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CorEvitas Statistical Analysis Plan: Analysis of tofacitinib initiators with PsA: Phase II Follow-up Analysis

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Title: Analysis of tofacitinib initiators with PsA

Overall Aim: To describe baseline demographic, therapy history, and disease activity characteristics and assess change in disease activity measures six months after initiation of tofacitinib

To accomplish the overall aim, we will:

Objective 1: Summarize patient characteristics at baseline and calculate changes in various disease activity measures over time among all eligible initiators of tofacitinib

Objective 2: Summarize patient characteristics at baseline and calculate changes in various disease activity measures separately for monotherapy and combination therapy initiators, and compare these groups

Definitions:

- Oral small molecules (OSMs): methotrexate, leflunomide, sulfasalazine, apremilast
- Tofacitinib monotherapy: initiation of tofacitinib with no other (pre-existing or new) DMARD prescriptions
- Tofacitinib combination therapy: initiation of tofacitinib with a concomitant (pre-existing or new) prescription of at least one OSM

Registry description:

CorEvitas' Psoriatic Arthritis/Spondyloarthropathy Registry is a prospective, multicenter, observational disease–based registry that was started March 2013.

From initiation until April 2017, inclusion criteria in the registry were as follows:

- Meet diagnostic criteria for psoriatic arthritis (PsA), ankylosing spondylitis (AS), axial or peripheral SpA
- Age ≥ 18 years of age as of the patient's PsA/SpA diagnosis
- Subject must be able and willing to provide consent

From April 2017 until February 2018, the inclusion criteria were modified as follows:

- Meet diagnostic criteria for ankylosing spondylitis (AS), axial or peripheral SpA or PsA
- Age ≥ 18 years of age as of the patient's PsA/SpA diagnosis
- Subjects needed to be diagnosed with psoriatic arthritis (PsA) by their rheumatologist or meet the modified New York classification criteria for ankylosing spondylitis (AS)
- Subjects needed to be a newly prescribed (first time) user of an FDA-approved eligible biologic for the treatment of PsA or AS at time of enrollment. Eligible biologics for inclusion in the registry include abatacept, adalimumab, certolizumab, etanercept, golimumab, infliximab, secukinumab, ustekinumab (only FDA approved for PsA).

From February 2018 until October 2018, the inclusion criteria were modified as follows:

- Non-biologic medications have been added as eligible medications for enrollment of patients diagnosed with Psoriatic Arthritis.
- Eligibility for Psoriatic Arthritis patients has been expanded to include patients currently on an eligible medication at the time of enrollment.

From October 2018 until August 2019, the enrollment criteria were modified as follows:

- For PsA patients, only incident users (either prescribed or actually receiving first dose on the day of the enrollment visit) of eligible medications are eligible. Patients who are prevalent users (currently receiving a medication or first dose received prior to the enrollment visit) are no longer eligible for new enrollment.
- 1:2 enrollment ratio is defined as one (1) IL-17 inhibitor or JAK-inhibitor to every two (2) biologics.

From August 2019 forward, the enrollment criteria were expanded as follows:

- Apremilast (Otezla) has been added as an eligible medication at enrollment.
- Eligible diagnoses at enrollment will now include PsA, AS (per modNY), or Axial Spondyloarthritis (per ASAS), radiographic or non-radiographic.

CorEvitas patients and their rheumatologists complete questionnaires, including information on laboratory measurements and radiographic results from routine visits, at approximately 6-month intervals.

Study Cohort:

For this analysis, the eligible population will be selected using the following criteria:

- Have a diagnosis of PsA
- Initiate tofacitinib monotherapy or in combination with OSMs (pre-existing or concurrent) during or after December 2017
- Have a follow-up visit occurring six (± 3) months after initiation

Initiators will be ineligible for analysis if:

Any initiations result in a combination of tofacitinib with TNFi or non-TNFi bDMARDs, whether multiple initiations occur at the same time or a new therapy is added to an existing regimen

Analysis:

<u>Milestone 1:</u>

Consider the demographic, patient, and disease characteristics of all eligible tofacitinib initiators in **Table 1**. Categorical variables will be examined using frequencies and proportions. Continuous variables will be summarized using descriptive statistics (mean, standard deviation, minimum, 25% percentile, median, 75% percentile, maximum).

