Trial record **1 of 1** for: PV-10-MM-31

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PV-10 vs Chemotherapy or Oncolytic Viral Therapy for Treatment of Locally Advanced Cutaneous Melanoma

This study is currently recruiting participants.

See Contacts and Locations

Verified September 2017 by Provectus Pharmaceuticals (Provectus Biopharmaceuticals, Inc.)

Sponsor:
Provectus Biopharmaceuticals, Inc.

ClinicalTrials.gov Identifier:
NCT02288897

First Posted: November 11, 2014
Last Update Posted: September 26, 2017

Information provided by (Responsible Party):
Provectus Pharmaceuticals (Provectus Biopharmaceuticals, Inc.)

Full Text View | Tabular View | No Study Results Posted | Disclaimer

How to Read a Study Record

Purpose

This is an international multicenter, open-label, randomized controlled trial (RCT) of single-agent intralesional PV-10 versus systemic chemotherapy or intralesional oncolytic viral therapy to assess treatment of locally advanced cutaneous melanoma in patients who (1) are not candidates for targeted therapy and (2) are not candidates for an immune checkpoint inhibitor. Subjects in the comparator arm will receive the Investigator's choice of dacarbazine (DTIC), temozolomide (TMZ) or intralesional talimogene laherparepvec as determined by Investigator preference and standard of care in the Investigator's country or region. Effectiveness will be assessed by comparison of progression-free survival (PFS) between all intent-to-treat (ITT) subjects in the two study treatment arms.

Condition	Intervention	Phase
Cutaneous Melanoma	Drug: PV-10 (10% rose bengal disodium) Drug: Dacarbazine, temozolomide or talimogene laherparepvec	Phase 3

Study Type: Interventional

Study Design: Allocation: Randomized
Intervention Model: Parallel Assignment
Masking: Single (Outcomes Assessor)
Masking Description:
Blinded review by independent review committee (IRC) for primary and key secondary endpoints.
Primary Purpose: Treatment

Official Title: PV-10 Intralesional Injection vs Systemic Chemotherapy or Oncolytic Viral Therapy for Treatment of Locally Advanced Cutaneous Melanoma

Resource links provided by NLM:

MedlinePlus related topics: Melanoma

Drug Information available for: Rose bengal Temozolomide

Genetic and Rare Diseases Information Center resources: Melanoma, Familial Carcinoid Tumor Neuroepithelioma

U.S. FDA Resources

Further study details as provided by Provectus Pharmaceuticals (Provectus Biopharmaceuticals, Inc.):

Primary Outcome Measures:

- Progression-free survival (PFS) [Time Frame: Assessed every 12 weeks up to 18 months]

Secondary Outcome Measures:

- Complete response rate (CRR) [Time Frame: Assessed every 12 weeks up to 18 months]
- Duration of complete response [Time Frame: Assessed every 12 weeks up to 18 months]
- Overall survival (OS) [Time Frame: Assessed every 12 weeks up to 18 months]
- Number of participants with adverse events [Time Frame: Assessed every 4 weeks until 28 days after last treatment]

  Safety and tolerability will be assessed by monitoring the frequency, duration, severity and attribution of adverse events and evaluating changes in laboratory values and vital signs.

Other Outcome Measures:

- Change in domain scores from baseline using the patient reported Skindex-16 instrument [Time Frame: Assessed 12 weeks after Day 1]

Estimated Enrollment:	225
Study Start Date:	April 2015
Estimated Study Completion Date:	October 2018
Estimated Primary Completion Date:	September 2018 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: PV-10 Subjects will receive intralesional PV-10 to all Study Lesions on study Day 1. PV-10 should be re-administered at 28-day intervals until complete response, disease progression or study termination occurs.	Drug: PV-10 (10% rose bengal disodium)
Active Comparator: Chemotherapy or Oncolytic Viral Therapy Subjects will receive (a) dacarbazine (intravenously at 850 m/m2) or temozolomide (orally at 200 mg/m2 daily for 5 consecutive days), administered at consecutive 28-day intervals, or (b) intralesional talimogene laherparepvec administered on an initial 21 interval	Drug: Dacarbazine, temozolomide or talimogene laherparepvec

followed by consecutive 14 day intervals, until complete response, disease progression or study termination occurs.	

Detailed Description:

Subjects will be randomized using a 2:1 treatment allocation (i.e. two-thirds of the subjects will receive PV-10).

Subjects in the comparator arm who have completed at least 1 cycle of study treatment and who meet the study protocol definition of disease progression but do not have evidence of visceral metastases will be eligible to enter the crossover portion of the study and receive PV-10. Subjects crossing over must meet all study inclusion and exclusion criteria for clinical laboratories, thyroid function, concurrent or intercurrent illness and pregnancy at the time of crossover.

Assessment of progression will be performed by an Independent Review Committee (IRC) based on Response Evaluation Criteria in Solid Tumors (RECIST) ver. 1.1 criteria. Events signaling progression include increase in size and/or number of lesions, distant or nodal disease progression, or death. All secondary endpoints involving disease response and progression will be based on the IRC determination.

