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PHASE III

MARINER Will Provide Insights into the Potential Benefit of Once-daily Rivaroxaban in Protecting Medically Ill Patients from Venous Thromboembolism (VTE) Following Hospital Discharge

Phase III Study of Oral, Once-daily Rivaroxaban 10 mg

Medically Ill Patients Following Hospital Discharge

8,000 Patients from 15 Countries

Patients who have been hospitalised for the treatment of acute medical illnesses have a 50% risk of developing VTE during their hospital stay, and many are not diagnosed until after discharge[1]. Preventative treatment for VTE is, therefore, important in this group of patients and there exists a need to explore thromboprophylaxis in this high-risk patient population.

The Phase III MARINER Study will evaluate the efficacy and safety of once-daily rivaroxaban to reduce the risk of symptomatic VTE in medically ill patients for up to 45 days after hospital discharge.

MARINER Study Design[2]

Randomised, double-blind, controlled, event-driven, global study in medically ill patients at risk of VTE after hospital discharge

Rivaroxaban 10 mg OD (7.5 mg OD in patients with renal impairment)

Placebo

Study duration 45 days with 30-day follow-up

Primary efficacy endpoint: symptomatic VTE and VTE-related death
Primary safety endpoint: major bleeding

The extensive evaluation of rivaroxaban to protect different patient populations at risk of venous and arterial thromboembolism (VAT), makes it the most studied novel OAC in the world. Rivaroxaban (Xarelto®) is already approved for five indications in seven areas of use and its investigation - both completed and ongoing - will include more than 275,000 patients in clinical trials and real world settings.

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About the Study Patient Population

Key inclusion criteria:

Patients must be 40 years and older, with an increased risk of VTE and must have been hospitalised for at least three consecutive days and up to 14 days for an acute medical condition such as, but not limited to:

- Congestive heart failure
- Acute respiratory insufficiency
- Acute exacerbation of COPD
- Acute ischaemic stroke
- Acute infectious or inflammatory diseases

Key exclusion criteria:

- Serious bleeding or severe head trauma within the last three months prior to entering the study
- Serious trauma within four weeks prior to entering the study
- History of haemorrhagic stroke
- Any medical condition that requires chronic use of anticoagulation

For more details, please visit www.clinicaltrials.gov

References

1) Streiff MB, Brady JP, Grant AM, et al. CDC Grand Rounds: Preventing Hospital-Associated Venous Thromboembolism. Centers for Disease Control and Prevention. March 7, 2014; 63(09);190-193. 2) ClinicalTrials.gov. A Study of Rivaroxaban (JNJ-39039039) on the Venous Thromboembolic Risk in Post-Hospital Discharge Patients (MARINER). Available at: http://clinicaltrials.gov/ct2/show/NCT02111564?term=mariner&rank=1. Accessed July 2014.