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POS0679

CLINICAL OUTCOMES UP TO WEEK (W) 48 IN THE ONGOING FILGOTINIB (FIL) LONG-TERM EXTENSION (LTE) TRIAL OF RHEUMATOID ARTHRITIS (RA) PATIENTS (PTS) WITH INADEQUATE RESPONSE (IR) TO METHOTREXATE (MTX) INITIALLY TREATED WITH FIL OR ADALIMUMAB (ADA) DURING THE PHASE 3 PARENT STUDY (PS)

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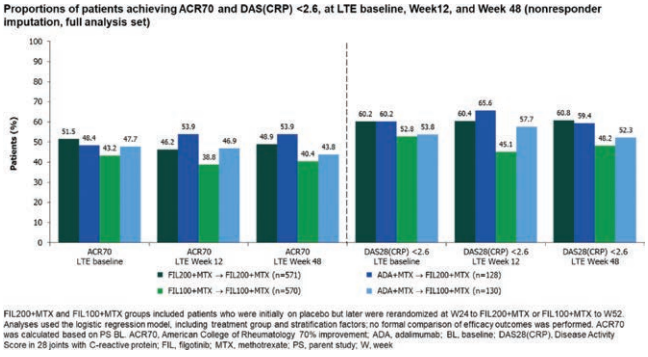
Background: The preferential Janus kinase-1 inhibitor FIL is approved for treatment of moderate to severe active RA in Europe and Japan.

Objectives: Efficacy and safety of FIL were assessed in pts with IR to MTX who completed a Phase 3 trial (NCT02889796)[1] and enrolled in an LTE (NCT03025308).

Methods: Pts completing the PS[1] on study drug were eligible to enter the LTE (data cutoff: June 1, 2020). Median exposure: 2.2 years (y). Efficacy data to W48 are reported for 4 treatment groups (all with background MTX): pts receiving FIL 200 mg (FIL200) or FIL 100 mg (FIL100) in the PS and continuing their dose in LTE (FIL200/FIL200, FIL100/FIL100) and ADA pts rerandomized, double blind, to FIL200 or FIL100 for LTE (ADA/FIL200, ADA/FIL100); safety data are reported.

Results: As of June 1, 2020, 522/571 (91%) FIL200/FIL200, 502/570 (88%) FIL100/FIL100, 118/128 (92%) ADA/FIL200, and 115/130 (89%) ADA/FIL100 pts remained on study drug. LTE baseline disease characteristics were similar between groups: mean duration of RA approximately 8.7 y; DAS28(CRP) 2.55, and mean concurrent MTX dosage was 15.0 mg/week. Proportions of pts achieving ACR20/50/70, DAS28(CRP) ≤3.2, <2.6, and CDAI ≤10, ≤2.8 were generally maintained in all LTE groups through W48 (Figure 1). Numerically greater proportions of pts met response criteria at W48 in the FIL200 groups vs FIL100, regardless of PS treatment. Treatment-emergent AEs (TEAE), serious AEs, and AEs Grade ≥3 were largely comparable between groups and lowest in ADA/FIL100. There were 10 deaths (Table 1). Exposure-adjusted incidence rates (EAIRs)/100 pt-y of exposure for deaths were lower for FIL/FIL vs ADA/FIL.



FIL200+MTX and FIL100+MTX groups included patients who were initially on placebo but later were rerandomized at W24 to FIL200+MTX or FIL100+MTX to W52. Analyses used the logistic regression model, including treatment group and stratification factors; no formal comparison of efficacy outcomes was performed. ACR70 was calculated based on PS BL. ACR70, American College of Rheumatology 70% improvement; ADA, adalimumab; BL, baseline; DAS28(CRP), Disease Activity Score in 28 joints with C-reactive protein; FIL, filgotinib; MTX, methotrexate; PS, parent study; W, week

Figure 1.

