INCIDENCE RATE AND CHARACTERIZATION OF HERPES ZOSTER IN PATIENTS WITH MODERATE-TO-SEVERE RHEUMATOID ARTHRITIS: AN UPDATE FROM BARICITINIB CLINICAL STUDIES

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Background: Baricitinib (BARI) is a selective inhibitor of Janus kinases (JAK) 1 and JAK2, approved for the treatment of moderately to severely active rheumatoid arthritis (RA) in adults in over 50 countries, including the United States, Europe and Japan. Due to their disease and associated therapy with disease-modifying anti-rheumatic drugs (DMARDs), RA patients (pts) have an increased risk of herpes zoster (HZ) compared with the general population. Furthermore, the incidence of HZ is increased in RA pts treated with BARI versus placebo (PBO). Objectives: To determine the long-term overall and geographical incidence, time to first event and risk factors for HZ in BARI-treated RA pts. Methods: Data were pooled from nine completed Phase I, II, and III studies of BARI in RA pts, including six randomised, PBO-controlled studies (0–24 weeks in DMARD-inadequate responders, including RA-BUILD, RA-BEACON and the long-term extension study, RA-BEYOND [data cut off February 13, 2018], and active-controlled studies with methotrexate (MTX); RA-BEGIN study in DMARD-naïve pts) and adalimumab (RA-BEAM study in MTX-inadequate responders). The HZ incidence was evaluated for all RA pts who had ever received BARI (any dose) and the HZ incidence rate (IR) was calculated as the number of pts with an HZ event per 100 patient-years of observation (PYO). Exposure included up to 28 days after treatment cessation, and was censored at the HZ event date. Univariate and multivariate Cox proportional hazard regression models were used to evaluate risk factors for HZ.

Results: Of 3770 RA pts treated with BARI, median age at study entry was 54 years (range 29–90 years), approximately one-quarter were each from North America (n=840; 22%), EU (783; 21%), Asia (959; 25%) and Central America (760; 20%), median time from RA diagnosis was 5 years, 2938 (78%) and 1754 (47%) were on concomitant MTX and CS, respectively. The median time to first HZ event was 538 days and the overall IR of HZ was 3.3/100 PYO, which did not increase significantly over time (Fig 1). Twenty-six (8%) cases were multidermalomat, and no visceral disease was noted. Thirteen (4%) cases had received prior HZ vaccination. Multivariate analyses showed that older age (hazard ratio [HR] 1.30, 95% confidence interval [CI] 1.17, 1.43) and geographical region (Asia, especially Japan, Taiwan and South Korea; HR 1.82, 95% CI 1.28, 2.58; Fig 2) were associated with a higher risk of HZ. Comparison of HZ incidence in BARI-treated RA pts did not increase over time and the majority of HZ events were monodermalomat and uncomplicated. Pts who were older and those from Asia were at increased risk of a HZ event.


REFERENCE: