AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: AZD7325
ACTIVE INGREDIENT: AZD7325

Study No: D1140C00015
A Phase I, Single-Center, Randomized, Double-Blind, Placebo-Controlled, Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of AZD7325 When Given in Multiple Ascending Oral Doses in Healthy Male Japanese Subjects

Developmental Phase: I
Study Completion Date: N/A
Date of Report: N/A

OBJECTIVES:

Primary objective of the study is to assess the safety and tolerability of multiple ascending oral doses of AZD7325 compared to placebo in healthy male Japanese subjects by assessment of adverse events, vital signs, physical examinations, laboratory parameters, ECGs and EEG.

Secondary objective of the study is to evaluate and characterize the pharmacokinetics of AZD7325 when given orally in multiple ascending doses by assessment of drug concentration in plasma and urine, and to evaluate the effects on VAS, Ataxia assessments and CogState Battery (cognition).

METHODS:

This will be a double-blind, placebo-controlled, randomized, parallel-group design within each dose group, ascending-dose, single centre study, with the objective to assess the safety, tolerability, pharmacokinetic profile and pharmacodynamics of AZD7325. The study will be conducted at one center in Japan.

12 healthy male Japanese subjects aged 20 to 45 years of age inclusive will be allocated to each dose panel and randomized to receive a dose of either AZD7325 (n=9) or placebo (n=3).

AZD7325 will be provided in a capsule. The dose and dose regimen of AZD 7325 will be 5 mg twice daily (5 mg*2/day), 10 mg once daily, 15 mg twice daily (15 mg*2/day) and 50 mg once daily. Subjects will receive 7-day repeated once daily or twice daily oral doses of the investigational product.

The duration of each subject's participation will be up to 50 days including: up to 30 day screening period, 10days/9nights in the study site, follow-up visit 5 to 10 days post discharge from the study site.

The following outcome variables will be measured.

- Safety
  - The incidence and severity of adverse events, abnormalities in vital sign assessments, clinical laboratory parameters, physical examination, telemetry, electrocardiograms (ECG) and Electroencephalogram (EEG).
- Pharmacokinetics
  - Plasma and urine concentrations of AZD7325. The PK parameters Cmax, tmax, tlag, AUC, AUC(0-t), AUC(0-τ), t1/2λz, CL/F, Ae, fe, CLR, R(AUC) and Cmin 4β-OH cholesterol
- Pharmacodynamics
  - Bond-Lader Visual Analogue Scale (VAS), Ataxia assessments and CogState Battery(cognition).
- Genetics
  - Genetic analysis of the genes related to AZD7325 treatment may be performed.

Participation in the exploratory genetic study is optional for the subject. All subjects randomized into the study will have the option to donate a blood sample for pharmacogenetic analysis. Subjects will not be excluded from participating in the study if they refuse to consent to the genetic analysis. Blood samples for this analysis will be taken only after the subject has given informed consent for the analysis. The analysis and results from pharmacogenetic testing will be handled and reported separately from the main study.

RESULTS:

This study was stopped before any subjects received AZD7325. No results were generated.