In **Table 2**, we will present the therapy status of initiators at the six-month follow-up visit.

Table 3 will examine the outcomes of interest at the six-month follow-up visit. Binary outcomes will be presented as response rates with 95% CI using normal approximation to binomial proportions, and summary statistics (n, mean (SD), [P0,P25,P50,P75,P100]) baseline, six-month, and change in continuous outcomes will also be presented.

Milestone 2:

The analyses stratified by mono- and combination therapy for this milestone will be completed when the sample reaches at least 100 initiators in both mono- and combination therapy groups.

Consider the demographic, patient, and disease characteristics of the tofacitinib monotherapy and combination therapy initiators in **Table 4**. Categorical variables will be examined using frequencies and proportions, and, when sample size allows for significance testing, differences across therapy patterns will be tested using chi-square or Fisher exact tests. Continuous variables will be summarized using descriptive statistics (n, mean, standard deviation, minimum, 25% percentile, median, 75% percentile, maximum). When sample size allows for significance testing, differences across therapy groups will be tested using Wilcoxon rank sum tests.

In **Table 5**, we will present the therapy status of initiators at the six-month follow-up visit.

Table 6 will examine the outcomes of interest at the six-month follow-up visit. The change from baseline to six months in continuous outcomes will be analyzed using an analysis of covariance model with fixed effects for treatment group and baseline value. For continuous outcomes, we will not impute missing values. Also, for those discontinuing therapy prior to follow-up, we will use the value immediately prior to discontinuation as the follow-up value. We will present LS Means (standard error) for each therapy group as well as the difference in the LS Means (standard error), 95% CI and p-value. Binary outcomes will be presented as response rates with 95% CIs using normal approximation to binomial proportions. We will provide comparisons of response rates between groups with 95% CIs and p-values using normal approximation for the difference in binomial proportions. As a supportive analysis, treatment difference between the groups will be assessed using logistic regression models with treatment group as the sole covariate. For binary outcomes, we will impute non-response for missing values and for those patients discontinuing therapy prior to follow-up.

In **Table 7**, we will present summary statistics (n, mean (SD), [P0,P25,P50,P75,P100]) for continuous outcomes featured in Table 3 at baseline, six months, and the difference from baseline to six months overall and by therapy group.

Characteristics of Interest:

The following characteristics will be assessed on index date:

- Age
- Sex
- Race
- Work status
- BMI (continuous and categorical)
- Duration of PsA symptoms
- Time since PsA diagnosis
- Time since onset of PsO
- Physician-reported comorbidity history

    - Cerebro-cardiovascular disease (CVD) [a]
    - Depression
    - Diabetes mellitus
    - Any cancer (excluding NMSC)
    - NMSC
    - HTN
    - Hyperlipidemia
    - Crohn's disease
    - Anxiety
    - Psoriasis
    - Fibromyalgia
    - Serious infections [b]
    - Metabolic syndrome
    - Ulcerative colitis
    - Uveitis
- Smoking status
    - Former, Current, Never
    - Number cigarettes smoked per day
    - Smoking duration
- Alcohol use
    - Yes/No
    - Number drinks per week
- Therapy history
    - History of prior biologic use
    - History of prior TNFi use
    - History of prior non-TNFi bDMARD use
    - History of prior OSM use
    - Current OSM use
        - Current MTX use
    - Current NSAID use
    - Current opioid use
    - Current aspirin use
    - Current prednisone use
- Disease activity measures
    - Tender joint count (28 and 68)
    - Swollen joint count (28 and 66)
    - Enthesitis
    - SPARCC count
    - LEI count
    - Dactylitis
    - Dactylitis count
    - Nail VAS
    - BSA (continuous and categorical)
    - CRP
    - ESR
    - Clinical global assessment of PsO (continuous and categorical).
- Composite measures
    - MDA

