Correction

Safety Profile of Baricitinib in Patients with Active Rheumatoid Arthritis with over 2 Years Median Time in Treatment

Smolen JS, Genovese MC, Takeuchi T, Hyslop DL, Macias WL, Rooney T, et al. Safety profile of baricitinib in patients with active rheumatoid arthritis with over 2 years median time in treatment. J Rheumatol 2019;46:7-18.

In Table 1, Phase II, NCT01469013 is mentioned twice. The second occurrence is unnecessary.

In the Results section, page 9, last paragraph, the first sentence should read as follows: "The herpes zoster IR was significantly higher for 4 mg compared to placebo (4.3 vs 1.0) and **was numerically higher** for 4 mg compared to 2 mg in 2 mg-4 mg–extended." Bold face indicates words added for clarity.

Table 4. Adverse events (AE) detail.

- Three AE (EAIR ≥ 0.2) and their data have been added under the category "Temporary interruption because of AE ≥ 0.2 EAIR for 4 mg–treated patients in placebo-4 mg, n (EAIR)." See below.
- Under the category "Permanent discontinuation because of AE ≥ 0.2 EAIR for 4 mg–treated patients in placebo-4 mg, n (EAIR)," in the row for infections and infestations, under the 2mg-4mg-extended set, for baricitinib 4 mg, the p value is < 0.05, indicating significance.

Table 5. The corrected table is below. Changes are indicated in bold face.

- HDL numbers have been corrected.
- Units for hemoglobin were corrected to g/dl.
- Hemoglobin < 10 g/dl: the corrected values for baricitinib 2 mg and baricitinib 4 mg under the Placebo-2 mg–4 mg set are 33/462 (7.1) and 35/467 (7.5), respectively.
- In the Placebo-4 mg set, under Baricitinib 4 mg, the corrected values for ALT ≥ 3× ULN are 15/987 (1.5), and for ALT ≥ 5× ULN, 7/988 (0.7).

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Table 4. Additional data.

Variables	Placebo-4mg (6 studies, to Week 24)	2mg-4mg-extended, 4 Studies			
	Placebo	Baricitinib 4 mg	Baricitinib 2 mg	Baricitinib 4 mg	All-bari-RA
Temporary interruption because of AE ≥ 0.2 EAIR for 4 mg–treated patients in placebo-4 mg, n (EAIR)					
Skin and subcutaneous tissue disorders	2 (0.5)	6 (1.5)	2 (0.4)	5 (0.8)	26 (0.4)
Respiratory thoracic and mediastinal disorders	2 (0.5)	5 (1.2)	6 (1.1)	6 (1.0)	49 (0.7)
Surgical and medical procedures	2 (0.5)	4 (1.0)	4 (0.7)	8 (1.3)	65 (1.0)

AE: adverse events; EAIR: exposure-adjusted incidence rates; bari: baricitinib; RA: rheumatoid arthritis.

Table 5 (Corrected). Changes in selected laboratory values and clinical chemistry (weeks 0–24).[a]

