Fexinidazole Phase IIIb study

4th JOINT EANETT/HAT PLATFORM
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Study design

- Prospective, multicentre, open-label, cohort study, assessing the effectiveness of fexinidazole in adults and children with HAT at any stage
- 174 patients planned (in- and out-patients)
- 3 investigational sites in Democratic Republic of the Congo.
Primary objective

- To assess the effectiveness of fexinidazole administered to in- and out-patients with g-HAT at all stages of the disease
  - Success or failure at 12 and 18 months after the end of the treatment.
Secondary objectives

- To assess the safety of fexinidazole
- To assess treatment compliance and the feasibility of patient self-management of treatment intake
  - Presence of fexinidazole in the blood samples 24hrs after last treatment dose
  - Leftover tablets and compliance interview
- To assess the acceptability of the proposed packaging and understanding of the instructions for use
  - Questionnaire at the beginning and at the end of the treatment period
- To assess the PK of fexinidazole and its main metabolites in the blood (inpatients only)
Treatment / Packaging

• Different dose according to patient weight: $\geq \text{ou } <35\text{ kg}$
FICHE D’INSTRUCTIONS

Fexinidazole Winthrop®
Fexinidazole
600 mg

Vale orale
Oral use
Adulte et enfant
Adult and child
≥ 35 kg

24 comprimés
24 tablets

SANOFI

CE MÉDICAMENT N’EST QUE POUR VOUS,
NE LE DONNEZ JAMAIS À QUELQU’UN
D’AUTRE.

UNE CONSULTATION MÉDICALE EST
OBLIGATOIRE.

POUR PRENDRE CE TRAITEMENT, SUIVEZ
TOUJOURS LES INSTRUCTIONS DU
MÉDECIN.

PRENDRE LE TRAITEMENT :

du jour 1 au jour 10

10 JOURS / 2 ETAPES :

ETAPES VERTE
ETAPES ORANGE

POUR CHAQUE PRISE :
en une fois par jour
au moment du repas

CALENDRIER :
cocher après chaque prise

La durée du traitement est de 10 jours sans interruption

DDi

Drugs for Neglected Diseases initiative
Eligible patients

- Extended patient population compared to previous trials
- Pregnant women (except 1st trimester)
- Breastfeeding women
- Children from age of 6
- Low body weight
- Any stage of the disease
- Concomitant diseases
Specific criteria for outpatients

- Karnofsky index > 50%
- Understanding of the treatment instructions
- No pregnancy or breastfeeding
- No neurological symptoms and medical and psychiatric contraindications for treatment
- Reachable and residing close to the investigator centre during the treatment period
Specificities for outpatients

- Caregiver:
  - Person designated to accompany the patient during the treatment period (give treatment, provide food, etc.)
  - Responsible to call the investigator in case of AE/SAE and for any question
- Possibility of hospitalization if patient is unable to continue the treatment at home
- PK will be measured at the end of the treatment period as an indicator of compliance
- Interview at the IMP dispensing and after the end of the treatment
Interview on the dispensing day

- Specific questionnaire designed with Sanofi
- Check the comprehension of the instructions for use of the treatment by both patient and caregiver:
  - Was the packaging enough?
  - Was investigator help needed?
- Evaluation of patient self-management of treatment intake
Interview at the end of treatment period

- Verification of treatment compliance
- Understanding and acceptability of packaging and instructions sheet via specific questionnaire designed with Sanofi
- Collection of adverse events and concomitant medication taken by the patient
Specific explicative images developed for the consent process
Thank you for your attention