    - DAPSA (continuous and categorical)
    - cDAPSA (continuous and categorical)
    - PASDAS
    - CDAI (continuous and categorical)
- Patient reported outcome measures
    - Patient pain
    - Patient-reported fatigue
    - Patient global skin assessment
    - HAQ-DI
    - HAQ-S
    - EQ-5D
    - WPAI domains (4 categories)
- Psoriatic nail dystrophy
- Spinal mobility measures
    - Occiput to wall distance
    - Modified Schober

[a] CVD includes: cardiac revascularization procedure (CABG, stent, angioplasty), ventricular arrhythmia, cardiac arrest, myocardial infarction, acute coronary syndrome, unstable angina, other coronary artery disease, CHF (with and without hospitalization), stroke, transient ischemic attack, other CV, deep vein thrombosis, peripheral arterial disease, pulmonary embolism, and carotid artery disease
[b] Serious infections include: joint bursa infection, cellulitis, sinusitis, candida, diverticulitis, sepsis, pneumonia, bronchitis, gastroenteritis, meningitis, urinary tract infection, upper respiratory infection, tuberculosis, and other infection

At the six-month follow-up visit, the following will be assessed:
Among those not in the specified disease activity state, achievement of:

- Minimal Disease Activity
- Body Surface Area Score of 0
- PASDAS < 3.2
- Resolution of enthesitis
- Resolution of dactylitis
- Clinical Global Assessment of PsO – achievement of "Clear" or "Almost Clear"

Baseline to six months change in:

- cDAPSA
- DAPSA
- PASDAS
- HAQ-DI
- Low Disease Activity as defined by cDAPSA (cDAPSA ≤ 13)
- BSA
- CDAI
- Tender joint count (68)
- Swollen joint count (66)
- Patient global skin assessment
- Patient pain
- Patient fatigue
- Clinical Global Assessment of PsO
- WPAI Domains

Feasibility Assessment and Projections:

Using the October 1, 2021 version of the PsA registry, we have identified the following therapy patterns among initiators of tofacitinib

	Eligible Initiations, N (%)
All tofacitinib initiations	213
Monotherapy	132 (62.0)
Combination with OSMs only	81 (38.0)
Combination with MTX	58 (71.6)

	Monotherapy	Combination with OSMs
Eligible Initiators	132	81
Six-month visit	59 (44.7%)	55 (67.9%)

Shell Tables

Table 1. Patient demographic characteristics among all tofacitinib initiators

All Patients, N	Overall
Age (years), n, Mean (SD), [P0,P25,P50,P75,P100]	
Female, n/N (%)	
Race, n/N (%)	
White	
Black	
Asian	
Other	
Work Status, n/N (%)	
Full Time/Part Time	
Retired	
Disabled	
Other	
BMI (kg/m^2), n, Mean (SD), [P0,P25,P50,P75,P100]	
BMI Category (kg/m^2), n/N (%)	
< 25	
25 to < 30	
30 +	
Duration of PsA Symptoms (years), n, Mean (SD), [P0,P25,P50,P75,P100]	
Time Since PsA Diagnosis (years), n, Mean (SD), [P0,P25,P50,P75,P100]	

All Patients, N	Overall
Time Since PsO Onset (years), n, Mean (SD), [P0,P25,P50,P75,P100]	
Psoriasis, n/N (%)	
Psoriatic Nail Dystrophy, n/N (%)	
History of Comorbidities, n/N (%)	
CVD[b]	
Depression	
Diabetes	
Malignancy[c]	
NMSC	
Hypertension	
Hyperlipidemia	
Crohns Disease	
Anxiety	
Fibromyalgia	
Serious Infections[d]	
Metabolic Syndrome	
Ulcerative Colitis	
Uveitis	
Smoking Status, n/N (%)	
Never	
Previous	
Current	
Cigarettes per day, n, Mean (SD), [P0,P25,P50,P75,P100]	
Smoking duration, n, Mean (SD), [P0,P25,P50,P75,P100]	
Alcohol Use, n/N (%)	
Number drinks per week, n, Mean (SD), [P0,P25,P50,P75,P100]	
Prior Biologics, n, Mean (SD), [P0,P25,P50,P75,P100]	
Number of Prior Biologics, n/N (%)	
0	
1	
2 +	
Prior TNFs, n, Mean (SD), [P0,P25,P50,P75,P100]	
Number of Prior TNFs, n/N (%)	
0	
1	
2 +	
Prior non-TNFs, n, Mean (SD), [P0,P25,P50,P75,P100]	
Number of Prior non-TNFs, n/N (%)	

