Abstract FRI0115 – Table 1. Cross-sectional indirect comparison of ISP after injection between adalimumab CFF and ABP 501.

Time point of pain assessment	Within 2 minutes		Within 5 minutes		15 minutes after injection	
Investigational products	CFF-RP vs. CCF-RP		ABP 501 vs. CCF-RP		CFF-RP vs. CCF-RP	
Study	Study 1	Study 2	RA study baseline visit	PsO study baseline visit	Study 1	Study 2
Overall number of subjects	62	60	526	343	62	60
Mean (SD) [n] ISP VAS score for CCF-RP (cm)	3.3 (2.2) [62]	4.2 (2.8) [60]	2.1 (2.3) [262]	1.9 (2.0) [173]	1.0 (1.52) [62]	1.0 (1.61) [60]
Mean (SD) [n] ISP VAS score for ABP 501/CCF-RP (cm)	1.6 (2.1) [62]	0.9 (1.1) [60]	1.0 (1.6) [264]	0.5 (0.8) [170]	0.9 (1.66) [62]	0.4 (1.08) [60]
Difference in mean VAS score (cm)	1.7	3.3	1.1	1.4	0.1	0.6
Cohen's d statistic (95% confidence interval)	0.80 (0.42, 1.19)	1.56 (1.19, 1.94)	0.56 (0.39, 0.73)	0.92 (0.76, 1.08)	0.06 (-0.22, 0.34)	0.44 (0.20, 0.69)

Conclusions: Compared with CCF-RP, both ABP 501 and CFF-RP were associated with lower injection site pain perception.

REFERENCE:

[1] Nash P, et al. *Rheumatol Ther* 2016;3(2):257–270.

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FRI0116

IMPACT OF PRIOR BIOLOGIC USE ON TREATMENT RESPONSE IN PATIENTS WITH RHEUMATOID ARTHRITIS RECEIVING ADALIMUMAB IN ROUTINE CLINICAL CARE: RESULTS FROM THE PASSION STUDY

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Background: It is recognised that early diagnosis and treatment are important in maximising long-term quality of life in patients (pts) with rheumatoid arthritis (RA). Prior biologic disease modifying antirheumatic drug (bDMARD) use has been shown to affect treatment response to further biologic therapy including adalimumab (ADA).

Objectives: To evaluate the impact of prior bDMARD use on clinical and pt-reported outcomes in pts enrolled in the PASSION study.

Methods: PASSION was a 78-wk postmarketing, multinational, observational study that assessed the effectiveness of ADA in pts with moderate to severe RA receiving ADA in routine clinical care in the context of participation in the voluntary AbbVie pt support program. Pts with an insufficient response to ≥ 1 DMARD (1 prior bDMARD was allowed) and newly initiating ADA were enrolled and categorised as bDMARD-naïve or bDMARD-experienced. For the present analysis, ADA treatment response was determined by evaluating least squares (LS) mean change from baseline for multiple clinical and pt-reported outcomes (table 1). Missing data for each efficacy endpoint were imputed using last observation carried forward, and differences between groups for efficacy endpoints at wks 24, 52, and 78 were based on ANCOVA models adjusting for baseline and demographic variables (table 1). Additionally, the percentages of pts at each time point (observed population) who achieved HAQ-DI minimal clinically important difference (MCID; improvement from baseline of ≥ 0.22) were assessed.

Results: Of 1025 pts included in the intent-to-treat population, 182 were bDMARD-experienced and 843 were bDMARD-naïve at baseline. There were no significant differences between groups in sex, race, ethnicity, weight, height, body mass index, TJC28, SJC28, and pain at baseline. However, bDMARD-

experienced pts were significantly older, had longer RA duration, and had lower values for HAQ-DI, DAS28(CRP), CDAI, SDAI, PtGA, and PhGA than bDMARD-naïve pts at baseline ($p < 0.05$ for all). ADA treatment response was significantly higher for bDMARD-naïve vs bDMARD-experienced pts at all timepoints for HAQ-DI, DAS28(CRP), CDAI, PtGA, and pain, at wks 24 and 52 for SDAI, and at wk 24 for TJC28 and SJC28 (table 1). In the observed population, a large percentage of bDMARD-naïve and bDMARD-experienced pts achieved HAQ-DI MCID at wk 24 (67% and 60%), wk 52 (71% and 65%), and wk 78 (74% and 59%).

