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Safety and Efficacy of Atiprimod Treatment for Patients With Low to Intermediate Grade Neuroendocrine Carcinoma

This study is currently recruiting patients.

Verified by Callisto Pharmaceuticals October 2006

Sponsored by: Callisto Pharmaceuticals

Information provided by: Callisto Pharmaceuticals

ClinicalTrials.gov Identifier: NCT00388063

Purpose

This study will evaluate the safety and efficacy of atiprimod treatment in patients with low to intermediate grade neuroendocrine carcinoma who have metastatic or unresectable local-regional cancer and who have either symptoms (diarrhea, flushing and/or wheezing) despite standard therapy (octreotide) or progression of neuroendocrine tumor(s).

Condition	Intervention	Phase
Neuroendocrine Carcinoma	Drug: Atiprimod	Phase II

[MedlinePlus](#) related topics: [Cancer](#); [Cancer Alternative Therapies](#)

[Genetics Home Reference](#) related topics: [Cancer](#)

Study Type: Interventional

Study Design: Treatment, Non-Randomized, Open Label, Uncontrolled, Single Group Assignment, Safety/Efficacy Study

Official Title: A Phase II Open-Label Study of the Safety and Efficacy of Atiprimod Treatment for Patients With Low to Intermediate Grade Neuroendocrine Carcinoma

Further study details as provided by Callisto Pharmaceuticals:

Primary Outcomes: Reduction of symptoms (diarrhea, flushing and/or wheezing); Progression of neuroendocrine tumor(s)

Secondary Outcomes: Adverse events

Expected Total Enrollment: 42

Study start: October 2006; Expected completion: December 2007

Last follow-up: November 2007; Data entry closure: December 2007

For carcinoid, despite the many cytotoxic chemotherapy trials that have been conducted, no regimen has demonstrated a response rate of more than 20% using the criterion of a 50% reduction of bidimensionally measurable disease. In the more recently reported ECOG phase III study of chemotherapy in carcinoid

tumors (E1281), patients were randomly assigned to treatment with 5-fluorouracil (5FU) plus doxorubicin or 5FU plus streptozocin. The median progression free survival durations were disappointing. They were 4.5 months in the 5FU plus doxorubicin arm and 5.3 months in the 5FU plus streptozocin arm. Overall survival durations recorded in the trial were also suboptimal at 15 and 24 months respectively. There is no clear survival benefit for cytotoxic chemotherapy.

This is a phase II, multi-center, open-label study of the safety and efficacy of atiprimod treatment in patients with low to intermediate grade neuroendocrine carcinoma who have metastatic or unresectable local-regional cancer and who have either symptoms (diarrhea, flushing and/or wheezing) despite standard therapy (octreotide) or progression of neuroendocrine tumor(s) (defined as the appearance of one or more new lesions or a 20% increase in the sum of the longest diameter of target lesions during the 6 months prior to enrollment). A maximum of 40 evaluable patients will be enrolled in this study. Atiprimod will be administered orally as a single daily dose of 120 mg/day for 14 days, followed by a 14-day treatment-free period (i.e., 1 treatment cycle = 28 days).

▶ Eligibility

Ages Eligible for Study: 18 Years and above, Genders Eligible for Study: Both

Criteria

Inclusion Criteria:

- Patient must have documented histologic proof of low or intermediate grade neuroendocrine carcinoma. Both carcinoid (any site; atypical/intermediate grade carcinoid is allowed) and islet cell (pancreatic endocrine tumor) will be eligible. Patient with neuroendocrine tumors associated with MEN1 syndrome will be eligible.
- Patients must have either metastatic or unresectable local-regional cancer. Patients with brain metastases are allowed on study, but they must have evaluable target lesions elsewhere.
- Patients must have measurable disease, as defined by RECIST.
- Patients must have either symptoms (diarrhea, flushing and/or wheezing) despite standard therapy (octreotide) or progression of neuroendocrine tumor(s) (defined as the appearance of one or more new lesions or a 20% increase in the sum of the longest diameter of target lesions during the 6 months prior to enrollment).
- Patients must be >18 years of age at the time of signing informed consent.
- Patients with prior hepatic artery embolization must have residual measurable disease.
- Patients must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 (Appendix C).
- Patients must understand and voluntarily sign an informed consent document.
- Patients must have adequate organ function defined as follows: Absolute granulocyte count (AGC) >1,500/mm³, hemoglobin >8 g/dl, platelets >100,000/mm³, serum bilirubin <1.5 x upper limit of normal (ULN), serum creatinine <1.5 mg/dL, SGOT ≤Grade 1 per NCI CTCAE, SGPT ≤Grade 1 per NCI CTCAE.
- Women of child bearing potential (WCBP) must have a negative serum or urine pregnancy test. In addition sexually active WCBP must agree to use adequate contraceptive methods (oral, injectable or implantable hormonal contraceptive; tubal ligation; intra-uterine devices; barrier contraceptive with spermicide; or vasectomized partner).

Exclusion Criteria:

- Concurrent chemotherapy, immunotherapy, radiotherapy, or investigational therapy. Concurrent octreotide (Sandostatin and Sandostatin LAR) will be allowed if treatment started at least 3 months prior to the first dose of study drug, no increases in octreotide dosage are made while on study, and the patient meets all other eligibility criteria.
- Patients who have received chemotherapy, immunotherapy, radiotherapy or investigational therapy within 30 days prior to the first dose of study drug, except for octreotide.
- Patients who have received >2 prior cytotoxic chemotherapy regimens. Chemotherapy used as a radiosensitizer will be considered one prior cytotoxic chemotherapy regimen.
- Minor surgery within 1 week prior to the first dose of study drug or major surgery within 4 weeks prior to the first dose of study drug.
- If women of child-bearing potential, pregnant, lactating or not using adequate contraception.
- Clinically relevant active infection or serious co-morbid medical conditions that are uncontrolled or whose control may be jeopardized by the complications of this therapy
- Psychiatric disorders rendering patients incapable of complying with the requirements of the protocol.
- Osseous metastasis as only site of disease.
- Prior or concurrent malignancy, except for the following: adequately treated basal cell or squamous cell skin cancer, or other adequately treated in situ cancer, or any other cancer from which the patient has been disease free for five years.
- Any condition which, in the opinion of the Investigator, places the patient at unacceptable risk if he/she were to participate in the study.
- As atiprimod is a potent inhibitor of CYP2D6, the use of drugs that are substrates of CYP2D6 (e.g. beta blockers, antidepressants, and antipsychotic) will not be allowed while on study.

▶ Location and Contact Information

Please refer to this study by ClinicalTrials.gov identifier NCT00388063

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▶ More Information

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Health Authority: United States: Food and Drug Administration

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