All Patients, N	Overall
0	
1	
2 +	
Prior OSMs, n, Mean (SD), [P0,P25,P50,P75,P100]	
Number of Prior OSMs, n/N (%)	
0	
1	
2 +	
Current OSM Use, n/N (%)	
Current MTX Use, n/N (%)	
Current NSAID Use, n/N (%)	
Current Opioid Use, n/N (%)	
Current Aspirin Use, n/N (%)	
Prednisone Use, n/N (%)	
None	
Missing Dose	
Dose < 10 mg	
Dose ≥ 10 mg	
Tender Joints (28), n, Mean (SD), [P0,P25,P50,P75,P100]	
Tender Joints (68), n, Mean (SD), [P0,P25,P50,P75,P100]	
Swollen Joints (28), n, Mean (SD), [P0,P25,P50,P75,P100]	
Swollen Joints (66), n, Mean (SD), [P0,P25,P50,P75,P100]	
Enthesitis, n/N (%)	
SPARCC Enthesitis Count, n, Mean (SD), [P0,P25,P50,P75,P100]	
LEI Count, n, Mean (SD), [P0,P25,P50,P75,P100]	
Dactylitis, n/N (%)	
Dactylitis Count, n, Mean (SD), [P0,P25,P50,P75,P100]	
CDAI, n, Mean (SD), [P0,P25,P50,P75,P100]	
CDAI Category, n/N (%)	
Remission (CDAI ≤ 2.8)	
Low (2.8 < CDAI ≤ 10)	
Moderate (10 < CDAI ≤ 22)	
High (22 < CDAI)	
Minimal Disease Activity, n/N (%)	
DAPSA, n, Mean (SD), [P0,P25,P50,P75,P100]	
DAPSA Category, n/N (%)	
DAPSA ≤ 4	
4 < DAPSA ≤ 14	

All Patients, N	Overall
14 < DAPSA ≤ 28	
28 < DAPSA	
cDAPSA, n, Mean (SD), [P0,P25,P50,P75,P100]	
cDAPSA Category, n/N (%)	
cDAPSA ≤ 3	
3 < cDAPSA ≤ 13	
13 < cDAPSA ≤ 27	
27 < cDAPSA	
PASDAS, n, Mean (SD), [P0,P25,P50,P75,P100]	
PASDAS ≤ 3.2	
3.2 < PASDAS ≤ 4.2	
4.2 < PASDAS ≤ 6	
6 < PASDAS	
Nail VAS, n, Mean (SD), [P0,P25,P50,P75,P100]	
Body Surface Area (%), n, Mean (SD), [P0,P25,P50,P75,P100]	
BSA Category (%), n/N (%)	
0	
> 0 to < 3	
3 to < 10	
≥ 10	
CRP (mg/L), n, Mean (SD), [P0,P25,P50,P75,P100]	
ESR (mm/hr), n, Mean (SD), [P0,P25,P50,P75,P100]	
Patient Pain (0-100 VAS), n, Mean (SD), [P0,P25,P50,P75,P100]	
Patient Fatigue (0-100 VAS), n, Mean (SD), [P0,P25,P50,P75,P100]	
Patient Global Skin Assessment (0-100 VAS), n, Mean (SD), [P0,P25,P50,P75,P100]	
Clinical Global Assessment of PsO [I], n, Mean (SD), [P0,P25,P50,P75,P100]	
Clinical Global Assessment of PsO [I] Category, n/N (%)	
Clear/Almost Clear	
Mild	
Moderate	
Severe	
HAQ-DI, n, Mean (SD), [P0,P25,P50,P75,P100]	
HAQ-S, n, Mean (SD), [P0,P25,P50,P75,P100]	
EQ-5D, n, Mean (SD), [P0,P25,P50,P75,P100]	
WPAI Domains (%), n, Mean (SD), [P0,P25,P50,P75,P100]	
Work Time Missed	
Impairment While Working	
Overall Work Impairment	

