

Randomised study of dacarbazine versus dacarbazine plus G3139 (Bcl-2 Antisense Oligonucleotide, Genasense™) in patients with advanced malignant melanoma

Submission date 06/11/2002	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/11/2002	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 08/02/2019	Condition category Cancer	☐ Individual participant data

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)

NCT00016263

Protocol serial number

GM301

Study information

Scientific Title

Randomised study of dacarbazine versus dacarbazine plus G3139 (Bcl-2 Antisense Oligonucleotide, Genasense™) in patients with advanced malignant melanoma

Study objectives

To compare the effectiveness of dacarbazine with or without oblimersen (G3139) in treating patients who have advanced malignant melanoma.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malignant melanoma stages III and IV

Interventions

Patients will be randomly assigned to one of two groups:

1. Patients in group one will receive dacarbazine once every 3 weeks for up to eight courses in the absence of disease progression.
2. Patients in group two will receive 5 days of G3139 followed by an infusion of dacarbazine. Treatment may be repeated every 3 weeks for up to eight courses in the absence of disease progression.

After completion of the study patients will be evaluated every 2 months for a maximum of 2 years from the time of randomization.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Dacarbazine versus dacarbazine plus G3139 (Bcl-2 Antisense Oligonucleotide, Genasense™)

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2004

Eligibility

Key inclusion criteria

1. Measurable disease
2. No brain metastases
3. At least 4 weeks since biological therapy, radiation therapy or surgery
4. No previous chemotherapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2000

Date of final enrolment

31/12/2004

Locations

Countries of recruitment

United States of America

Study participating centre

Genta Incorporated

Berkeley Heights

United States of America

NJ 07922

Sponsor information

Organisation

Genta Incorporated (USA)

Funder(s)

Funder type

Industry

Funder Name

Genta Incorporated (USA)

Funder Name

Aventis (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	08/02/2019	Yes	No