MSB0010718C in Subjects With Merkel Cell Carcinoma

This study is currently recruiting participants. (see Contacts and Locations)

Verified March 2015 by EMD Serono

Sponsor:
EMD Serono

Information provided by (Responsible Party):
EMD Serono

ClinicalTrials.gov Identifier:
NCT02155647

First received: June 2, 2014
Last updated: March 9, 2015
Last verified: March 2015
History of Changes

Purpose

This is a multicenter, international, single-arm, open-label, Phase 2 trial to evaluate the efficacy and safety of **MSB0010718C** in subjects with metastatic Merkel cell carcinoma (MCC) who must have received one line of chemotherapy for the treatment of metastatic MCC.

Condition	Intervention	Phase
Carcinoma, Merkel Cell	Drug: **MSB0010718C**	Phase 2

Study Type: Interventional
Study Design: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase II, Open-label, Multicenter Trial to Investigate the Clinical Activity and Safety of **MSB0010718C** in Subjects With Merkel Cell Carcinoma

Resource links provided by NLM:

Genetic and Rare Diseases Information Center resources: APUDoma Carcinoid Tumor Merkel Cell Carcinoma Neuroepithelioma

U.S. FDA Resources

Further study details as provided by EMD Serono:

Primary Outcome Measures:

- Confirmed Best Overall Response (BOR) [Time Frame: Up to 3 years] [Designated as safety issue: No]

  BOR is defined as the confirmed best response (complete response [CR] or partial response [PR]) according to Response Evaluation Criteria in Solid Tumors (RECIST Version 1.1) as determined by Independent Endpoint Review Committee (IERC), obtained from start of study drug until documented disease progression, assessed every 6 weeks. CR or PR must be confirmed by a subsequent tumor assessment preferably at the next scheduled 6-weekly assessment, but no sooner than 5 weeks after the initial documentation of CR or PR.

Secondary Outcome Measures:

- Duration of response [Time Frame: Up to 3 years] [Designated as safety issue: No]

  Duration of response is defined as time from first observation of response (CR or PR) until first observation of documented disease progression or death when death occurs within 12 weeks of the last tumor assessment whichever occurs first.

- Progression-Free Survival (PFS) Time [Time Frame: Up to 3 years] [Designated as safety issue: No]

  PFS time is defined as the time from first administration of study drug until first observation of disease progression or death when death occurs within 12 weeks of the last tumor assessment whichever occurs first.

- Overall Survival (OS) Time [Time Frame: Up to 3 years] [Designated as safety issue: No]

  OS time is defined as the time from first administration of study drug until date of death.

- Number of subjects with Treatment-Emergent Adverse Events according to the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE) Version 4.0 [Time Frame: Baseline up to 10 weeks after last dose administration]
  [Designated as safety issue: Yes]

Estimated Enrollment:	84
Study Start Date:	June 2014
Estimated Study Completion Date:	January 2017
Estimated Primary Completion Date:	January 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: **MSB0010718C**	Drug: **MSB0010718C** **MSB0010718C** (anti-PD-L1) will be administered at a dose of 10 milligram per kilogram (mg/kg) as 1-hour intravenous infusion once every 2 weeks until therapeutic failure, significant clinical deterioration, unacceptable toxicity, or any criterion for withdrawal from the trial or investigational medicinal product occurs. Other Name: anti-PD-L1

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Signed written informed consent
- Male or female subjects aged greater than or equal to 18 years
- Histologically proven MCC
- Progressive disease after receiving 1 line of chemotherapy for metastatic MCC
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1 at trial entry
- Disease must be measurable with at least 1 uni-dimensional measurable lesion by RECIST Version 1.1 (including skin lesions)
- Adequate hematological, hepatic and renal function as defined in the protocol
- Effective contraception for both male and female subjects if the risk of conception exists
- Fresh biopsy or archival tumor tissue

Exclusion Criteria:

