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Completed 

A Study of DEDN6526A in Patients With Metastatic or Unresectable Melanoma

ClinicalTrials.gov ID  NCT01522664

Sponsor  Genentech, Inc.

Information provided by  Genentech, Inc. (Responsible Party)

Last Update Posted  2016-11-02

Study Details Tab

Study Overview

Brief Summary

This multicenter, open-label study will assess the safety and pharmacokinetics of DEDN6526A in patients with metastatic or unresectable melanoma. Cohorts of patients will receive escalating doses of DEDN6526A by intravenous infusion on Day 1 of each 21-day cycle. In the absence of disease progression or unacceptable toxicity, patients may continue to receive DEDN6526A for up to 17 cycles (1 year).

Official Title

A Phase I, Open-Label Study of the Safety and Pharmacokinetics of Escalating Doses of DEDN6526A in Patients With Metastatic or Unresectable Melanoma

Conditions

Malignant Melanoma

Intervention / Treatment

- Drug: DEDN6526A

Other Study ID Numbers

- G027935

Study Start

2012-03

Primary Completion (Actual)

2015-06

Study Completion (Actual)

2015-06

Enrollment (Actual)

53

Study Type

Interventional

Phase

Phase 1

Resource links provided by the National Library
of Medicine 

[MedlinePlus Genetics](https://medlineplus.gov/genetics/) (<https://medlineplus.gov/genetics/>) related topics:
[Melanoma](https://medlineplus.gov/genetics/condition/melanoma) (<https://medlineplus.gov/genetics/condition/melanoma>)

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>) related topics:
[Melanoma](https://medlineplus.gov/melanoma.html) (<https://medlineplus.gov/melanoma.html>)

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>)

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (<https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>).


This study has 6 locations

United States


California Locations

 Los Angeles, California, United States,
90025


Florida Locations

 Sarasota, Florida, United States,
34232

Michigan Locations

 Detroit, Michigan, United States,
48201

Tennessee Locations

 Nashville, Tennessee, United States,
37203

Australia

New South Wales Locations

 Camperdown, New South Wales,
Australia, 2050

Victoria Locations

 East Melbourne, Victoria, Australia,
3002

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About](#)

Eligibility Criteria

Description

Inclusion Criteria:

- Adult patients, ≥ 18 years of age
- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
- Histologically confirmed metastatic melanoma (AJCC stage IV) or unresectable melanoma (AJCC Stage III)
- Prior failure of ≥ 1 prior treatment regimens for metastatic or unresectable melanoma due to disease progression or unacceptable toxicity and for whom no standard therapy is available
- Measurable disease according to RECIST criteria
- Adequate bone marrow, liver and renal function
- Female patients of childbearing potential and male patients with female partners of childbearing potential must agree to use one highly effective form of non-hormonal contraception or two effective forms of non-hormonal contraception

Ages Eligible for Study [?]

18 Years and older (Adult, Older Adult)

Sexes Eligible for Study [?]

All

Accepts Healthy Volunteers [?]

No

through the course of the study treatment and for 6 months after the last dose of study treatment

Exclusion Criteria:

- Treatment with cytotoxic or antibody based therapy within 21 days prior to first dose of study treatment, or with any other anti-cancer therapy within 5 half-lives of the therapy prior to first dose of study treatment
- Known active infection (including HIV and atypical mycobacterial disease, but excluding fungal infection of the nail beds)
- Current Grad ≥ 2 toxicity (except alopecia or anorexia) from prior therapy
- Grade ≥ 2 peripheral neuropathy
- History of severe allergic or anaphylactic reactions to monoclonal antibody therapies (or recombinant antibody-related fusion proteins)
- Clinically significant history of liver disease, including viral or other hepatitis, current alcohol abuse, or cirrhosis
- Untreated or active central nervous system (CNS) metastases (progressing or

requiring anticonvulsants or corticosteroids for symptomatic control)

- Evidence of significant uncontrolled concomitant disease or disorder
- Pregnant or lactating women
- Prior treatment with any other antibody-drug conjugate (ADC) compound containing monomethyl auristatin E (MMAE) for the treatment of melanoma
- Previous participation in a clinical trial within 30 days of the day of first study drug administration (Cycle 1, Day 1)

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment

Allocation ⓘ : Non-Randomized

Interventional Model ⓘ : Single Group Assignment

Masking ⓘ : None (Open Label)

Arms and Interventions

Participant Group/Arm ⓘ	Intervention/Treatment ⓘ
Experimental: Single group	Drug: DEDN6526A <ul style="list-style-type: none">• Multiple ascending doses

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Safety: Incidence of adverse events		assessed on an ongoing basis and up to 90 days following last dose of study

		treat ment
Maximum tolerated dose/dose- limiting toxicities		appro ximat ely one year after study start
Determinatio n of recommen ded Phase II dose		appro ximat ely 2 years

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Pharmacokinetics: Area under the concentration-time curve		Pre-dose, 30 min. and 4, 24, 48 hours post-dose and

		Days 7, 10, 15, 17 Cycles 1-4, pre-dose and 30 min. post-dose Cycle 5 and every other cycle thereafter
Anti-therapeutic antibody (ATA) levels		Pre-dose Day 1 Cycles 1-4, and within 30 days post last dose
Tumor response (tumor		up to approximat

assessment
s according
to RECIST
criteria)

ely 1
year

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Genentech, Inc.

Investigators ⓘ

- Study Director: Clinical Trials, Genentech, Inc.

Publications

From PubMed

These publications are automatically filled in from PubMed, a public database of scientific and medical articles, and may or may not be about the study.

- [Sandhu S, McNeil CM, LoRusso P, Patel MR, Kabbarah O, Li C, Sanabria S, Flanagan WM, Yeh RE, Brunstein F, Nazzal D, Hicks R, Lemahieu V, Meng R, Hamid O, Infante JR. Phase I study of the anti-endothelin B receptor antibody-drug conjugate DEDN6526A in patients with metastatic or unresectable cutaneous, mucosal, or uveal melanoma. Invest New Drugs. 2020 Jun;38\(3\):844-854. doi: 10.1007/s10637-019-00832-1. Epub 2019 Aug 5. \(https://pubmed.ncbi.nlm.nih.gov/31385109\)](https://pubmed.ncbi.nlm.nih.gov/31385109)

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2012-01-20

First Submitted that Met QC Criteria ⓘ

2012-01-27

First Posted (Estimated) ⓘ

2012-01-31

Study Record Updates

Last Update Submitted that Met QC Criteria ⓘ

2016-11-01

Last Update Posted (Estimated) ⓘ

2016-11-02

Last Verified ⓘ

2016-11

More Information

[Terms related to this study](#)

Additional Relevant MeSH Terms

Neuroendocrine Tumors
Neuroectodermal Tumors
Neoplasms, Germ Cell and
Embryonal
Neoplasms by Histologic Type
Neoplasms
Neoplasms, Nerve Tissue
Nevi and Melanomas
Skin Neoplasms
Neoplasms by Site
Skin Diseases
Skin and Connective Tissue
Diseases
Melanoma