Title: A pharmacoepidemiological study of Rivaroxaban use and potential adverse outcomes in routine clinical practice in the United Kingdom

Progress Report - EUPAS11299

This PASS category 1 study is being conducted in collaboration with the Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE), a member of the ENCePP, in the population based healthcare database The Health Improvement Network (THIN) in the UK. The primary objective of this prospective cohort study is to characterize the drug utilization, safety and effectiveness of rivaroxaban in approved indications under clinical practice conditions.

The study is currently ongoing. A Progress Report for this reporting period is provided below and includes descriptive statistics of the study cohort accrued from January 1, 2012 to December 31, 2017.

In total, 24 988 rivaroxaban patients and 43 416 warfarin patients were identified as first time users of these drugs in the THIN database during the study period according to criteria described in the study protocol. Among those, 18 325 (73.3%) and 43 080 (99.2%) were classified as naïve (no use of any oral anticoagulant) users of rivaroxaban and warfarin, respectively. The proportion of naïve users of rivaroxaban has increased from the earlier years and is now closer to the proportion of naïve users of warfarin. In first time users of rivaroxaban, 0.2% (n=43), 0.3% (n=68), 4.3% (n=1087), 14.7% (n=3683), 70.2% (n=17 549), 10.1% (n=2 534), and 0.1% (n=24) were prescribed an initial daily dose of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, respectively. Thus the majority of patients were prescribed the 20 mg dose. The study investigator is currently undertaking validation analyses to ascertain the study safety outcomes.

In summary, a manual review of computerized medical records as well as of free-text comments (which include referral letters specialists, hospital discharge letters and results of diagnostic tests) of patients identified with an outcome of interest is being performed.

Study finalization is estimated for 2020.