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FRI0357

IMPROVED PAIN AND FATIGUE WITH IXEKIZUMAB TREATMENT IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS AND PREVIOUS INADEQUATE RESPONSE TO TNF INHIBITORS: THREE YEAR FOLLOW-UP FROM A PHASE 3 STUDY (SPIRIT-P2)

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Background: Psoriatic arthritis (PsA) is a chronic and complex inflammatory disease with both articular and extra-articular symptoms. Pain and fatigue are two of the most common patient-reported symptoms. Improvements in pain and fatigue have been demonstrated with up to 2 years of treatment with ixekizumab (IXE) in patients who had an inadequate response or intolerance to tumor necrosis factor inhibitors (TNFi).^{1,2}

Objectives: To report improvements in pain and fatigue in TNFi-experienced patients with PsA who were treated with IXE for 3 years (156 weeks).

Methods: SPIRIT-P2 (NCT02349295) was a 156-week, Phase 3 study that included patients who met the Classification Criteria for Psoriatic Arthritis (CASPAR) and had an inadequate response or intolerance to 1 or 2 TNFi. Although there was a placebo group through Week 24, these data were derived only from patients in the intent-to-treat population randomized to IXE at baseline. After a 160-mg starting dose, patients received 80mg subcutaneous IXE every 2 or 4 weeks (Q2W or Q4W). Patients self-rated their symptoms using the Joint Pain Visual Analog Scale (Joint Pain VAS; 0 [none] to 100 [worst imaginable]), the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36; with the domains ranging from 0 [worst] to 100 [best]), and the Fatigue Severity Numeric Rating Scale (Fatigue NRS; 0 [none] to 10 [worst imaginable]). Minimum clinically important difference (MCID) cutoffs were ≥ 10 for Joint Pain VAS, ≥ 5 for SF-36 domains, and ≥ 3 for Fatigue NRS. Missing values were imputed by modified baseline observation carried forward for continuous variables and modified non-responder imputation for categorical variables.

Figure. Pain and fatigue outcomes after 156 weeks of treatment with ixekizumab. Mean change from baseline is shown for (A) Joint pain VAS, (B) SF-36 bodily pain domain, (C) Fatigue NRS, and (D) SF-36 vitality domain. IXE=ixekizumab; NRS=numeric rating scale; Q2W=every 2 weeks; Q4W=every 4 weeks; SF-36= Medical Outcomes Study 36-Item Short Form Health Survey; VAS=visual analog scale.

Results: The proportions of patients who completed Week 156 were 70/122 (57.4%) in the IXE Q4W group and 55/123 (44.7%) in the IXE Q2W group. At Week 156, mean change from baseline for the Joint Pain VAS was -28.9 (IXE Q4W) and -25.3 (IXE Q2W) (Fig. A). In addition, 51.8% of patients on IXE reported clinically meaningful improvement of joint pain (56.1% IXE Q4W, 47.5% IXE Q2W) at Week 156. Patients reported an 18-point mean improvement in the SF-36 bodily pain domain at Week 156 (Fig. B). Patients also reported improvements in fatigue up to Week 156 (Fig. C), with 35.0% of patients achieving the MCID on the Fatigue NRS (39.4% IXE Q4W, 30.6% IXE Q2W). Improvement in fatigue was supported by a 14-point mean improvement in the vitality domain of the SF-36 at Week 156 (Fig. D).

Conclusion: In patients with PsA who had an inadequate response or intolerance to TNFi, improvements in pain and fatigue were sustained through 3 years of IXE treatment in both the Q2W and Q4W treatment groups.

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FRI0358

USAGE OF C-REACTIVE PROTEIN TESTING IN THE DIAGNOSIS AND MONITORING OF PSORIATIC ARTHRITIS (PSA): RESULTS FROM A REAL-WORLD SURVEY IN THE US AND EUROPE

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Background: C-reactive protein (CRP) is an important non-specific marker of both acute and chronic inflammation and can be elevated in patients with PsA. The role of CRP in the management of PsA is unclear.

Objectives: To describe how CRP testing is implemented in real-world clinical practice for disease management of PsA.