An interim assessment of efficacy and safety will be performed by the IRC when 50% of the events required for the primary endpoint have occurred.

Eligibility

Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Sexes Eligible for Study: All
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

1. Age 18 years or older, male or female
2. Histologically or cytologically confirmed melanoma

3. Recurrent, satellite or in-transit locally advanced cutaneous or subcutaneous melanoma metastases (i.e., AJCC Stage IIIB, IIIC or Stage IV M1a with no active nodal metastases)
4. At least 1 measurable Target Lesion that can be accurately measured by calipers or computed tomography (CT) consisting of:
    - at least one cutaneous lesion (each lesion ≥ 10 mm in longest diameter or up to 5 lesions having a sum of longest diameters ≥ 10 mm); and/or
    - at least one subcutaneous lesion (each lesion ≥ 10 mm in longest diameter by CT);
    - where Target Lesions should be at least 10 mm from any other lesion
5. No lesion > 50 mm in longest diameter; and no more than 50 lesions
6. Calculated required PV-10 dose ≤ 15 mL (based on total tumor burden)
7. Performance Status: Eastern Cooperative Oncology Group (ECOG) 0-2
8. Not a candidate for treatment with an immune checkpoint inhibitor (e.g., failed or did not tolerate prior therapy, or due to co-morbidities, pre-existing autoimmune disease, drug unavailability or standard of care)
9. Not a candidate for targeted therapy with BRAF or combined BRAF/MEK inhibitors (e.g., failed or did not tolerate prior therapy, BRAF V600 wild-type or due to drug unavailability or standard of care)
10. Clinical Laboratories:
    - Absolute neutrophil count (ANC) ≥ 1.5 x 10^9/L and platelet count ≥100 x 10^9/L
    - Creatinine ≤ 3 times the upper limit of normal (ULN)
    - Estimated creatinine clearance (CrCl) or estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m2
    - Total bilirubin ≤ 3 times the upper limit of normal (ULN)
    - Aspartate transaminase (AST), alanine transaminase (ALT) and alkaline phosphatase (ALP) ≤ 5 times the upper limit of normal (ULN)
    - Lactate dehydrogenase (LDH) ≤ 2 times the upper limit of normal (ULN).
11. Thyroid function abnormality ≤ Grade 2
12. Candidate for at least one comparator drug:
    - Subjects must be candidates for at least one of the designated comparator drugs

Exclusion Criteria:

1. Presence or history of visceral melanoma metastasis
2. Presence of active nodal metastases (e.g., radiologic or clinical evidence of current nodal disease)
3. Presence of more than 50 melanoma lesions

4. Radiation therapy to any Study Lesion within 6 weeks of initial study treatment.
5. Chemotherapy or other systemic cancer therapy within 4 weeks of initial study treatment (6 weeks for nitrosoureas or mitomycin), or regional chemotherapy (limb infusion or perfusion) within 12 weeks of initial study treatment
6. Immunotherapy for cancer within 4 weeks of initial study treatment
7. Local treatment (e.g., surgery, cryotherapy, laser ablation) to any Study Lesion within 4 weeks of initial study treatment
8. Anti-tumor vaccine therapy within 6 weeks of initial study treatment.
9. Investigational agents within 4 weeks of initial study treatment.
10. Concurrent or Intercurrent Illness:
    - Impaired wound healing or other extremity complications due to diabetes mellitus in subjects whose Study Lesions are located in an extremity
    - Severe peripheral vascular disease in subjects whose Study Lesions are located in an extremity
    - Significant concurrent or intercurrent illness, psychiatric disorders, or alcohol or chemical dependence that would, in the opinion of the Investigator, compromise the subject's safety or compliance or interfere with interpretation of study results.
    - Uncontrolled thyroid disease or cystic fibrosis
    - Clinically significant acute or unstable cardiovascular, cerebrovascular (stroke), renal, gastrointestinal, pulmonary, immunological, endocrine, or central nervous system disorders
11. Pregnancy:
    - Female subjects who are pregnant or lactating
    - Female subjects who have positive serum pregnancy test taken within 14 days of study treatment
    - Female subjects of child-bearing potential who are unwilling to use highly effective contraception (e.g., combined (estrogen and progestogen containing) or progestogen-only hormonal contraceptives, intrauterine devices, bilateral tubal ligation, vasectomized partner, sexual abstinence or equivalent measures) for the duration of study treatment
12. Contraindication for all comparators:
    - Subjects with contraindications to all of the designated comparator drugs

Contacts and Locations

Information from the National Library of Medicine

To learn more about this study, you or your doctor may contact the study research staff using the contact information provided by the sponsor.

Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02288897***

Contacts

Contact: Eric Wachter, Ph.D. +1 865 769 4011 ext 23 wachter@pvct.com

Locations

United States, California

Sharp Memorial Hospital - Clinical Oncology Research **Recruiting**
San Diego, California, United States, 92123
Contact: Cathy Wood 858-939-5062 cathy.wood@sharp.com
Principal Investigator: Kristen Rice, M.D.