All Patients, N	Overall
Activity Impairment	
Spinal Mobility Measures (cm), n, Mean (SD), [P0,P25,P50,P75,P100]	
Occiput to Wall Distance	
Modified Schober	

SD = standard deviation, P0 = minimum, P25 = 25th percentile, P50 = median, P75 = 75th percentile, P100 = maximum
[a] p-values from chi-square or Fisher exact tests for categorical variables and from Wilcoxon rank-sum tests for continuous variables, included for descriptive purposes only
[b] History of cardiovascular disease includes history of: hypertension, hyperlipidemia, cardiac revascularization procedure (CABG, stent, angioplasty), ventricular arrythmia, cardiac arrest, myocardial infarction, acute coronary syndrome, unstable angina, CHF (with and without hospitalization), stroke, transient ischemic attack, other CV, deep vein thrombosis, peripheral arterial disease, peripheral arterial thrombosis, urgent peripheral revascularization, peripheral ischemia/gangrene, pulmonary embolism, carotid artery disease, and hemorrhage.
[c] Malignancy includes breast cancer, lung cancer, lymphoma, skin cancer (squamous cell), and other cancers.
[d] Serious infections include the following: joint/bursa infection, cellulitis, sinusitis, diverticulitis, sepsis, pneumonia, bronchitis, gastroenteritis, meningitis, urinary tract infection, upper respiratory infection, tuberculosis, and other infections.
[e] Biologics: Humira, Enbrel, Cimzia, Simponi, Remicade, Orencia, Taltz, Cosentyx, Stelara
[f] TNFs: Humira, Enbrel, Cimzia, Simponi, Remicade
[g] non-TNFs: Orencia, Taltz, Cosentyx, Stelara
[h] cDMARDs: MTX, Arava, Azulfidine, Otezla
[i] Clinical Global Assessment of PsO is scored on a five-point scale from 0-4, with corresponding interpretations of Clear, Almost Clear, Mild, Moderate, and Severe, respectively.

Table 2. Therapy status six months post-initiation

	Overall
All Patients, N	
Remain on tofacitinib, n (%)	
Discontinued tofacitinib, n (%) [a]	
Switched to a bDMARD, n (%) [b]	

[a] This group consists of those discontinuing tofacitinib and not initiating a bDMARD at or prior to the six-month follow-up visit
[b] This group consists of those discontinuing tofacitinib and initiating a bDMARD at or prior to the six-month follow-up visit

Table 3. Summary statistics of continuous outcomes at baseline, six months, and change from baseline to six months

		Overall
All Initiators, N		
Achievement of:		Response Rate (95% CI)
LDA (cDAPSA)		
Minimal Disease Activity		
Body Surface Area Score of 0		
PASDAS < 3.2		
Resolution of enthesitis		
Resolution of dactylitis		
Clinical Global Assessment of PsO – Clear or Almost Clear		

		Overall
		n, mean (SD), [P0,P25,P50,P75,P100]
cDAPSA	Baseline	
	Six Months	
	Difference [a]	
DAPSA	Baseline	
	Six Months	
	Difference [a]	
PASDAS	Baseline	
	Six Months	
	Difference [a]	
HAQ-DI	Baseline	
	Six Months	
	Difference [a]	
BSA	Baseline	
	Six Months	
	Difference [a]	
CDAI	Baseline	
	Six Months	
	Difference [a]	
Tender joint count (68)	Baseline	
	Six Months	
	Difference [a]	
Swollen joint count (66)	Baseline	
	Six Months	
	Difference [a]	
Patient global skin assessment	Baseline	
	Six Months	
	Difference [a]	
Patient pain	Baseline	
	Six Months	
	Difference [a]	
Patient fatigue	Baseline	
	Six Months	
	Difference [a]	

