SAFETY OF BARicitinib IN JAPANESE PATIENTS WITH RHEUMATOID ARTHRITIS (RA): THE 2020 INTERIM REPORT FROM ALL-CASE POST MARKETING SURVEILLANCE IN CLINICAL PRACTICE

T. Fujii, T. Atsumi, N. Okamoto, N. Takahashi, N. Tamura, A. Nakajima, A. Nakajima, H. Matsuno, N. Tsujimoto, A. Nishikawa, T. Ishii, T. Takeuchi, M. Kuwana, T. Takagi, W. wakayama Medical University Department of Rheumatology and Clinical Immunology, Wakayama, Japan; *Hokkaido University, Department of Rheumatology, Endocrinology and Metabolism, Faculty of Medicine, Sapporo, Hokkaido, Japan; *Osaka Medical College, Department of Rheumatology, and Allergy of Pediatrics, Takatsuk, Osaka, Japan; *Nagoya University Graduate School of Medicine, Department of Orthopaedics/Rheumatology, Nagoya, Japan; *Juntendo University School of Medicine, Department of Internal Medicine and Rheumatology, Tokyo, Japan; Ueno Touski Clinic, Ueno Touski Clinic, Fukushima, Japan; *Mie University Faculty of Medicine, Center for Rheumatic Diseases, Mie, Japan; Matsuno Clinic for Rheumatic Diseases, Yokama, Japan; *Eli Lilly Japan K.K., Kobe, Japan; *Keio University School of Medicine, Division of Rheumatology, Tokyo, Japan; *Nippon Medical School Graduate School of Medicine, Department of Allergy and Rheumatology, Tokyo, Japan; *Yamagata University Faculty of Medicine, Department of Orthopaedic Surgery, Yamaga, Japan

Background: An all-case post-marketing surveillance (PMS) of baricitinib (Bari), that started in Sep 2017, collects safety and effectiveness for the first 24 ws of treatment and continues to collect serious adverse events (SAEs) for 3 yrs. Objectives: To evaluate Bari safety in RA patients (pt) in clinical practice.

Methods: We report pt baseline demographics and adverse events (AEs) up to 24 ws for pts whose case report files for 24 wk data were completed as of Jun 2020.

Results: Data from 3445 pts were analyzed (females=80%, mean age=64y, mean RA duration 12y). Bari dose regimen was as follows: 4mg, 60g, 2mg, 27%, 4mg->2mg, 5g, 4mg, 4%, 2%, 0%. Concomitant use of MTX was as follows: 65% and 48%, respectively, 74% continued treatment for 24 ws. AE and SAE were recognized in 887 (28%) and 122 pts (4%), respectively. 6 pts died of pneumonia, aspiration pneumonia, bacterial pneumonia, cerebral infarction, ILD, aspiration pneumonia, adenocarcinoma, and colorectal cancer. Major AEs were as follows: herpes zoster=3%, liver dysfunction=3%, serious infection=1%, anemia=1%, hyperlipidemia=1%, malignancy=0.3%, interstitial pneumonia=0.2%, MAGE=0.1%, and VTE=0.1%.

Conclusion: Data do not show new safety concerns and encourage guideline-compliant use of Bari.