

## PHASE IIIb

**PIONEER AF-PCI will Provide Physicians with Further Insights to Guide Treatment Decisions for Patients with Atrial Fibrillation (AF) Undergoing Percutaneous Coronary Intervention (PCI)**

**Phase IIIb Study:  
Addressing  
Unanswered Clinical  
Questions**

**First Study of  
a Novel OAC  
in this Patient  
Group**

**2,100 Patients from  
14 Countries**

PIONEER AF-PCI is a Phase IIIb study that will assess the safety of two rivaroxaban treatment strategies and an adjusted-dose vitamin K antagonist (VKA) strategy in patients with AF who undergo PCI with stent placement.

Patients with non-valvular AF undergoing PCI with stent placement are at a heightened risk of blood clots, which can trigger severe consequences including stroke. Despite this, there is currently a lack of clinical evidence for optimal treatments in this patient population who require anticoagulation therapy for stroke prevention and are concomitantly treated with dual antiplatelet therapy.

### PIONEER AF-PCI Study Design<sup>1</sup>

First patient was enrolled in May 2013

**Open-label, randomised, controlled study in 2,100 patients with AF undergoing PCI with stent placement**

**Rivaroxaban 15 mg OD  
+ Clopidogrel**

**Rivaroxaban 2.5 mg BID +  
Dual Antiplatelet Therapy**

**VKA (target INR 2-3) +  
Dual Antiplatelet Therapy**

**Rivaroxaban 15 mg OD  
+ Low-dose ASA**

**VKA (target INR 2-3)  
+ Low-dose ASA**

**12-month study with those patients on the treatment strategies including dual antiplatelet therapy being switched to a second phase of the treatment strategy after 1, 6 or 12 months (pre-specified before randomisation)**

**Primary endpoint: clinically significant bleeding (includes: TIMI\* major bleeding, minor bleeding and bleeding requiring medical attention)**

**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.**

#### References

<sup>1</sup> ClinicalTrials.gov. A Study Exploring Two Strategies of Rivaroxaban (JNJ39039039; BAY-59-7939) and One of Oral Vitamin K Antagonist in Patients With Atrial Fibrillation Who Undergo Percutaneous Coronary Intervention (PIONEER AF-PCI). Available at: <http://clinicaltrials.gov/ct2/show/study/NCT01830543>. Accessed January 2015. \*The TIMI scale is one of the most well-known risk scoring methods for a patient hospitalised with a heart attack. Using a patient's current vital health information as a guide, the TIMI scale provides a numerical value for the patient's potential prognosis, including short-term risk of death