		Overall
Clinical Global Assessment of PsO	Baseline	
	Six Months	
	Difference [a]	
Work time missed	Baseline	
	Six Months	
	Difference [a]	
Impairment while working	Baseline	
	Six Months	
	Difference [a]	
Overall work impairment	Baseline	
	Six Months	
	Difference [a]	
Activity impairment	Baseline	
	Six Months	
	Difference [a]	

[a] Calculated as six-month value minus baseline value

Table 4. Patient demographic characteristics by monotherapy and combination therapy, among all tofacitinib initiators

	Overall	*Mono*	*Combo*	*p-value*
All Patients, N				
Age (years), n, Mean (SD), [P0,P25,P50,P75,P100]				
Female, n/N (%)				
Race, n/N (%)				
White				
Black				
Asian				
Other				
Work Status, n/N (%)				
Full Time/Part Time				
Retired				
Disabled				
Other				
BMI (kg/m^2), n, Mean (SD), [P0,P25,P50,P75,P100]				
BMI Category (kg/m^2), n/N (%)				
< 25				
25 to < 30				
30 +				
Duration of PsA Symptoms (years), n, Mean (SD), [P0,P25,P50,P75,P100]				
Time Since PsA Diagnosis (years), n, Mean (SD), [P0,P25,P50,P75,P100]				
Time Since PsO Onset (years), n, Mean (SD), [P0,P25,P50,P75,P100]				
Psoriasis, n/N (%)				
Psoriatic Nail Dystrophy, n/N (%)				
History of Comorbidities, n/N (%)				
CVD[b]				
Depression				
Diabetes				
Malignancy[c]				
NMSC				
Hypertension				
Hyperlipidemia				
Crohns Disease				
Anxiety				
Fibromyalgia				
Serious Infections[d]				
Metabolic Syndrome				

	Overall	Mono	Combo	p-value
Ulcerative Colitis				
Uveitis				
Smoking Status, n/N (%)				
Never				
Previous				
Current				
Cigarettes per day, n, Mean (SD), [P0,P25,P50,P75,P100]				
Smoking Duration, n, Mean (SD), [P0,P25,P50,P75,P100]				
Alcohol Use, n/N (%)				
Number drinks per week, n, Mean (SD), [P0,P25,P50,P75,P100]				
Prior Biologics, n, Mean (SD), [P0,P25,P50,P75,P100]				
Number of Prior Biologics, n/N (%)				
0				
1				
2 +				
Prior TNFs, n, Mean (SD), [P0,P25,P50,P75,P100]				
Number of Prior TNFs, n/N (%)				
0				
1				
2 +				
Prior non-TNFs, n, Mean (SD), [P0,P25,P50,P75,P100]				
Number of Prior non-TNFs, n/N (%)				
0				
1				
2 +				
Prior OSMs, n, Mean (SD), [P0,P25,P50,P75,P100]				
Number of Prior OSMs, n/N (%)				
0				
1				
2 +				
Current OSM Use, n/N (%)				
Current MTX Use, n/N (%)				
Current NSAID Use, n/N (%)				
Current Opioid Use, n/N (%)				
Current Aspirin Use, n/N (%)				
Prednisone Use, n/N (%)				
None				
Missing Dose				