Conclusion: During the LTE through W48, response rates generally were maintained for FIL/FIL and ADA/FIL pts. Though there were differences between LTE groups, safety was largely comparable and consistent with PS observations[1] and previously reported results from 7 trials[2]: rates of AEs of special interest were low; all confidence intervals were overlapping. Limitation: the LTE was not formally randomized for comparison between FIL/FIL and ADA/FIL treatment groups, the groups were of unequal size, and the switch from ADA to FIL for LTE was by design, rather than based on disease activity.

Table 1. EAIRs of TEAEs in LTE, as of June 1, 2020

1TEAE, n (%)	3FIL200+MTX → FIL200+MTX	6ADA+MTX → FIL200+MTX	9FIL100+MTX → FIL100+MTX	12ADA+MTX → FIL100+MTX
2EAIR (95% CI)	4n=571	7n=128	10n=570	13n=130
	5PYE=859.4	8PYE=197.8	11PYE=852.3	14PYE=192.6
TEAE	429 (75.1)	91 (71.1)	443 (77.7)	88 (67.7)
	49.9 (45.4, 54.9)	46.0 (37.5, 56.5)	52.0 (47.4, 57.0)	45.7 (37.1, 56.3)
TEAE Grade ≥3	64 (11.2)	15 (11.7)	72 (12.6)	7 (5.4)
	7.4 (5.8, 9.5)	7.6 (4.6, 12.6)	8.4 (6.7, 10.6)	3.6 (1.7, 7.6)
TE serious AE	52 (9.1)	13 (10.2)	60 (10.5)	9 (6.9)
	6.1 (4.6, 7.9)	6.6 (3.8, 11.3)	7.0 (5.5, 9.1)	4.7 (2.4, 9.0)
Death	3 (0.5)	2 (1.6)	3 (0.5)	2 (1.5)
	0.3 (0.1, 1.1)	1.0 (0.3, 4.0)	0.4 (0.1, 1.1)	1.0 (0.3, 4.2)
TE infections	243 (42.6)	52 (40.6)	249 (43.7)	43 (33.1)
	28.3 (24.9, 32.1)	26.3 (20.0, 34.5)	29.2 (25.8, 33.1)	22.3 (16.6, 30.1)
TE serious infections	7 (1.2)	2 (1.6)	13 (2.3)	1 (0.8)
	0.8 (0.4, 1.7)	1.0 (0.3, 4.0)	1.5 (0.9, 2.6)	0.5 (0.1, 3.7)
Opportunistic infections	2 (0.4)	0	2 (0.4)	0
	0.2 (0, 0.8)	0 (0, 1.9)	0.2 (0, 0.8)	0 (0, 1.9)
TE herpes zoster	16 (2.8)	5 (3.9)	13 (2.3)	1 (0.8)
	1.9 (1.1, 3.0)	2.5 (1.1,6.1)	1.5 (0.9, 2.6)	0.5 (0.1, 3.7)
TE MACE (adjudicated)	1 (0.2)	0	3 (0.5)	3 (2.3)
	01 (0, 0.6)	0 (0, 1.9)	0.4 (0.1, 1.1)	1.6 (0.5, 4.8)
TE DVT/PE (adjudicated)	3 (0.5)	0	3 (0.5)	0
	0.3 (0.1, 1.0)	0 (0, 1.9)	0.4 (0.1, 1.0)	0 (0, 1.9)
Malignancies (excluding NMSC)	5 (0.9)	3 (2.3)	4 (0.7)	0
	0.6 (0.2, 1.4)	1.5 (0.5, 4.7)	0.5 (0.1, 1.2)	0 (0, 1.9)
NMSC	3 (0.5)	0	2 (0.4)	0
	0.3 (0.1, 1.0)	0 (0, 1.9)	0.2 (0, 0.8)	0 (0, 1.9)

DVT, deep vein thrombosis; MACE, major adverse cardiovascular event; NMSC, nonmelanoma skin cancer; PE, pulmonary embolism; TE, treatment-emergent

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POS0680

PHYSICIANS' REASONS FOR PRESCRIBING JANUS KINASE INHIBITORS (JAKI) IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA), AND ASSOCIATED ALIGNMENT BETWEEN PHYSICIANS AND PATIENTS IN A REAL-WORLD CLINICAL SETTING

