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

Progress Report - EUPAS11145

This PASS category 1 study is being conducted in the claims-based German Pharmacoepidemiological Research Database (GePaRD) at the Leibniz Institute for Prevention Research and Epidemiology - BIPS GmbH, Germany, a member of the ENCePP. 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.

This progress report is based on data collected from 09 Dec 2011 to 31 Dec 2015. The data included in GePaRD encompass one small and local Statutory Health Insurance provider (SHI), one regional SHI which used to be regional but now has members all over Germany, and two large nationally operating SHIs representing approximately 24 million insurants. This report describes baseline characteristics of new users of rivaroxaban and phenprocoumon including prior medical history, comorbidities, comedications, risk factors, and renal function.

The total number of subjects who were dispensed rivaroxaban and phenprocoumon were 179 120 and 404 849, respectively. The overall study cohort included 178 427 (99.6%) first-time users of rivaroxaban and 167 167 (40.9%) first-time users of the phenprocoumon. Among the first-time rivaroxaban users, 0.1% (n=96), 20% (n=36 094), 30% (n=53 437) and 46% (n=82 270) were prescribed rivaroxaban 2.5 mg, 10 mg, 15 mg and 20 mg tablets, respectively. 3.7% (n=6 530) received multiple strengths. The most common indication in new users of rivaroxaban as well as phenprocoumon was stroke prevention in atrial fibrillation (SPAF) consisting of 89 122 first-time users of rivaroxaban of which 63 641 (71%) were classified as naïve. The second most common indication was VTE, and corresponding figures were 40 818 and 24 213 (59%), respectively.

The mean age at cohort entry was 68.2±13.9 years for first-time naïve rivaroxaban users and 69.9±12.8 years for first-time naïve phenprocoumon users. The proportion of women was higher in rivaroxaban cohort compared to the phenprocoumon cohort (52.4% vs 46.9%). Among naïve first-time users of rivaroxaban or phenprocoumon with SPAF as the indication, the mean CHA2DS2VASc score was 3.8±1.8 and 4.1±1.7, respectively; and the mean modified HAS-BLED score was 3.0±1.3 and 3.1±1.3, respectively. Overall, the proportion of severe renal failure (stage 5, eGFR<15 or dialysis) was lower in the rivaroxaban cohort (3.8%) compared to the phenprocoumon cohort (9.9%).

Study finalization is estimated for 2020.