	Overall	Mono	Combo	p-value
Dose < 10 mg				
Dose ≥ 10 mg				
Tender Joints (28), n, Mean (SD), [P0,P25,P50,P75,P100]				
Tender Joints (68), n, Mean (SD), [P0,P25,P50,P75,P100]				
Swollen Joints (28), n, Mean (SD), [P0,P25,P50,P75,P100]				
Swollen Joints (66), n, Mean (SD), [P0,P25,P50,P75,P100]				
Enthesitis, n/N (%)				
SPARCC Enthesitis Count, n, Mean (SD), [P0,P25,P50,P75,P100]				
LEI Count, n, Mean (SD), [P0,P25,P50,P75,P100]				
Dactylitis, n/N (%)				
Dactylitis Count, n, Mean (SD), [P0,P25,P50,P75,P100]				
CDAI, n, Mean (SD), [P0,P25,P50,P75,P100]				
CDAI Category, n/N (%)				
Remission (CDAI ≤ 2.8)				
Low (2.8 < CDAI ≤ 10)				
Moderate (10 < CDAI ≤ 22)				
High (22 < CDAI)				
Minimal Disease Activity, n/N (%)				
DAPSA, n, Mean (SD), [P0,P25,P50,P75,P100]				
DAPSA Category, n/N (%)				
DAPSA ≤ 4				
4 < DAPSA ≤ 14				
14 < DAPSA ≤ 28				
28 < DAPSA				
cDAPSA, n, Mean (SD), [P0,P25,P50,P75,P100]				
cDAPSA Category, n/N (%)				
cDAPSA ≤ 3				
3 < cDAPSA ≤ 13				
13 < cDAPSA ≤ 27				
27 < cDAPSA				
PASDAS, n, Mean (SD), [P0,P25,P50,P75,P100]				
Nail VAS, n, Mean (SD), [P0,P25,P50,P75,P100]				
Body Surface Area (%), n, Mean (SD), [P0,P25,P50,P75,P100]				
BSA Category (%), n/N (%)				
0				
> 0 to < 3				
3 to < 10				
≥ 10				

	Overall	Mono	Combo	p-value
CRP (mg/L), n, Mean (SD), [P0,P25,P50,P75,P100]				
ESR (mm/hr), n, Mean (SD), [P0,P25,P50,P75,P100]				
Patient Pain (0-100 VAS), n, Mean (SD), [P0,P25,P50,P75,P100]				
Patient Fatigue (0-100 VAS), n, Mean (SD), [P0,P25,P50,P75,P100]				
Patient Global Skin Assessment (0-100 VAS), n, Mean (SD), [P0,P25,P50,P75,P100]				
Clinical Global Assessment of PsO [i], n, Mean (SD), [P0,P25,P50,P75,P100]				
Clinical Global Assessment of PsO [i] Category, n/N (%)				
Clear/Almost Clear				
Mild				
Moderate				
Severe				
HAQ-DI, n, Mean (SD), [P0,P25,P50,P75,P100]				
HAQ-S, n, Mean (SD), [P0,P25,P50,P75,P100]				
EQ-5D, n, Mean (SD), [P0,P25,P50,P75,P100]				
WPAI Domains (%), n, Mean (SD), [P0,P25,P50,P75,P100]				
Work Time Missed				
Impairment While Working				
Overall Work Impairment				
Activity Impairment				
Spinal Mobility Measures (cm), n, Mean (SD), [P0,P25,P50,P75,P100]				
Occiput to Wall Distance				
Modified Schober				

SD = standard deviation, P0 = minimum, P25 = 25th percentile, P50 = median, P75 = 75th percentile, P100 = maximum

[a] p-values from chi-square or Fisher exact tests for categorical variables and from Wilcoxon rank-sum tests for continuous variables, included for descriptive purposes only

[b] History of cardiovascular disease includes history of: hypertension, hyperlipidemia, cardiac revascularization procedure (CABG, stent, angioplasty), ventricular arrythmia, cardiac arrest, myocardial infarction, acute coronary syndrome, unstable angina, CHF (with and without hospitalization), stroke, transient ischemic attack, other CV, deep vein thrombosis, peripheral arterial disease, peripheral arterial thrombosis, urgent peripheral revascularization, peripheral ischemia/gangrene, pulmonary embolism, carotid artery disease, and hemorrhage.

[c] Malignancy includes breast cancer, lung cancer, lymphoma, skin cancer (squamous cell), and other cancers.

[d] Serious infections include the following: joint/bursa infection, cellulitis, sinusitis, diverticulitis, sepsis, pneumonia, bronchitis, gastroenteritis, meningitis, urinary tract infection, upper respiratory infection, tuberculosis, and other infections.

