EXECUTIVE SUMMARY

- The approval of non-vitamin K antagonist oral anticoagulants (NOACs) has changed prescribing patterns for stroke prevention in atrial fibrillation (AF) worldwide.\(^1\) There is a need to further understand how these agents are being used in clinical practice.

- GLORIA™-AF is one of the largest global AF registry programs, collecting long-term effectiveness and safety data on a range of antithrombotics including warfarin, acetylsalicylic acid (ASA) and NOACs for stroke prevention in AF, as well as clinical outcomes from patients receiving no antithrombotic treatment\(^2\).

- GLORIA™-AF will enrol up to 56,000 patients newly diagnosed with AF at risk of stroke from up to 2,200 sites in nearly 50 countries worldwide, investigating patient characteristics that influence antithrombotic prescribing choice\(^2\).

- The first baseline results of GLORIA™-AF show regional differences in patterns of antithrombotic therapy. While vitamin K antagonists (VKAs) are still widely used, an increased uptake of NOACs could be observed. However, despite high stroke risk, large proportions of patients - particularly in Asia - remain undertreated with ASA only, or receive no treatment for stroke prevention\(^3\).

- Future results of GLORIA™-AF - Phases II and III - will inform about the safety and effectiveness of antithrombotic therapy and advance current and future AF management.
The Need for Effective Stroke Prevention in Atrial Fibrillation (AF)

Preventing stroke is the primary goal of treatment in patients with AF for which antithrombotic therapy is essential. VKAs, like warfarin, were used for stroke prevention in AF for decades, however due to the limitations associated with the treatment considerable fluctuations in efficacy and safety can occur.

To address the shortcomings of VKAs, several NOACs have been developed. Dabigatran etexilate was the first NOAC to be approved in the European Union for stroke prevention in AF in August 2011, and is now approved in over 100 countries worldwide. Other NOACs are the Factor Xa inhibitors, which include rivaroxaban (first approved in December 2011) and apixaban (first approved in 2012), as well as edoxaban (first approved in 2015).

What is GLORIA™-AF?

GLORIA™-AF (Global Registry on Long-Term Oral Antithrombotic Treatment in Patients with Atrial Fibrillation) is a large, multinational, prospective registry program designed to characterise the treatment of patients newly diagnosed with non-valvular AF at risk of stroke. With up to 56,000 patients planned to be enrolled from up to 2,200 sites in nearly 50 countries, GLORIA™-AF is one of the largest AF registry programs currently running worldwide. GLORIA™-AF will provide important real-world information on antithrombotic prescribing patterns and patient outcomes.

Why a Registry?

- Real-world data provide information on the AF population at risk for stroke
- The effect of new oral anticoagulants entering the market can be investigated and changes in treatment patterns and outcome events evaluated in a real-world population
- Large patient numbers in a broad population reflect how antithrombotic treatment is used in a real-world setting
- Patient population reflects real-world comorbidities

Disease registries are an effective tool to observe the course of a disease and to collect data to evaluate treatment effectiveness and safety, investigate variations in outcomes and to provide insight into factors that affect patient survival.

Real-world data allow the exploration of disease management patterns, treatment safety monitoring and identification of optimisation strategies in clinical practice, which are vital for studying broad patient populations in relation to comorbidities and comediations.
The GLORIA™-AF Registry Program Objectives

1. Characterise patients newly diagnosed with non-valvular AF at risk of stroke on a global level
2. Define study patterns, predictors and outcomes of different treatment regimes for stroke prevention in non-valvular AF
3. Collect data on the safety and effectiveness of antithrombotic treatments, such as the long-time standard of care VKAs, i.e. warfarin, and NOACs such as dabigatran etexilate

Phases of the GLORIA™-AF Registry Program

The novel three-phase design of the GLORIA™-AF Registry Program includes propensity scoring to ensure that there are no significant differences in baseline patient characteristics between treatment groups that might bias the results. Furthermore, useful information is being collected to assess changes in prescribing patterns of antithrombotic therapies over time and across different regions of the world. The knowledge gained from the registry program will advance the management of AF in clinical practice.

Phase I
Undertaken to collect information on antithrombotic prescribing patterns prior to the approval of NOACs in many countries worldwide, enrolling patients from May 2011 to January 2013

Phase II
Began after the approval of the first NOAC, dabigatran etexilate, and collects data on the safety and effectiveness of dabigatran etexilate for two years, as well as baseline characteristics of all patients eligible for inclusion into the registry

Phase III
Began when there was sufficient overlap of patient characteristics between dabigatran etexilate and warfarin treatment groups. Phase III follows patients for three years to evaluate the safety and effectiveness of dabigatran etexilate versus warfarin using patient outcome data. Information regarding the overall safety and effectiveness of other antithrombotic treatments will also be collected.
The GLORIA™-AF Registry Program is ongoing in nearly 50 countries, enrolling up to 56,000 AF patients from up to 2,200 sites worldwide.¹

Patients are grouped into five regions:

- Asia
- Europe
- North America
- Latin America
- Africa/Middle East

GLORIA™-AF involves a range of clinical settings including general practices, specialist offices, community hospitals, university hospitals, outpatient care centres and anticoagulation clinics.¹

To date nearly 35,000 patients have been included in the GLORIA™-AF Registry Program.⁹
Baseline Results from GLORIA™-AF

Global and regional treatment patterns of antithrombotic therapies for stroke prevention in AF, and patient characteristics from more than 16,000 patients in GLORIA™-AF Phase I and II, have been published in scientific journals and presented at various scientific conferences.\(^3\)\(^{13} - \)\(^{16}\)

Results from GLORIA™-AF Phase II show regional differences in patterns of AF management for stroke prevention. While VKAs are still widely used an increased uptake of NOACs could be observed with a preference for NOACs over VKA in regions like North America and Europe. However, despite high stroke risk, large proportions of patients undertreated with ASA only, or receive no treatment for stroke prevention; this is most pronounced in Asia.\(^3\)

First Clinical Outcome Results from GLORIA™-AF

Presented at the ESC Congress 2016, the first outcome results from Phase II of the GLORIA™-AF Registry support the safety and effectiveness profile of dabigatran etexilate.\(^17\) Findings from 2,932 patients newly diagnosed with non-valvular AF treated with dabigatran etexilate and followed for two years demonstrate:

- **A low incidence of safety outcomes for patients treated with dabigatran etexilate:**
  - Only 1.12% of dabigatran-treated patients experienced a major bleed and only 0.54% experienced a life-threatening bleed

- **Dabigatran etexilate effectively reduced the risk of stroke for non-valvular AF patients:**
  - Less than 1% of dabigatran-treated patients experienced a stroke (0.63%)

- **The safety and effectiveness of dabigatran etexilate was maintained over two years of follow up in routine clinical care**\(^17\)
GLORIA™-AF Registry Program

References