Abstract FRI0116 – Table 1. Least Squares Mean Change from Baseline in Efficacy Measures by Prior bDMARD Use at Each Study Visit (Intent-to-Treat Population, LOCF)

Measure	Visit	bDMARD-Naïve		bDMARD-Experienced		Naïve vs Experienced
		N	LS Mean Change (SE)	N	LS Mean Change (SE)	
TJC28	Week 24	787	-6.05 (1.064)	164	-4.87 (1.136)	0.015*
	Week 52	795	-4.75 (1.122)	166	-3.99 (1.198)	0.139
	Week 78	797	-7.02 (1.190)	167	-6.03 (1.271)	0.066
SJC28	Week 24	787	-4.75 (0.750)	165	-3.96 (0.800)	0.019*
	Week 52	795	-4.23 (0.781)	167	-3.65 (0.833)	0.099
	Week 78	797	-5.87 (0.846)	168	-5.28 (0.903)	0.124
HAQ-DI	Week 24	799	-0.44 (0.107)	168	-0.29 (0.114)	0.001**
	Week 52	807	-0.52 (0.116)	171	-0.31 (0.124)	<0.001***
	Week 78	808	-0.49 (0.120)	171	-0.31 (0.128)	<0.001***
DAS28(CRP)	Week 24	721	-1.83 (0.263)	148	-1.34 (0.283)	<0.001***
	Week 52	748	-1.62 (0.275)	154	-1.27 (0.296)	0.007**
	Week 78	755	-2.05 (0.288)	154	-1.67 (0.310)	0.005**
CDAI	Week 24	743	-16.77 (2.299)	159	-13.65 (2.458)	0.003**
	Week 52	753	-14.48 (2.401)	161	-12.10 (2.568)	0.030*
	Week 78	756	-20.14 (2.570)	161	-17.18 (2.749)	0.011*
SDAI	Week 24	703	-18.27 (2.539)	147	-14.45 (2.731)	0.001**
	Week 52	729	-16.16 (2.613)	152	-13.42 (2.807)	0.025*
	Week 78	734	-21.59 (2.756)	152	-19.09 (2.960)	0.052
Pt Pain	Week 24	799	-22.21 (4.940)	168	-17.04 (5.283)	0.019*
	Week 52	806	-19.50 (5.124)	171	-14.27 (5.473)	0.022*
	Week 78	807	-32.40 (5.281)	171	-26.87 (5.642)	0.019*
PtGA	Week 24	799	-21.22 (4.819)	168	-13.31 (5.159)	<0.001***
	Week 52	807	-20.34 (4.998)	171	-14.01 (5.346)	0.005**
	Week 78	808	-28.60 (5.132)	171	-21.60 (5.490)	0.002**
PhGA	Week 24	763	-30.49 (4.482)	161	-27.25 (4.824)	0.118
	Week 52	771	-28.40 (4.616)	162	-26.00 (4.966)	0.260
	Week 78	774	-34.24 (4.855)	163	-30.24 (5.223)	0.074

***, **, * statistically significant at $P < 0.001$, 0.01, and 0.05 levels, respectively for LS mean difference. Missing data were imputed for each efficacy endpoint using LOCF. The differences between two groups in efficacy endpoints at week 24, 52 and 78 were based on ANCOVA models adjusting for baseline and demographic variables (sex, race, ethnicity, age [years], PSP participation [ever (PSP users) vs never (PSP non-users)], diagnosis RA duration [years]).

ANCOVA, analysis of covariance; bDMARD, biologic disease modifying antirheumatic drug; CDAI, Clinical Disease Activity Index; DAS28(CRP), 28-joint Disease Activity Score C-Reactive Protein; HAQ-DI, Health Assessment Questionnaire Disability Index; LOCF, last observation carried forward; PhGA, physician global assessment of disease activity; PSP, Patient Support Program; PtGA, patient global assessment of disease activity; SDAI, Simplified Disease Activity Index; SJC28, Swollen 28-Joint Count; TJC28, Tender-28-Joint Count.

Conclusions: Among pts with moderate to severe RA that initiated ADA treatment in the PASSION study, bDMARD-naïve pts achieved significantly larger improvements from baseline to wk 78 in a variety of clinical and pt-reported outcomes compared with bDMARD-experienced pts. A large proportion of both bDMARD-naïve and bDMARD-experienced pts achieved HAQ-DI MCID with ADA treatment.

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