United States, Florida

Mount Sinai Comprehensive Cancer Center **Recruiting**
Miami Beach, Florida, United States, 33140
Contact: Christy M Estevez 305-674-2121 ext 53760
Christina.Estevez@msmc.com
Principal Investigator: Jose Lutzky, MD

United States, Kentucky

University of Louisville School of Medicine **Recruiting**
Louisville, Kentucky, United States, 40202
Contact: Mary Healey 502-629-3327 mary.healey@louisville.edu
Principal Investigator: Charles Scoggins, M.D.

United States, Missouri

Washington University School of Medicine - Dermatology **Recruiting**
Saint Louis, Missouri, United States, 63110
Contact: Mary Tabacchi, CCRC 314-362-8171 mtabacchi@wustl.edu
Principal Investigator: Lynn Cornelius, MD

United States, New Hampshire

Dartmouth-Hitchcock Medical Center **Recruiting**

Lebanon, New Hampshire, United States, 03756
Contact: Darcie Findley, CCRC 603-650-4595 darcie.l.findley@hitchcock.org
Principal Investigator: Keisuke Shirai, MD

United States, New Jersey

Atlantic Health System **Recruiting**
Morristown, New Jersey, United States, 07960
Contact: Molly Maurer 973-714-6341 molly.maurer@atlantichealth.org
Principal Investigator: Eric Whitman, M.D.

United States, North Carolina

Wake Forest Baptist Health **Recruiting**
Winston-Salem, North Carolina, United States, 27157
Contact: Angela Howell 336-713-3155 anhowell@wakehealth.edu
Principal Investigator: Paul Savage, MD, FACP

United States, Oklahoma

Oklahoma Cancer Specialists and Research Institute **Recruiting**
Tulsa, Oklahoma, United States, 74146
Contact: Jan Byerly, RN, BSN, OCN 918-505-3201 ext 4076
Jan.Byerly@OCSRI.ORG
Principal Investigator: Edward Yob, DO

United States, Pennsylvania

St Luke's University Hospital and Health Network **Recruiting**
Easton, Pennsylvania, United States, 18045
Contact: Robyn Rex 484-503-4152 Robyn.Rex@sluhn.org
Principal Investigator: Sanjiv Agarwala, M.D.

Penn State Hershey Cancer Institute **Recruiting**
Hershey, Pennsylvania, United States, 17033
Contact: Jennifer Hallman, RN, BSN 717-531-0003 ext 287412
jhallman@pennstatehealth.psu.edu
Principal Investigator: Rogerio Neves, MD

United States, Texas

M.D. Anderson Cancer Center **Recruiting**
Houston, Texas, United States, 77030
Contact: Donna Branham 713-563-3527 dbranham@mdanderson.org
Principal Investigator: Merrick Ross, M.D.

United States, Utah

Huntsman Cancer Institute **Recruiting**
Salt Lake City, Utah, United States, 84112
Contact: Tamara Willis 801-587-4767 Tamara.Willis@hci.utah.edu
Principal Investigator: Robert Andtbacka, M.D.

Australia, Queensland

Princess Alexandra Hospital **Recruiting**
Brisbane, Queensland, Australia, 4102
Contact: Janine Thomas +61 (07) 3844-8500 Janine.thomas@mater.uq.edu.au
Principal Investigator: Mark Smithers, M.D.

Germany

Department of Dermatology, University Hospital Schleswig-Holstein **Not yet recruiting**
Kiel, Germany

Italy

IRCCS Instituto Nazionale Tumori "Fondazione Giovanni Pascale" **Recruiting**
Napoli, Italy

Istituto Dermopatico dell'Immacolata (IDI IRCCS) **Recruiting**
Rome, Italy

Azienda Sanitaria Azienda Ospedaliera Universitaria Senese **Recruiting**
Siena, Italy

Sponsors and Collaborators

Provectus Biopharmaceuticals, Inc.

Investigators

Study Director:	Eric Wachter, Ph.D.	Provectus Biopharmaceuticals, Inc.
Principal Investigator:	Sanjiv Agarwala, M.D.	St Luke's University Hospital and Health Networl

More Information

Responsible Party:	Provectus Biopharmaceuticals, Inc.
ClinicalTrials.gov Identifier:	NCT02288897 History of Changes
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Keywords provided by Provectus Pharmaceuticals (Provectus Biopharmaceuticals, Inc.):

Stage III
Stage IIIB
Stage IIIC
Stage IV (M1a)
Stage 3
Stage 4
IVM1a
IV(M1a)
IV-M1a
in-transit
in transit
intransit
satellite
recurrent

Additional relevant MeSH terms:

Melanoma
Neuroendocrine Tumors
Neuroectodermal Tumors
Neoplasms, Germ Cell and Embryonal
Neoplasms by Histologic Type
Neoplasms
Neoplasms, Nerve Tissue
Nevi and Melanomas
Temozolomide
Antineoplastic Agents, Alkylating
Alkylating Agents
Molecular Mechanisms of Pharmacological Action
Antineoplastic Agents