Trial Description

Title

AXINAB AXirubicin-e® IN Adjuvant Breast Cancer
Non - interventional study on the efficacy and tolerability of epirubicin in the treatment of
breast cancer

Trial Acronym

AXINAB

URL of the trial

[---]*

Brief Summary in Lay Language

In this prospective non-interventional study no recommendation is made for diagnosis, treatment, enforcement and ongoing study conduct. Non-interventional studies are intended to reflect the actual treatment procedure and its results. This study was reported by axios Pharma GmbH according to § 67 paragraph 6 of the AMG (German Drug Law) to the BfArM (Study No 2076) and relevant institutions defined there (GKV, PKV, KBV). A list of participating doctors and sites is thereby transmitted at regular intervals and is going to be updated. Due to legal requirements pharmaceuticals used in non-interventional trials must not be provided as pharmaceutical samples.
For quality assurance monitoring visits can take place at sites which are chosen randomly here and without the influence of axios Pharma GmbH. This non-interventional study was submitted prior to your start of an ethics committee and positive.
The AXINAB trial is a non-interventional study (NIS). In the CRF all variables are are recorded, which could be relevant for subsequent evaluation and analysis. If parameters listed in CRF are not assessed in local practice of routine they will not be questioned, since it is the main objective of this trial to reflect the variation of local standards of care. Last but not least study participation is independent from treatment decision. This means, a patient should be included only after decision for a certain therapy and in accordance with the SPC.
The objective of this non-interventional study is to evaluate the efficacy, tolerability and side-effect profile of epirubicin, in this case axirubicin-e ®, in daily practice under routine conditions. Patients for whom therapy with this preparation according to the SPC is a therapy option and who meet the inclusion and exclusion criteria of this non-interventional study (NIS-AWB) are eligible. Besides the SPC listed safety and efficacy information this trial will focus on additional aspects of interest which were not or only partly addressed in trials leading to marketing authorization. These study specific target questions are listed below.

Brief Summary in Scientific Language

Besides the already known SPC listed information regarding safety and efficacy the following target questions are going to be addressed:

- What regimens including dosing with epirubicin are used in practice routine qualitatively, meaning what kind of combinations are observed , and quantitatively, meaning what are their percentages?

- To what extent has the infusion rate administered according to local standard of care influence on therapy response and cardiovascular toxicity assessed by ECG and echocardiography (LEFV)?

- To what extent are patients with reduced performance status (ECOG) or of advanced age (> 70) more affected by side effects than patients with lower age and better general condition ?

- Are there unknown side effects not observed so far or has the frequency pattern of already known side effects to be revised?

- How do antiemetic and supportive concomitant medications influence the tolerability and the frequency of therapy specific side effects?

The study design of a non-interventional study appears to be suitable in order to answer the questions outlined above especially when they are investigated in a routine practice setting. Therefore, this protocol does not include any instructions, except SPC, in order to reflect the current standard of care use. E.g. no recommendations are specified in terms of dosing, patient clientele, treatment regimens and treatment intervals.

Organizational Data

- DRKS-ID: **DRKS00006019**
- Date of Registration in DRKS: **2014/03/21**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **Bo/43/2013 , Ethikkommission bei der Ärztekammer Niedersachsen**

Secondary IDs

Health condition or Problem studied

- ICD10: **C50 - Malignant neoplasm of breast**
- Free text: **Side effects of chemotherapy with Axirubicin-e with a focus on cardiotoxicity and impaired quality of life.**

Interventions/Observational Groups

- Arm 1: **Ca. 600 patients will be observed with newly diagnosed or secondary cancer breast cancer over a recruitment period of a total of 5 years. Approximately 40-50 oncology practices and selected outpatient clinics will participate. The individual observation period per patient in this case comprises the entire adjuvant chemotherapy and follow-up visits every 6 months over a period of at least 2 years.**
  The observation is carried out prospectively , therefore therapy starts after enrollment in this study.

  All data must be strictly in accordance with the existing source data (file, lab results , etc.). About 5% of the data will be reviewed by clinical monitors for reasons of quality assurance. Not assessed parameters will not be followed up in order to keep the approach of a non-interventional study. These parameters will be documented as “not done”. Documentation should be performed in a timely manner within a time frame of 12 weeks after assessment which will enable early detection of safety issues. Timely documentation increases also the data quality significantly and allows study-accompanying interim analyzes . Serious adverse events (SAE) and pregnancies are to be reported within 24 hours of becoming aware. Pregnancy is also to be reported up to 90 days after end of therapy. Methods of documentation comprise the enrollment form, demographic data including ECOG and Karnofsky Index, baseline anamnestic data of the underlying disease like TNM-staging, grading and tumor markers, medical history, concomitant diseases and medications, anamnestic data of tumor, current therapy data, end of therapy and follow-up visits based on a state of the art CRF for oncologic trials.

Characteristics

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

Primary Outcome

Locally differentiated use of Axirubicin-e in anti-cancer regimens

Secondary Outcome

Additional data regarding the safety profile of AXirubicin-e

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Bielefeld**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/03/24**
- Target Sample Size: **600**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Diagnosed breast cancer for which Axirubicin-e represents a therapeutic option according to SPC
- Informed Consent including data protection informed consent

Exclusion criteria

Not applicable

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Further trial documents **Beobachtungsplan**

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*