Methods: A cross-sectional study among patients with PsA recruited by rheumatologists and dermatologists was conducted in France, Germany, Italy, Spain, UK and US. Data were collected from Jun-Aug 2018 via physician-completed patient record forms. Use of CRP testing was obtained by asking the physician to state (yes/no) whether CRP was used to aid PsA diagnosis, confirm the patient's PsA and to monitor the patient's PsA. Where physicians stated use of CRP testing, they were then asked to provide the number of CRP tests conducted in the last 12 months.

Results: Data were collected for 2270 patients with PsA (595 US, 1675 EU). In EU, 78.7% of patients had CRP conducted to aid diagnosis (vs 43.4% in US) and 72.0% had CRP conducted to monitor their condition (vs 34.6% in US). Patients seen by rheumatologists (vs dermatologists) were at least 50% more likely to have CRP used for monitoring purposes, this difference being most pronounced in the US. In EU, CRP was conducted a mean [SD] of 2.7 [1.7] times in the last 12 months, versus 2.0 [1.4] in the US. Country level usage of CRP testing is shown in Table 2.

Table 1. Patient demographic and clinical characteristics

	Overall (n=2270)	EU5 (n=1675)	US (n=595)
Patient seen by rheumatologist, n (%)	1130 (49.8)	834 (49.8)	296 (49.7)
Age, mean [SD]	46.6 [13.3]	48.1 [13.1]	50.0 [13.5]
Female, n (%)	1047 (46.1)	774 (46.2)	273 (45.9)
BMI, mean [SD]	26.8 [4.7]	26.3 [4.3]	28.1 [5.5]
Caucasian, n (%)	2051 (90.4)	1551 (92.6)	500 (84.0)
Current smoker, n (%)	403 (20.3)	352 (24.3)	51 (9.5)
Employment, n (%)	1271 (58.2)	894 (55.6)	377 (65.3)
-Working full-time			
Current disease severity, n (%)			
-Mild	1702 (75.0)	1253 (74.8)	449 (75.5)
-Moderate/Severe	568 (25.0)	422 (25.2)	146 (24.5)
Current treatment, n (%)			
-Receiving bDMARD*	1231 (54.2)	910 (54.3)	321 (53.9)
-Receiving tsDMARD*	251 (11.1)	121 (7.2)	130 (21.8)
-Receiving csDMARD*	835 (36.8)	698 (41.7)	137 (23.0)
-Receiving opioid	55 (2.4)	29 (1.7)	26 (4.4)
Total number of HCP visits in last 12months, mean [SD]	6.5 [5.8]	7.0 [6.3]	5.0 [3.6]

*bDMARD: biologic DMARD, tsDMARD: targeted synthetic DMARD, csDMARD: conventional synthetic DMARD

Table 2. Purpose and frequency of CRP testing

CRP conducted...	EU5 (n=1675)	France (n=277)	Germany (n=360)	Italy (n=360)	Spain (n=369)	UK (n=309)	US (n=595)
To aid diagnosis, n (%)	1319 (78.7)	233 (84.1)	282 (78.3)	283 (78.6)	315 (85.4)	206 (66.7)	258 (43.4)
To confirm PsA, n (%)	692 (41.3)	83 (30.0)	156 (43.3)	151 (41.9)	179 (48.5)	123 (39.8)	110 (18.5)
To monitor PsA, n (%) [n]	1190 (72.0)	209 (75.7)	261 (74.1)	256 (72.9)	283 (77.1)	181 (59.2)	203 (34.6)
	[1652]	[276]	[352]	[351]	[367]	[306]	[586]
Patients with ≥1 CRP in last 12 months, n (%)	1355 (80.9)	238 (85.9)	291 (80.8)	304 (84.4)	319 (86.4)	203 (65.7)	255 (42.9)
Number conducted in last 12months, mean [SD]	2.7 [1.7]	3.1 [2.5]	2.4 [1.7]	2.5 [1.3]	2.6 [1.2]	2.9 [2.0]	2.0 [1.4]

Conclusion: The majority (80.9%) of patients with PsA in EU5 had at least one CRP test in the last 12 months, versus 42.9% in the US. CRP is more commonly used for diagnosis and monitoring of PsA in Europe compared to the US and is more commonly ordered by rheumatologists than dermatologists.