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Background: Shared decision making, a cornerstone of RA management[1], allows physicians and their patients to make informed decisions about their treatment goals and choice of care. As new treatments become available, it is important to understand rheumatologists' reasons for choosing JAKi.
Objectives: This survey evaluated rheumatologists' clinical and patient centric reasons for choosing JAKi, in addition to exploring alignment between rheumatologists and RA patients in terms of treatment choice and satisfaction.
Methods: The Adelphi RA Disease Specific Programme™[2] is a large, multinational, point-in-time survey conducted amongst rheumatologists and their consulting patients with RA in Europe (Belgium, France, Germany, Italy, Spain, UK) between January and October 2020. Physicians completed record forms for up to 10 consecutive RA patients, collecting demographic, clinical and treatment data, and reasons for current treatment choice. Patients were invited to complete a patient questionnaire to assess their satisfaction with ongoing treatment (5-point scale), and perceptions of shared decision making for the current treatment.
Results: 316 rheumatologists provided data for 3121 patients, of whom 1130 (36.2%) completed patient reported questionnaires. Overall, 67% were female, mean age was 53 years (SD 14), 23% had moderate-high disease activity score (DAS28: >3.2). 68% of patients were currently receiving either a biologic or targeted synthetic disease-modifying antirheumatic drug (DMARD; defined here as advanced therapy, AT), 72% were on first line AT. Overall, physicians and their patients were aligned that a conversation took place about a treatment decision (n=855, 79% net alignment), and this was a shared treatment decision (n=814, 75% net alignment). 15% of patients not taking an AT were reported to have a clinical condition warranting one; reasons for not taking AT included patients' concerns about infection (24%), conventional synthetic DMARDs were tolerable and safe in the patient (18%), and patient dislike of infusions/injections (17%). Of 2143 patients receiving AT, 19% were prescribed JAKi; 57% as monotherapy, 43% as combination therapy. For physician stated reasons for choice of JAKi, factors were driven by both perceptions of clinical efficacy and onset of action, as well as factors relating to patient acceptability such as method of delivery and ease of use (Table 1). With respect to JAKi treatment (n=135 patient-physician pairs), 62% of physicians and their patients were aligned on satisfaction, however 30% of patients reported less satisfaction than their consulting physician (Figure 1).

Table 1. Physician stated clinical and patient centric reasons for prescribing a JAKi in their patients with RA (data are percentage of patients; n=397)

Reasons for prescribing JAKi	Patients (%)
Top 5 clinical reasons	
Strong overall efficacy	74
Fast onset of action	49
Inhibition of disease progression	42
Strong efficacy as monotherapy	39
Achievement of clinical remission	37
Top 5 patient centric reasons	
Acceptability of method of delivery for the patient	39
Enabling patient to perform everyday tasks/activities	36
Ease of product use (for the patient)	33
Improvement or maintenance of quality of life	30
Improving patient's mood/state of mind	14

Conclusion: Communicating the choice of pharmacological therapy to patients with RA has become increasingly complex for physicians with expansion of approved treatments. In this subgroup of patients on JAKi, the drug attributes considered as reasons for prescribing were driven by clinical factors as well as by patient centric attributes. Although communications between patients and physicians were largely aligned, better understanding of patient expectations might serve to improve messaging about treatment options and resulting satisfaction.
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[1] Smolen JS et al. *Ann Rheum Dis* 2017;76.
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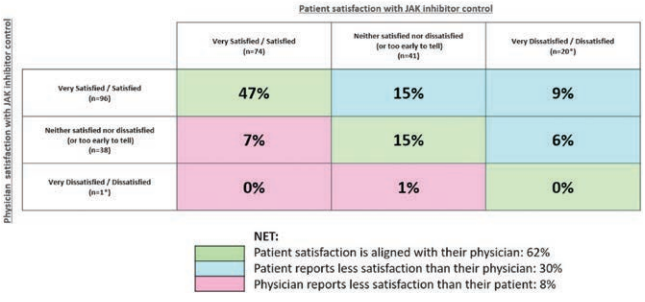
Figure. Level of alignment between physician and patient-reported satisfaction with JAKi



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