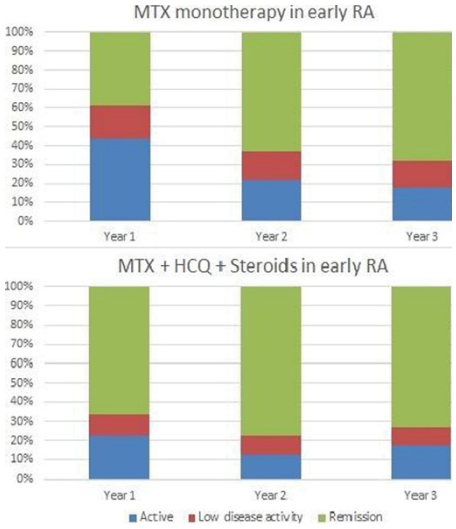

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OP0228

OP0229

EFFECT OF BASELINE SERUM CRP LEVELS ON CLINICAL EFFICACY IN RHEUMATOID ARTHRITIS PATIENTS TREATED WITH FILGOTINIB: POST-HOC ANALYSIS FROM TWO PHASE 2B STUDIES

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Background: Filgotinib (GLPG0634, GS-6034) is an oral, selective JAK1 inhibitor that has shown a favorable safety and efficacy profile both as add-on to methotrexate (MTX) and as monotherapy in two 24-week placebo-controlled phase 2B studies in active rheumatoid arthritis (RA) patients with inadequate response to MTX (MTX-IR)[1,2].

Objectives: To assess effect of baseline serum CRP levels on clinical efficacy in MTX-IR RA patients treated with filgotinib.

Methods: Patients were randomized in a double blind manner to placebo (PBO) or one of 3 daily doses of filgotinib (50mg, 100mg or 200mg) for 24 weeks. In the DARWIN 1 study, filgotinib on the background of MTX was evaluated as once (QD) or twice daily treatment. In the DARWIN 2 study once-daily filgotinib was assessed as monotherapy. The inclusion criterion for CRP was amended during the studies and decreased over time from 13.5 mg/L to 6.3 mg/L. This post hoc analysis included patients treated with the selected Phase 3 filgotinib doses, 100mg and 200mg QD, and PBO. Efficacy outcomes were analyzed by baseline CRP level (low: ≤9 mg/L and high: >9 mg/L, with 9mg/L as ULN).

Results: Baseline disease activity was high, with mean DAS28(CRP) scores of 5.6 and 5.7 in the low CRP subgroups for DARWIN 1 and DARWIN 2, respectively, and 6.3 in the high CRP subgroups for both studies. Mean CRP levels at baseline were elevated (16.3 - 35.3 mg/L). In both low and high CRP subgroups, patients on filgotinib 100mg or 200mg QD for 12 weeks showed efficacy over PBO, as measured by change from baseline in DAS28(CRP), CDAI and HAQ-DI, and ACR20 (Table 1). Despite slight numerical differences, baseline CRP level had no consistent effect on filgotinib efficacy, neither for endpoints including CRP (DAS28(CRP) or ACR20) nor for endpoints not including CRP (CDAI). Results were similar across both studies.

Table 1. Change from baseline in key efficacy parameters at Week 12 by CRP subgroup (mean (SE))

	DARWIN 1			DARWIN 2		
	PBO	Filgotinib 100mg QD	Filgotinib 200mg QD	PBO	Filgotinib 100mg QD	Filgotinib 200mg QD
Low CRP subgroup (≤9 mg/L)						
N	33	25	15	11	20	20
DAS28 (CRP)	-1.2 (0.30)	-2.2 (0.24)	-2.2 (0.32)	-0.9 (0.55)	-2.1 (0.33)	-2.3 (0.25)
CDAI	-18.3 (3.52)	-23.7 (2.66)	-25.1 (3.45)	-11.5 (6.19)	-25.8 (3.53)	-27.4 (3.05)
HAQ-DI	-0.21 (0.121)	-0.76 (0.133)	-0.64 (0.100)	-0.12 (0.163)	-0.74 (0.172)	-0.74 (0.158)
High CRP subgroup (>9 mg/L)						
N	53	60	71	61	50	49
DAS28	-1.2 (0.15)	-2.3 (0.19)	-2.5 (0.15)	-1.0 (0.17)	-2.0 (0.19)	-2.3 (0.19)
CDAI	-15.6 (2.04)	-23.8 (2.08)	-25.5 (1.67)	-11.7 (1.94)	-23.3 (2.38)	-24.1 (2.12)
HAQ-DI	-0.49 (0.080)	-0.61 (0.087)	-0.78 (0.076)	-0.25 (0.074)	0.65 (0.081)	-0.74 (0.086)
ACR20 by subgroup, n (%)						
Low CRP	15 (45%)	19 (76%)	10 (67%)	2 (18%)	13 (65%)	16 (80%)
High CRP	23 (43%)	35 (58%)	49 (69%)	19 (31%)	33 (66%)	34 (69%)

Conclusions: Post hoc analysis of two Phase 2B studies in MTX-IR RA patients suggests that filgotinib treatment once daily at 100mg and 200mg both on the background of MTX and as monotherapy is consistently associated with improved clinical outcomes compared to placebo, regardless of baseline CRP levels.

References:

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OP0230

THE EFFECTIVENESS OF ZOSTER VACCINE IN RA PATIENTS SUBSEQUENTLY TREATED WITH TOFACITINIB

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Background: Rheumatoid arthritis (RA) patients (pts) are at increased risk of herpes zoster (HZ). The most recent ACR guidelines of 2015 recommend vaccination in pts aged ≥50 years prior to starting biologic DMARDs or tofacitinib,[1]