

ENGAGE

A Randomized, Double-Blind, Double-Dummy, Parallel Group, Multi-Center, Multi-National Study of Evaluation of Efficacy and Safety of DU-176b Versus Warfarin in Subjects with Atrial Fibrillation – Effective Anticoagulation with Factor Xa Next Generation in Atrial Fibrillation (ENGAGE –AF TIMI – 48).

Phase III

Purpose

Is to demonstrate the safety and efficacy profile, in two different dose regimens of DU-176b, (an investigational new drug being tested for the prevention of stroke/systemic embolic events (SEE)), in individuals with atrial fibrillation. Patients will be randomized to one of three treatment groups: High Dose Regimen, Low Dose Regimen & Warfarin. The expected duration of the study is 24 months.

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

Inclusion Criteria

- Male & Females: 21 years or older
- Able to provide written informed consent
- History of documented AF within the prior 12 months
- A moderate to high risk of stroke, as defined by CHADS2 index score of at least 2

Exclusion Criteria

- Transient atrial fibrillation secondary to other reversible disorders
- Subjects with moderate or severe mitral stenosis, unresected atrial myxoma, or a mechanical heart valve
- Subject with any contraindication for anticoagulant agents
- Subjects with conditions associated with high risk of bleeding or have known or suspected hereditary or acquired bleeding disorders
- Females of childbearing potential including the following: history of tubal-ligation / less than 2 years post-menopausal

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

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