced melanoma and baseline lactate dehydrogenase (LDH) less than or equal to 0.8 x upper limit of normal (ULN). LDH is a biomarker strongly associated with improved outcomes in a recent trial of dacarbazine plus Genasense®.

Ethics approval required
Old ethics approval format

Ethics approval(s)
USA: The University of Texas, M.D. Anderson Cancer Center, Office of Protocol Review, approved in July 2007
France: The Salvator Hospital, Comite de Protection des Personnes Sud-Mediterranee I, Marseille, approved in October 2007

Other sites will also obtain ethics approval before recruitment of participants.

Study design
Phase III, multicentre, randomised (1:1), double-blind, placebo-controlled, parallel-group trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Melanoma

Interventions
Protocol therapy is administered in 21-day cycles for up to 8 cycles.

Subjects in the dacarbazine plus Genasense® group receive Genasense® 7 mg/kg/day by continuous intravenous infusion beginning on Day 1 and continuing for 5 days (120 hours) plus dacarbazine 1,000 mg/m^2 as a 60-minute intravenous infusion immediately following the conclusion of the Genasense® infusion.

Subjects in the dacarbazine plus placebo group receive placebo (that is, locally available commercial 0.9% sodium chloride injection) by continuous intravenous infusion beginning on Day 1 and continuing for 5 days (120 hours) plus dacarbazine 1000 mg/m^2 as a 60-minute intravenous infusion immediately following the conclusion of the placebo infusion.

In both treatment groups, subjects who are responding or have stable disease after 8 cycles of therapy may, at the Investigator's discretion, continue that same therapy for up to 8 additional cycles.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Genasense® and dacarbazine

Primary outcome(s)
Progression-free survival and overall survival

Key secondary outcome(s))
1. Response rate
2. Durable response rate
3. Duration of response
4. Safety

Follow-up every 2 months for up to 24 months from date of randomisation.

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. At least 18 years of age, both males and females
2. Histologically confirmed diagnosis of melanoma
3. Progressive disease that is not surgically resectable, or metastatic Stage IV disease
4. Low LDH (defined as LDH less than or equal to 0.8 x ULN)
5. Chemotherapy naïve
6. Measurable disease
7. Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 1
8. At least 4 weeks and recovery from effects of major prior surgery or other therapy, including immunotherapy, radiation therapy, or cytokine, biologic or vaccine therapy
9. Adequate organ function

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Prior cytotoxic chemotherapy, including regional perfusion, or prior Genasense® treatment
2. Primary ocular or mucosal melanoma
3. Bone-only metastatic disease
4. History or presence of brain metastasis or leptomeningeal disease
5. Significant medical disease other than cancer
6. Organ allograft

Date of first enrolment
01/07/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
United Kingdom

Australia

Austria

Canada

Czech Republic

France

Germany

Italy

Spain

Switzerland

United States of America

Study participating centre

University Medical Centre
Tuebingen
Germany
72074

Sponsor information

Organisation
Genta Incorporated (USA)

Funder(s)

Funder type
Industry

Funder Name
Genta Incorporated (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	10/10/2006	14/02/2019	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes