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## **THROMBOSIS RESEARCH INSTITUTE TO ANNOUNCE NEW REAL-WORLD GARFIELD-AF REGISTRY INSIGHTS IN ATRIAL FIBRILLATION AT ESC CONGRESS 2016**

- *A Satellite Symposium and three GARFIELD-AF presentations, including a Registry Session, will highlight the importance of understanding how physicians manage the risk of stroke in patients with atrial fibrillation in everyday practice*
- *ESC Congress 2016 coincides with GARFIELD-AF registry milestone, exceeding enrolment target of 57,000 patients*

**London, United Kingdom, 15<sup>th</sup> August 2016** – New analyses from the Global Anticoagulant Registry in the FIELD–Atrial Fibrillation (GARFIELD-AF) will be presented at ESC Congress 2016, to be held in Rome, Italy, from August 27<sup>th</sup> to August 31<sup>st</sup> 2016 – with a focus on the importance of risk stratification and tailored management strategies to inform the evolution of everyday clinical practice. Better risk stratification schemes and appropriately prescribed and monitored antithrombotic therapy can help physicians to reduce the incidence of stroke in patients with atrial fibrillation (AF) and prevent the burdensome consequences of stroke for patients and their families.

GARFIELD-AF is the largest ongoing prospective AF registry, and enrolment is now complete, with over 57,000 patients recruited across five cohorts. This year, a new risk stratification tool based on the global data from GARFIELD-AF will be unveiled at the ESC Registry Session on AF:

*Identifying patients with atrial fibrillation and “truly low” thromboembolic risk who are poorly characterized by CHA<sub>2</sub>DS<sub>2</sub>-VASc: Superior performance of a novel machine learning tool in GARFIELD-AF (7075)*

- Registry Session: Registries Atrial Fibrillation
- Monday 29<sup>th</sup> August 2016 at 08:30 CEST, Raphael – The Hub

Risk assessment now focuses on improved identification of truly low-risk patients with AF who do not need any antithrombotic therapy using risk stratification tools. This session, presented by Professor Keith AA Fox from the University of Edinburgh, Edinburgh, United Kingdom, will compare the performance of CHA<sub>2</sub>DS<sub>2</sub>-VASc with a novel computer-generated (machine learning) approach to risk modelling for low-risk patients with AF using contemporary data from GARFIELD-AF.

Further important insights from GARFIELD-AF will be presented in a Satellite Symposium and two moderated poster presentations:

*Risk profiles and the quality of stroke prevention for patients with atrial fibrillation: Results from the GARFIELD-AF registry*

- Satellite Symposium sponsored by the Thrombosis Research Institute (TRI)
- Saturday 27<sup>th</sup> August 2016 at 15:30–17:00 CEST, Cairo Room, Village 3

An expert faculty will explore questions using data from newly diagnosed patients with AF in GARFIELD-AF, on topics including the risk of early mortality, risk scoring schemes for patients, management of low-risk patients and the characteristics of patients receiving different antithrombotic therapies.

*Do baseline characteristics account for geographical variations in event rates in patients with newly diagnosed atrial fibrillation? The GARFIELD-AF registry (P83627)*

- Moderated poster session: Antithrombotic therapy in atrial fibrillation
- Monday 29<sup>th</sup> August 2016 at 15:35–16:25 CEST, Moderated poster station – Poster Area

Professor Keith A. A. Fox will present an analysis of geographical variability in all-cause mortality, stroke/systemic embolism (SE) and major bleeding observed in patients with newly diagnosed nonvalvular AF from GARFIELD-AF.

*Vitamin K antagonist control for patients with nonvalvular atrial fibrillation in Eastern and Southeastern Asia: An analysis of event rates from GARFIELD-AF (P83239)*

- Moderated poster session: Antithrombotic therapy in atrial fibrillation
- Tuesday 30<sup>th</sup> August 2016 at 10:05–10:55 CEST, Moderated poster station – Poster Area

Professor Shinya Goto from Tokai University, Isehara, Japan, will present an analysis of the association between international normalised ratios, used to measure of the intensity of anticoagulation, and the rates of stroke/SE, major bleeding and all-cause mortality in patients from Eastern and Southeastern Asia receiving vitamin K antagonists (based on data from GARFIELD-AF).

### **About the GARFIELD-AF registry**

GARFIELD-AF is a pioneering, independent academic research initiative led by an international steering committee under the auspices of the TRI, London, United Kingdom.

It is an international, observational, multicentre study of stroke prevention in patients with newly diagnosed AF. 2016 marks the end of the recruitment phase, and GARFIELD-AF has now exceeded its recruitment target of 57,000 patients. Patients were enrolled from over 1,000 centres in 35 countries worldwide, including the Americas, Europe, Africa and Asia-Pacific.

Contemporary understanding of AF is based on data gathered in controlled clinical trials. Whilst essential for evaluating the efficacy and safety of new treatments, these trials are not representative of everyday clinical practice and, hence, uncertainty persists about the real-life burden and management of this disease. GARFIELD-AF seeks to provide insights into the impact of anticoagulant therapy on thromboembolic and bleeding complications seen in this patient population. It will provide a better understanding of the potential opportunities for improving care and clinical outcomes amongst a representative and diverse group of patients and across distinctive populations. This should help physicians and healthcare systems to appropriately adopt innovation to ensure the best outcomes for patients and populations.

The registry started in December 2009. Four key design features of the GARFIELD-AF protocol ensure a comprehensive and representative description of AF; these are:

- Five sequential cohorts of prospective, newly diagnosed patients, facilitating comparisons of discrete time periods and describing the evolution of treatments and outcomes;

- Investigator sites that are selected randomly within carefully assigned national AF care setting distributions, ensuring that the enrolled patient population is representative;
- Enrolment of consecutive eligible patients regardless of therapy to eliminate potential selection bias;
- Follow-up data captured for a minimum of 2 and up to 8 years after diagnosis, to create a comprehensive database of treatment decisions and outcomes in everyday clinical practice.

Included patients must have been diagnosed with nonvalvular AF within the previous 6 weeks and have at least one risk factor for stroke; as such, they are potential candidates for anticoagulant therapy to prevent blood clots leading to stroke. It is left to the investigator to identify a patient's stroke risk factor(s), which need not be restricted to those included in established risk scores. Patients are included whether or not they receive anticoagulant therapy, so that the merit of current and future treatment strategies can be properly understood in relation to patients' individual risk profiles.

The GARFIELD-AF registry is funded by an unrestricted research grant from Bayer Pharma AG, Berlin, Germany.

### **The burden of AF**

Up to 2% of the global population has AF,<sup>1</sup> including around 8.8 million people in Europe<sup>2</sup> and 5–6.1 million in the United States.<sup>3</sup> It is estimated that its prevalence will at least double by 2050 as the global population ages.<sup>3</sup> AF is associated with a five-fold increase in stroke risk, and one out of five strokes is attributed to this arrhythmia.<sup>1</sup> Ischaemic strokes related to AF are often fatal, and those patients who survive are left more frequently and more severely disabled and have a greater risk of recurrence than patients with other causes of stroke.<sup>1</sup> Hence, the risk of mortality from AF-associated stroke is doubled and the cost of care is 50% higher.<sup>1</sup> AF occurs when parts of the atria emit uncoordinated electrical signals. This causes the chambers to pump too quickly and irregularly, not allowing blood to be pumped out completely.<sup>4</sup> As a result, blood may pool, clot and lead to thrombosis, which is the number one cardiovascular killer in the world.<sup>5</sup> If a blood clot leaves the left atrium, it could potentially lodge in an artery in other parts of the body, including the brain. A blood clot in an artery in the brain leads to a stroke. 92% of fatal strokes are caused by thrombosis.<sup>5</sup> People with AF also are at high risk for heart failure, chronic fatigue and other heart rhythm problems.<sup>6</sup> Stroke is a major cause of death and long-term disability worldwide – each year, 6.7 million people die<sup>7</sup> and 5 million are left permanently disabled.<sup>8</sup>

### **About the TRI**

The TRI is a charitable foundation and multidisciplinary research institute dedicated to the study of thrombosis and related disorders. TRI's mission is to provide excellence in thrombosis research and education, to develop new strategies to prevent and treat thrombosis and thereby enhance quality of care, improve clinical outcomes and reduce healthcare costs. The TRI is a member of University College London Partners' Academic Health Science Network. For more information, visit [www.tri-london.ac.uk](http://www.tri-london.ac.uk).

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