Treatment-emergent shifts, n/NAR (%)	Placebo-4 mg (6 studies, to Week 24)		Placebo-2 mg-4 mg (4 studies, to Week 24)		
	Placebo	Baricitinib 4 mg	Placebo	Baricitinib 2 mg	Baricitinib 4 mg
LDL[b], ≥ 130 mg/dl	70/517 (13.5)	243/577 (42.1)*	35/225 (15.6)	77/264 (29.2)‡	89/248 (35.9)
HDL[b], ≥ 60 mg/dl	**85/442 (19.2)**	**229/458 (50.0)***	**37/197 (18.8)**	**90/214 (42.1)‡**	**93/201 (46.3)**
Triglycerides, ≥ 500 mg/dl	7/979 (0.7)	5/943 (0.5)	5/497 (1.0)	5/444 (1.1)	1/444 (0.2)
Creatinine[b]					
> 1 ULN	21/989 (2.1)	29/951 (3.0)	12/484 (2.5)	12/444 (2.7)	18/441 (4.1)
> 1.5× ULN	4/1010 (0.4)	5/964 (0.5)	1/495 (0.2)	0/452	5/450 (1.1)□
CPK[b]					
> ULN	89/954 (9.3)	337/893 (37.7)*	52/494 (10.5)	103/451 (22.8)‡	167/438 (38.1)□
> 2.5× ULN	14/1021 (1.4)	52/950 (5.5)*	10/538 (1.9)	14/476 (2.9)	33/470 (7.0)□
> 5× ULN	5/1028 (0.5)	11/956 (1.2)	5/543 (0.9)	5/476 (1.1)	8/474 (1.7)
Hemoglobin					
< LLN	193/747(25.8)	204/696 (29.3)	100/407 (24.6)	91/343 (26.5)	102/360 (28.3)
< 10 **g/dl**	63/1040 (6.1)	60/968 (6.2)	28/536 (5.2)	**33/462 (7.1)**	**35/467 (7.5)**
< 8 **g/dl**	2/1059 (0.2)	1/988 (0.1)	1/544 (0.2)	2/477 (0.4)	0/474 (0)
Neutrophils[b], < 1000 cells/mm^3	1/1029 (0.1)	3/957 (0.3)	1/544 (0.2)	3/477 (0.6)	1/474 (0.2)
Lymphocytes, < 500 cells/mm^3	10/1052 (1.0)	8/987 (0.8)	2/541 (0.4)	6/476 (1.3)	3/473 (0.6)
Platelets					
< LLN	28/1030 (2.7)	16/967 (1.7)	12/523 (2.3)	6/466 (1.3)	5/462 (1.1)
> 600,000/mm^3	14/1055 (1.3)	23/983 (2.3)	9/542 (1.7)	7/472 (1.5)	13/473 (2.7)
Patients with any postbaseline elevation, n/N (%)[a] ALT					
> 1 ULN	134/932 (14.4)	221/902 (24.5)	59/469 (12.6)	66/431 (15.3)	100/435 (23.0)
≥ 3× ULN	14/1058 (1.3)	**15/987** (1.5)	2/544 (0.4)	7/474 (1.5)	6/474 (1.3)
≥ 5× ULN	4/1059 (0.4)	**7/988** (0.7)	0/544	3/477 (0.6)	4/474 (0.8)
≥ 10× ULN[c]	0/1059	2/988 (0.2)	0/544	1/477 (0.2)	1/474 (0.2)

* $p < 0.05$ for baricitinib 4 mg versus placebo. ‡ $p < 0.05$ for baricitinib 2 mg versus placebo. □ $p < 0.05$ for baricitinib 2 mg versus 4 mg. P value from Cochran-Mantel-Haenszel test stratified by study. [a] Data up to rescue. Lipid samples were collected at weeks 0 (baseline), 12, and 24, and other hematology/clinical assessments were collected at weeks 0, 1, 2, 4, 8, 12, 14, 16, 20, and 24. National Cholesterol Education Program Adult Treatment Panel III guidelines (2002) were used for lipids[19]. Common Terminology Criteria for Adverse Events v3.0 were used for other laboratory variables[20]. [b] There were differences in laboratory assay methodologies and only the laboratory data collected using the same methodology were pulled, therefore the number of patients at risk can differ slightly across analytes. [c] Of the 3 cases of ALT ≥ 10× ULN, 1 patient had cholecystitis (study RA-BEGIN), 1 patient was receiving isoniazid treatment (study RA-BEGIN), and 1 patient started methotrexate within 6 months of randomization (study RA-BEAM). ALT: alanine aminotransferase; CPK: creatine phosphokinase; HDL: high-density lipoprotein; LDL: low-density lipoprotein; LLN: lower limit of normal; NAR: number at risk; ULN: upper limit of normal.