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FRI0359

INTEGRATED SAFETY RESULTS OF TWO PHASE-3 TRIALS OF GUSELKUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS THROUGH THE PLACEBO-CONTROLLED PERIODS

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Background: DISCOVER 1 & 2 are phase 3 psoriatic arthritis (PsA) trials investigating guselkumab (GUS), an IL-23 inhibitor that specifically binds the IL-23p19 subunit. In both studies, GUS showed significant improvement vs placebo (PBO) through week (W) 24 in the PBO-controlled period.^{1,2}

Objectives: To present integrated safety results of DISC 1 & 2 through the PBO-controlled periods.

Methods: Adult patients (pts) with active PsA despite standard therapy were enrolled. All pts were biologic-naïve, except ~30% in DISC 1 with previous exposure to 1-2 TNF inhibitors. Pts were randomized to SC GUS 100mg Q4W; GUS 100mg at W0, W4, then Q8W; or PBO. Adverse events (AEs) and lab results were analyzed from pooled data.

Results: The rates of pts experiencing ≥1 AE, serious AE, infection, serious infection, and discontinuation due to an AE were similar between GUS and PBO (Table 1). There were 2 deaths, 3 malignancies, 2 Major Adverse Cardiac Events (MACE), and no opportunistic infections (treatment group not shown to prevent unblinding). Among the AEs reported by ≥5% pts in any group (Table 1), nasopharyngitis and elevated serum hepatic aminotransferases were more common with GUS vs PBO. Laboratory ALT and AST elevations were mostly mild, transient, and not associated with significant bilirubin elevation. There was a trend to decreased neutrophil count (mostly Grade 1, transient, and not associated with infection) with GUS vs PBO (Table 2). Low rates of injection-site reactions were seen with GUS vs PBO. Anti-drug antibody development was also low (Table 1).

Table 1. Patient Reported AEs, n (%)

	GUS 100mg Q8W	GUS 100mg Q4W	PBO
N	375	373	372
≥1 AE	182 (48.5)	182 (48.8)	176 (47.3)
≥1 Serious AE	7 (1.9)	8 (2.1)	12 (3.2)
Discontinuation due to AE	5 (1.3)	8 (2.1)	7 (1.9)
≥1 Infection	73 (19.5)	80 (21.4)	77 (20.7)
≥1 Serious infection	1 (0.3)	3 (0.8)	3 (0.8)
≥1 Opportunistic Infection (including Candida)	0	0	0
Active Tuberculosis	0	0	0
≥1 Injection-site reaction	5 (1.3)	4 (1.1)	1 (0.3)
Anti-GUS antibody +, n/N (%)	6/373 (1.6)	9/371 (2.4)	--
AEs* reported by ≥5% of patients in any treatment group			
Nasopharyngitis	26 (6.9)	19 (5.1)	17 (4.6)
Upper respiratory tract infection	13 (3.5)	23 (6.2)	17 (4.6)
Increased ALT	23 (6.1)	28 (7.5)	14 (3.8)
Increased AST	23 (6.1)	14 (3.8)	9 (2.4)

* Medical Dictionary for Regulatory Activities (MedDRA) preferred term

Table 2. Lab Results*

	GUS 100mg Q8W	GUS 100mg Q4W	PBO
N	373	371	370
ALT Increased (%)			
Grade 1	28.2	35.0	30.1
2	1.1	2.7	1.4
3-4	0.8	1.1	0.8
Neutrophil Count Decreased (%)			
Grade 1	5.6	5.9	3.2
2	1.6	1.6	0.8
3-4	0	0.3	0.3

* NCI toxicity grade
ALT=Alanine aminotransferase

Conclusion: GUS was safe and well tolerated through the PBO-controlled period in 2 randomized, phase 3 trials of patients with active PsA. There were no meaningful safety differences between the Q8W and Q4W groups, no significant safety issues identified when comparing GUS to PBO, and no safety signals with regards to infections, malignancy, and MACE. The safety profile of GUS Q4W and Q8W in PsA pts was generally consistent with that in the Phase 3 trials of GUS Q8W for psoriasis.^{3,4}

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