Dose-finding and Pharmacokinetic Study of DpC, Administered Orally to Patients With Advanced Solid Tumors

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT02688101

Recruitment Status : Completed
First Posted : February 23, 2016
Last Update Posted : February 21, 2019

Sponsor:
Collaborative Medicinal Development Pty Limited
Information provided by (Responsible Party):
Collaborative Medicinal Development Pty Limited

Study Description

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Brief Summary:
Multicenter, open-label, dose-escalation and pharmacokinetic study.

Condition or disease	Intervention/treatment	P

Neoplasms	Drug: DpC	Phase

Detailed Description:
Multicenter, open-label, phase 1 study of DpC administered orally to patients with advanced solid tumors. The study will be conducted in two parts. In the first phase successive cohorts of patients (3+3) will receive escalating doses of DpC until the maximum tolerated dose (MTD) is reached. MTD is based on tolerability observed during the first 28 days of treatment. The second part of the study involves treatment of expansion cohorts (10-15 patients each) in specific indications to confirm the tolerability of treatment at the recommended phase 2 dose and schedule and evaluate evidence of anti-tumor activity.

Study Design

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Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	14 participants
Allocation:	N/A
Intervention Model:	Single Group Assignment
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	A Phase 1 Dose-finding and Pharmacokinetic Study of DpC, Admi Solid Tumors
Actual Study Start Date :	April 11, 2016
Actual Primary Completion Date :	October 26, 2017
Actual Study Completion Date :	October 26, 2017

Arms and Interventions

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Arm	Interven
Experimental: DpC DpC capsules, administered orally	Drug: DpC iron chelator Other Name: Dp4cycH4mT

Outcome Measures

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Primary Outcome Measures :

1. Recommended phase 2 dose as determined by number of participants at each dose level with dose limiting toxicities [Time Frame: 36 months]

   Determine recommended phase 2 dose

Secondary Outcome Measures :

1. Maximum DpC plasma concentration [Cmax] following dosing on Days 1 and 28 based on blood draws taken at 1, 2, 4, 8, and 24 hours after dosing [Time Frame: 30 months]

   Maximum DpC plasma concentration

2. Area under the DpC plasma concentration vs. time curve [AUC] following dosing on Days 1 and 28 based on blood draws taken at 1, 2, 4, 8, and 24 hours after dosing [Time Frame: 30 months]

   DpC area under the plasma concentration vs. time curve

3. Number of patients with tumor responses as assessed by RECIST criteria [Time Frame: 36 months]

   number of tumor responses by RECIST criteria

Eligibility Criteria

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Information from the National Library of Medicine

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, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Signed informed consent prior to initiation of any study-specific procedures;
- Histologically or cytologically confirmed diagnosis of an advanced or metastatic solid tumor for which standard therapy either does not exist or has proven ineffective, intolerable, or unacceptable for the patient;
- At least one measurable lesion as defined by RECIST v1.1, except for patients with castrate resistant prostate cancer, who may be enrolled with objective evidence of disease per PCWG2 criteria, and patients with ovarian cancer who may be enrolled without measurable disease but who are evaluable by CA125 per GCIC criteria;
- life expectancy at least 3 months;
- ECOG performance status 0-1;
- Adequate bone marrow reserve, cardiac, renal and liver function, defined by
- absolute neutrophil count at least 1.5 x 10(9)/L;
- platelet count at least 100 x 10(9)/L;
- hemoglobin at least 9 g/dL;
- ferritin at least 50 ug/L;
- ECHO shows ejection fraction at least 50% and no evidence of cardiac dysfunction;
- creatinine clearance >50 mL/min (Cockcroft & Gault formula);

- AST/ALT no more than 3 x ULN (5 x ULN if liver or bone involvement);
- serum albumin at least 28 g/L;
- INR no more than 1.5 x ULN;
- At least 3 weeks since chemotherapy, immunotherapy, hormone therapy, r other anticancer therapy or surgical intervention or at least 3 half-lie for monoclonal antibodies;
- Patients with castrate-resistant prostate cancer must maintain ongoing androgen deprivation therapy to provide serum testosterone <50 mg/dL;
- Patients receiving bisphosphonate or denosumab therapy must be on stable doses for at least 4 weeks before initiating study treatment.

Exclusion Criteria:

- Inability to swallow oral medications or presence of a GI disorder deemed to jeopardize intestinal absorption of DpC;
- Persistent grade >1 clinically significant toxicities related to prior anticancer treatment (except alopecia);
- Known primary CNS malignancy or CNS involvement (except for brain mets that have been treated and are stable and patient is off steroids);
- History of prior to concomitant malignancies (other than fully excised non-melanoma skin cancer, cured in situ cervical carcinoma, early stage bladder cancer or DCIS of breast) within 3 years of study entry;
- History of atrial fibrillation or evidence of atrial enlargement on baseline ECHO;
- History of hemoglobinopathy;
- Current use of iron chelation therapy;
- Other serious illness or medial condition;
- Participation in another clinical trial or treatment with any investigational drug within 30 days prior to study entry;
- Current use of anticoagulants at therapeutic levels;
- Pregnant or breast-feeding patients and men and women of child-bearing potential not using effective contraception while on study treatment

Contacts and Locations

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT02688101***

Locations

Australia, New South Wales

Lifehouse Cancer Treatment Centre
Sydney, New South Wales, Australia

Australia, Victoria

Olivia Newton John Cancer Centre
Heidelberg, Victoria, Australia

Monash Cancer Center
Melbourne, Victoria, Australia

Peter MacCallum Cancer Centre
Melbourne, Victoria, Australia

Sponsors and Collaborators
Collaborative Medicinal Development Pty Limited

Investigators

Principal Investigator:	Linda Mileshkin, MD	Peter MacCallum Cancer Centre, Australia

More Information

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Responsible Party:	Collaborative Medicinal Development Pty Limited
ClinicalTrials.gov Identifier:	NCT02688101 History of Changes
Other Study ID Numbers:	CMD-2015-001

First Posted:	February 23, 2016	Key Record Dates
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Last Verified:	July 2017	