

SUPPLEMENTARY INFORMATION

Title: Clinical Characteristics of Registry Participants With Psoriatic Arthritis Initiating Guselkumab: An Analysis From the CorEvitas Psoriatic Arthritis/Spondyloarthritis Registry

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Detailed definition of cerebro-cardiovascular disease

Cerebro-cardiovascular disease includes cardiac revascularization procedure (coronary artery bypass graft, stent, or angioplasty), ventricular arrhythmia, cardiac arrest, myocardial infarction, acute coronary syndrome, unstable angina, other coronary artery disease, congestive heart failure (with and without hospitalization), stroke, transient ischemic attack, other cardiovascular disease, deep vein thrombosis, peripheral arterial disease, pulmonary embolism, and carotid artery disease.

Supplementary Table S1. Detailed summary of the CorEvitas PsA/SpA Registry inclusion/exclusion criteria

Current Registry Inclusion and Exclusion Criteria
Patients must be:
• At least 18 years of age; • Able and willing to provide written consent; and • One of the following: – Diagnosed with PsA and initiating (prescribed or starting) an eligible medication^{a,b} for the treatment of PsA at the enrollment visit – Meet the ASAS criteria for AxSpA, including radiographic or nonradiographic, and initiating (prescribed or starting) an eligible biologic^{b,c} for the treatment of AxSpA at the enrollment visit – Meet the modified New York classification criteria for AS and initiating (prescribed or starting) an eligible biologic^{b,c} for the treatment of AS at the enrollment visit
Patients must not be:
• Diagnosed with rheumatoid arthritis, systemic lupus erythematosus, or any other form of autoimmune inflammatory arthritis • Participating in or planning to participate in a clinical trial with an interventional research study of a nonmarketed or marketed investigational drug (eg, phase 1-4 clinical drug trial, postmarketing study, or registry study where drug is being provided); of note, concurrent participation in another observational registry study is not excluded
History of Inclusion Criteria
From initiation until April 2017, inclusion criteria in the registry were as follows:
• Meet diagnostic criteria for PsA, AS, or axial or peripheral SpA

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- Age ≥ 18 years of age as of the patient's PsA/SpA diagnosis.
 - Patient must be able and willing to provide consent.

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

- Patients needed to be diagnosed with PsA by their rheumatologist or meet the modified New York classification criteria for AS.
- Patients needed to be a newly prescribed (incident user) of a United States Food and Drug Administration-approved eligible biologic for the treatment of PsA or AS at the time of enrollment. Eligible biologics for inclusion in the registry include abatacept (approved for PsA only), adalimumab, certolizumab, etanercept, golimumab, infliximab, ixekizumab (approved for PsA only), secukinumab, and ustekinumab (approved for PsA only).
- Age ≥ 18 years of age as of the patient's PsA/SpA diagnosis.

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

- The following nonbiologic medications were added as eligible medications for enrollment of patients diagnosed with PsA: apremilast, leflunomide, methotrexate, sulfasalazine, and tofacitinib.
- Eligibility for patients with PsA was expanded to include patients currently on an eligible medication at the time of enrollment.

From October 2018 forward, inclusion criteria in the registry were modified as follows:

- For patients with PsA, 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.
 - Apremilast, leflunomide, methotrexate, and sulfasalazine are no longer eligible medications for PsA enrollments.
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From August 2019 forward, inclusion criteria in the registry were modified as follows:

- Apremilast is an eligible medication for patients with PsA.
- For patients with AxSpA or AS, eligible diagnoses have been expanded to include patients who meet ASAS classification criteria for AxSpA, including nonradiographic and radiographic.
- Direct switches from an originator biologic to a biosimilar satisfies the incident user requirement at enrollment.

From July 2020 forward, inclusion criteria in the registry were modified as follows:

- Guselkumab has been added as an eligible medication for PsA.

^aEligible treatments include United States Food and Drug Administration-approved nonbiologic, biologic, and biosimilar drugs prescribed for the treatment of PsA and any new medications approved for the treatment of PsA at enrollment.

^bTreatments are prescribed per the physician's decision, which must precede the decision to enroll the patient into the registry.

