NON-INTERVENTIONAL STUDY REPORT ABSTRACT

Title: An Active Surveillance, Post-Authorisation Safety Study (PASS) to Estimate Incidence Rates of Serious Infection, Malignancy, Cardiovascular (CV) and Other Safety Events of Special Interest among all Patients Treated with Ruxience for Rheumatoid Arthritis (RA) within the British Society for Rheumatology Biologics Register-Rheumatoid Arthritis (BSRBR-RA)

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Rationale and background: Approved in the EU on 1 April 2020, PF-05280586 (Ruxience) has been developed by Pfizer as a biosimilar to the licensed reference product, MabThera (rixutimab) which was the first therapeutic monoclonal antibody to target cells that have the CD20 marker on their surface. Pfizer proposed the assessment of safety events of special interest based on the Ruxience Risk Management Plan (RMP) v. 1.0 (infections including serious infections (Important Identified Risk), malignancies (Important Potential Risk), impact on cardiovascular disease (CVD) (Important Potential Risk) and use in pregnancy (Missing Information). This protocol describes a post-authorisation safety study (PASS) of Ruxience-exposed patients using actively collected prospective data included in the established BSRBR-RA. This study is designated as a Category 4 “Additional Pharmacovigilance Activities” in line with the reference product.

Research question and objectives: What are the incidence rates of safety events of special interest in patients with rheumatoid arthritis who are enrolled in the in the BSRBR-RA and initiate treatment with Ruxience?

The objectives were to estimate incidence rates of infections, including serious infections, malignancies, cardiovascular events, and events associated with use during pregnancy among patients with rheumatoid arthritis in the BSRBR-RA who initiate Ruxience.

Study design: This was an active surveillance study using existing data within the BSRBR-RA, an ongoing, prospective, observational cohort study started in 2001 with the primary aim of studying the safety of new therapies for RA during routine post-marketed clinical use in the United Kingdom (UK).

Setting: The study population was comprised of all patients with RA enrolled within the BSRBR-RA who initiate treatment with Ruxience during the study period.

Subjects and study size, including dropouts: This was a descriptive study without pre-specified hypotheses, therefore there was no minimum sample size requirement. All Ruxience-treated patients with data in the BSRBR-RA during the study period were included in the study.

Study Period: The study period start date was the date when the first patient identified in the BSRBR-RA with RA initiated Ruxience and ended approximately two years after the start date.

Variables and data sources: This study focused on specific variables routinely captured in the BSRBR-RA and include baseline patient characteristics (ie, clinical and demographic characteristics, comorbidities and current and past therapies), and safety events of special interest including serious infections, malignancies, CV events, and events associated with use during pregnancy. The BSRBR-RA was established in 2001 to study the safety of biologic therapies in RA patients living in the UK.

Results: During the study period, only 3 patients with RA initiated Ruxience in the BSRBR-RA. Patients were recruited from 3 UK hospitals that prescribed this treatment for RA. In terms of comparison cohorts, 2160 anti-tumor necrosis factor (TNF)-treated patients and 3694 conventional disease-modifying antirheumatic drugs (csDMARD)-treated patients were also recruited into the BSRBR-RA at any time since establishment of the registry. Due to data protection practices, data on patients starting Ruxience have not been stratified by gender, age or baseline characteristics. During the study period there were no safety events of special interest reported among the 3 patients who initiated Ruxience.

Discussion: Results of this study demonstrate that during the study period, Ruxience was very rarely prescribed for RA based on data from the BSRBR-RA. Due to this, no conclusions can be drawn about these data.

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