- Participation in another clinical trial within the past 30 days
- Concurrent treatment with a non-permitted drug
- Prior therapy with any antibody/drug targeting T-cell co-regulatory proteins (immune checkpoints) such as anti-programmed death 1 (PD-1), anti-programmed death ligand 1 (anti-PD-L1), or anticytotoxic T-lymphocyte antigen-4 (CTLA-4) antibody
- Concurrent anticancer treatment as defined in the protocol. Radiotherapy administered to superficial lesions is not allowed if such lesions are considered target lesions in the efficacy evaluation or may influence the efficacy evaluation of the investigational agent
- Major surgery for any reason, except diagnostic biopsy, within 4 weeks and/or if the subject has not fully recovered from the surgery within 4 weeks
- Concurrent systemic therapy with steroids or other immunosuppressive agents, or use of any investigational drug within 28 days before the start of trial treatment. Short-term administration of steroids (that is, for allergic reactions or the management of immune-related

adverse events [irAE]) is allowed

- Subjects with active central nervous system (CNS) metastases are excluded. Subjects with a history of treated CNS metastases (by surgery or radiation therapy) are not eligible unless they have fully recovered from treatment, demonstrated no progression for at least 2 months, and do not require continued steroid therapy
- Previous malignant disease (other than MCC) within the last 5 years with the exception of basal or squamous cell carcinoma of the skin or cervical carcinoma in situ
- Prior organ transplantation, including allogeneic stem-cell transplantation
- Known history of testing positive for human immunodeficiency virus (HIV) or known acquired immunodeficiency syndrome (AIDS) or any positive test for hepatitis B virus or hepatitis C virus indicating acute or chronic infection
- Active or history of any autoimmune disease (except for subjects with vitiligo) or immunodeficiencies that required treatment with systemic immunosuppressive drugs
- Known severe hypersensitivity reactions to monoclonal antibodies (Grade greater than or equal to [>=] 3 NCI-CTCAE Version 4.0), any history of anaphylaxis, or uncontrolled asthma (that is, 3 or more features of partially controlled asthma)
- Persisting toxicity related to prior therapy Grade >1 NCI-CTCAE Version 4.0; however, sensory neuropathy Grade less than or equal to (<=) 2 is acceptable
- Pregnancy or lactation
- Known alcohol or drug abuse
- Clinically significant (that is, active) cardiovascular disease: cerebral vascular accident or stroke (less than [<] 6 months prior to enrollment), myocardial infarction (<6 months prior to enrollment), unstable angina, congestive heart failure (New York Heart Association Classification Class >=II), or serious cardiac arrhythmia requiring medication
- All other significant diseases (for example, inflammatory bowel disease), which, in the opinion of the Investigator, might impair the subject's tolerance of trial treatment
- Any psychiatric condition that would prohibit the understanding or rendering of informed consent
- Legal incapacity or limited legal capacity
- Non-oncology vaccine therapies for prevention of infectious disease (for example, seasonal flu vaccine, human papilloma virus vaccine) within 4 weeks of trial drug administration. Vaccination while on trial is also prohibited except for administration of the inactivated influenza vaccine

Contacts and Locations

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, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02155647

Contacts

Contact: US Medical Information 888-275-7376

Contact: Merck KGaA Communication Center +49 6151 72 5200 service@merckgroup.com

Show 48 Study Locations

Sponsors and Collaborators

EMD Serono

Investigators

Study Director: Medical Responsible Merck KGaA

More Information

No publications provided

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ClinicalTrials.gov Identifier:	NCT02155647 History of Changes
Other Study ID Numbers:	100070-003, 2014-000445-79
Study First Received:	June 2, 2014
Last Updated:	March 9, 2015

Health Authority:	United States: Food and Drug Administration Australia: Department of Health and Ageing Therapeutic Goods Administration Austria: Federal Office for Safety in Health Care France: Agence Nationale de Sécurité du Médicament et des produits de santé Germany: Paul-Ehrlich-Institut Italy: The Italian Medicines Agency Japan: Pharmaceuticals and Medical Devices Agency Spain: Agencia Española de Medicamentos y Productos Sanitarios Switzerland: Swissmedic

Keywords provided by EMD Serono:
Carcinoma, Merkel Cell
MSB0010718C

Additional relevant MeSH terms:

Carcinoma, Merkel Cell	Neoplasms, Glandular and Epithelial
Adenocarcinoma	Neoplasms, Nerve Tissue
Carcinoma	Neuroectodermal Tumors
Carcinoma, Neuroendocrine	Neuroendocrine Tumors
DNA Virus Infections	Polyomavirus Infections
Neoplasms	Tumor Virus Infections
Neoplasms by Histologic Type	Virus Diseases
Neoplasms, Germ Cell and Embryonal	

ClinicalTrials.gov processed this record on March 12, 2015