PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Phase 2 Trial of Pemetrexed (Alimta™) Combined With Paclitaxel in Patients With Recurrent/Advanced Follicular, Papillary or Anaplastic Thyroid Cancer

Trial Acronym

Panthera

URL of the trial

[---]*

Brief Summary in Lay Language

The aims of this trial are to evaluate the efficacy and tolerability of pemetrexed + paclitaxel in patients with recurrent/advanced follicular, papillary or anaplastic thyroid cancer.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00005507**
- Date of Registration in DRKS: **2013/12/06**
- Date of Registration in Partner Registry or other Primary Registry: **2008/11/05**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT00786552 (ClinicalTrials.gov)**
- Sponsor-ID: **Panthera (University of Schleswig-Holstein)**

Health condition or Problem studied

- Free text: **Thyroid Cancer**
- ICD10: **C73 - Malignant neoplasm of thyroid gland**

Interventions/Observational Groups

- Arm 1: **Drug: pemetrexed + paclitaxel**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Rate of response; time frame: 6 weeks

Secondary Outcome

- Toxicity; time frame: weekly

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Medical Center II, University of Kiel, Kiel**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2008/11/30**
- Target Sample Size: **47**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Inclusion Criteria:

- Diagnosis of metastatic, histologically proven follicular/papillary or anaplastic thyroid cancer without clinically meaningful surgical or radiotherapeutic options and/or no amenability for radio-iodine therapy and evidence of progressive or symptomatic disease.

- No other forms of chemotherapy or investigational anticancer agents therapy for at least 4 weeks before enrollment in study.

- Performance status of 0 to 2 on the ECOG scale.

- Evidence of measurable disease according to the RECIST criteria.

- Prior radiation therapy and surgery allowed if completed at least 2 weeks prior to study enrollment, prior radioiodine treatment at least 3 months prior to study enrollment and patients must have recovered from the acute toxic effects of the treatment prior to study entry.

- Adequate organ function.

- No active infection (at the discretion of the investigator) or current central nervous system (CNS) metastases or history of central nervous system metastases or other serious concomitant systemic disorders incompatible with the study

(at the discretion of the investigator).

- No breast feeding nor pregnancy. For women of childbearing potential a negative serum pregnancy-test has to be performed 7 days prior to inclusion into the study.

- No coexisting second malignancy or history of prior malignancy within the last 5 years. (Excluding basal or squamous cell carcinoma of the skin, superficial bladder cancer and in situ carcinoma of the cervix with no evidence of recurrence).

- For men and women of childbearing potential appropriate contraceptive precautions should be taken during the trial and for 3 months afterwards.

- No significant cardiovascular disease in the form of abnormal electrocardiogram (ECG) coupled with clinical features of recent or recurrent symptomatic cardiac disease (including myocardial infarction within the last year, uncontrolled angina, arrhythmia or hypertension, severe congestive heart failure (NYHA >3)).

- No evidence of peripheral neuropathy greater than CTC Grade 1.

- No prior taxane and/or pemetrexed therapy.

- Ability to discontinue administration of acetysalicylate and other nonsteroidal anti-inflammatory agents (NSAID) for 2 days before, the day of, and 2 days after the dose of pemetrexed (5 days prior for long-acting agents such as piroxicam). Exceptions for selective cyclooxygenase II-inhibitors in analgesic treatment may be discussed.

- No clinically significant effusions (pleural or peritoneal), or albumin <2.5 g/dl at the time of study treatment application. The drainage of effusions prior to study treatment application is possible.

- Inability of oral intake of folic acid or intramuscular vitamin B12 supplementation.

- At least 18 years of age and absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial

- Before patient registration/randomization, written informed consent must be given according to ICH/GCP, and national/local regulations.

- Participation in another trial at the same time is not allowed.

Exclusion criteria

[---]*

Addresses

■ **Primary Sponsor**

University of Schleswig-Holstein

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 2
- Last processed date by ClinicalTrials.gov: 2013/12/01
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.