[e] Biologics: Humira, Enbrel, Cimzia, Simponi, Remicade, Orencia, Taltz, Cosentyx, Stelara

[f] TNFs: Humira, Enbrel, Cimzia, Simponi, Remicade

[g] non-TNFs: Orencia, Taltz, Cosentyx, Stelara

[h] cDMARDs: MTX, Arava, Azulfidine, Otezla

[i] Clinical Global Assessment of PsO is scored on a five-point scale from 0-4, with corresponding interpretations of Clear, Almost Clear, Mild, Moderate, and Severe, respectively.

Table 5. Therapy status six months post-initiation

	Overall	*Mono*	*Combo*	*p-value* [a]
All Patients, N				
Remain on tofacitinib, n (%)				
Discontinued tofacitinib, n (%) [b]				
Switched to a bDMARD, n (%) [c]				
Added OSM, n (%)				
Discontinued OSM, n (%)				

[a] p-value from chi-square test

[b] This group consists of those discontinuing tofacitinib and not initiating a bDMARD at or prior to the six-month follow-up visit

[c] This group consists of those discontinuing tofacitinib and initiating a bDMARD at or prior to the six-month follow-up visit

Table 6. Disease activity outcomes at six months

	Mono	*Combo*	*Mono vs Combo*		
Binary Outcomes	**Response Rate (95% CI) [a]**	**Response Rate (95% CI) [a]**	**Rate Difference (95% CI) [a]**	**p-value [a]**	**OR (95% CI)**
Achievement of:					
LDA (cDAPSA)					
Minimal Disease Activity					
Body Surface Area Score of 0					
PASDAS < 3.2					
Resolution of enthesitis					
Resolution of dactylitis					
Clinical Global Assessment of PsO – Clear or Almost Clear					
Continuous Outcomes	**LS Means (SE)**	**LS Means (SE)**	**Δ LS Means (SE) 95% CI**		
Baseline to six-month change in:					
cDAPSA					
DAPSA					
PASDAS					
HAQ-DI					
BSA					
CDAI					
Tender joint count					
Swollen joint count					
Patient global skin assessment					
Patient pain					
Patient fatigue					
Clinical Global Assessment of PsO					
Work Time Missed					
Impairment While Working					
Overall Work Impairment					
Activity Impairment					

[a] 95% CI for the response rate and 95% CI and p-value for the rate difference were based on normal approximation to binomial proportions. OR (95% CI) was based on a logistic regression model with treatment group as the sole covariate

Table 7. Summary statistics of continuous outcomes at baseline, six months, and change from baseline to six months

		Overall	*Mono*	*Combo*
All Initiators, N				
Continuous Outcome, n, mean (SD), [P0,P25,P50,P75,P100]				
cDAPSA	Baseline			
	Six Months			
	Difference [a]			
DAPSA	Baseline			
	Six Months			
	Difference [a]			
PASDAS	Baseline			
	Six Months			
	Difference [a]			
HAQ-DI	Baseline			
	Six Months			
	Difference [a]			
BSA	Baseline			
	Six Months			
	Difference [a]			
CDAI	Baseline			
	Six Months			
	Difference [a]			
Tender joint count (68)	Baseline			
	Six Months			
	Difference [a]			
Swollen joint count (66)	Baseline			
	Six Months			
	Difference [a]			
Patient global skin assessment	Baseline			
	Six Months			
	Difference [a]			
Patient pain	Baseline			
	Six Months			
	Difference [a]			

		Overall	*Mono*	*Combo*
Patient fatigue	Baseline			
	Six Months			
	Difference [a]			
Clinical Global Assessment of PsO	Baseline			
	Six Months			
	Difference [a]			
Work time missed	Baseline			
	Six Months			
	Difference [a]			
Impairment while working	Baseline			
	Six Months			
	Difference [a]			
Overall work impairment	Baseline			
	Six Months			
	Difference [a]			
Activity impairment	Baseline			
	Six Months			
	Difference [a]			

[a] Calculated as six-month value minus baseline value