

## AVERROES

*Apixaban versus Acetylsalicylic Acid (ASA) to Prevent Stroke or Systemic Embolism in Atrial Fibrillation Patients who have Failed or are Unsuitable for Vitamin K Antagonist Treatment: A Randomized Double Blind Trial*

### Study Phase III

#### Purpose

The of this clinical research study is to learn if apixaban is more effective than Acetylsalicylic Acid (ASA) in preventing strokes and systemic embolisms associated with subjects who have atrial fibrillation. The safety of this treatment will also be studied.

The study population will include those who meet the following inclusion/exclusion criteria, some of which are:

#### **Inclusion Criteria**

- Permanent or persistent atrial fibrillation documented by 12 lead ECG on the day of screening
- Men & Women  $\geq$  50 years of age
- Signed & dated, written informed consent to participate in this study.
- Presence of at least one of the following risk factors for stroke:
  - 1) Prior stroke or TIA
  - 2) Age  $\geq$  75 years
  - 3) Arterial hypertension on treatment
  - 4) Diabetes mellitus
  - 5) Heart failure. NYHA Class 2 or greater at time of enrollment
  - 6) Left ventricular ejection fraction 35% or less, documents within 6 months of enrollment
  - 7) Documented peripheral arterial disease (previous arterial revascularization, limb, or foot amputation, or current intermittent claudication with ankle-arm systolic blood pressure ratio  $<0.9$ )
  - 8) The patient is not currently receiving vitamin K antagonist therapy for one of the following reasons:
    - a. Previous vitamin K antagonist therapy has been demonstrated to be unsuitable and its use has been discontinued (e.g., poor anticoagulant control, adverse events, need for other treatments that may interact with VKA, patient unable or unwilling to adhere to dose or INR monitoring instructions)
    - b. Vitamin K antagonist therapy has not been previously used but would be expected to be unsuitable (e.g., unlikely to comply with dosing or monitoring requirement, need for other treatment which may interact with VKA, unlikely to adhere to restrictions on alcohol, diet or non-prescription medications, risk of VKA therapy considered to outweigh the risk of stroke or systemic embolism, patient is unwilling to take VKA).

## Exclusion Criteria

- Women who are pregnant or breastfeeding
- Conditions other than atrial fibrillation that require chronic anticoagulation (e.g., prosthetic mechanical heart valve, venous thromboembolism)
- Patient with serious bleeding in the last 6 months or at high risk of bleeding. This includes, but is not limited to:
  - Active peptic ulcer disease
  - Platelet count < 100,000/mm<sup>3</sup> or hemoglobin < 10g/dL
  - Recent stroke (within 10 days)
  - Documents hemorrhagic tendencies or blood dyscrasias
  - Current alcohol or drug abuse, or psychosocial reasons that make study participation impractical
  - Severe co-morbid condition with life expectancy of < 1 year
  - Severe renal insufficiency (serum creatinine > 2.5 mg/dL [221umol/L] or a calculated creatinine clearance < 25ml/min)
- ALT or AST > 2 x ULN or a total bilirubin > 1.5 x ULN (unless and alternative causative factor [e.g., Gilbert's syndrome] is identified)

To inquire if you are eligible for this study or hear more about it, please contact:

Pentucket Medical Associates  
Clinical Research Office  
(978) 469-5494