^cEligible biologic treatments include United States Food and Drug Administration-approved biologic and biosimilar drugs for the treatment of AS or AxSpA and any new biologics or biosimilars approved for the treatment of AS or AxSpA at enrollment.

AS, ankylosing spondylitis; ASAS, Assessment of Spondyloarthritis International Society; AxSpA, axial spondyloarthritis; PsA, psoriatic arthritis

Supplementary Table S2. Detailed definitions of disease activity measures and patient-reported outcomes used in the CorEvitas

PsA/SpA Registry

Disease Activity Measures	Definitions
Clinical Disease Activity Index (CDAI)	Calculated as swollen 28-joint count + tender 28-joint count + Patient Global Disease Activity (1-10) + Evaluator's Global Disease Activity (1-10)
Disease Activity Index of PsA (DAPSA)	Calculated as tender joint count (0-68) + swollen joint count (0-66) + Patient Global Assessment VAS (0-10 cm) + patient pain VAS (0-10 cm) + CRP (mg/dL)
Clinical DAPSA (cDAPSA)	The same as DAPSA except CRP is not included
Minimal Disease Activity Score (MDA)	Meeting 5 of the 7 following criteria: tender joint count ≤ 1 , swollen joint count ≤ 1 , Psoriasis Activity and Severity Index ≤ 1 or body surface area affected by psoriasis ≤ 3 , patient pain VAS ≤ 15 , Patient Global Disease Activity VAS ≤ 20 , health assessment questionnaire ≤ 0.5 , and tender enthesal points ≤ 1
Very Low Disease Activity Score (VLDA)	Meeting all 7 of the following criteria: tender joint count ≤ 1 , swollen joint count ≤ 1 , Psoriasis Activity and Severity Index ≤ 1 or body surface area affected by psoriasis ≤ 3 , patient pain VAS ≤ 15 , Patient Global Disease Activity VAS ≤ 20 , health assessment questionnaire ≤ 0.5 , and tender enthesal points ≤ 1
PsA Disease Activity Score (PASDAS)	Calculated as $(0.18 \times \sqrt{\text{Physician Global Assessment VAS [0-100 mm]}}) + (0.159 \times \sqrt{\text{Patient Global Assessment VAS [0-100 mm]}}) - (0.253 \times \sqrt{\text{Short Form 36 health survey physical component summary scale}}) + (0.101 \times \ln[66 \text{ swollen joint count} + 1]) + (0.048 \times \ln[68 \text{ tender joint count} + 1]) + (0.23 \times \ln[\text{Leeds Enthesitis Count} + 1]) + (0.377 \times \ln[\text{dactylitis count} + 1]) + (0.102 \times \ln[\text{CRP} + 1] + 2) \times 1.5$; categorized as Remission (≤ 1.9), Low Disease Activity (>1.9 and <3.2) Moderate (≥ 3.2 and <5.4) or High (≥ 5.4)
Ankylosing Spondylitis Disease Activity	Calculated as $0.12 \times \text{back pain} + 0.06 \times \text{duration of morning stiffness} + 0.11 \times \text{Patient}$

Score (ASDAS)–CRP	$\text{Global} + 0.07 \times \text{peripheral pain/swelling} + 0.58 \times \ln(\text{CRP} + 1)$
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Axial Involvement

Axial involvement for patients with PsA is defined by the following physician-reported criteria:

- PsA diagnosis along with any of the following:
 - Diagnosis of axial SpA (nonradiographic or radiographic) or AS
 - Physician-indicated spinal involvement or completed any of the mobility measurements (includes occiput-to-wall distance, lateral lumbar flexion, and lumbar flexion [Schöber])
 - Selected any of the criteria for diagnosing axial SpA within the clinical features section^a
 - Includes inflammatory back pain, ≥ 3 months back pain (age of onset < 45 years), low back pain and stiffness for > 3 months that improves with exercise but is not relieved by rest, limitation of motion of the lumbar spine in both the sagittal and frontal planes, active (acute) inflammation on magnetic resonance imaging highly suggestive of sacroiliitis associated with SpA, and sacroiliitis grade ≥ 2 bilaterally or grade 3-4 unilaterally by x-ray

Patient-Reported Outcome Measures	Definitions
Health Assessment Questionnaire Disability Index (HAQ-DI)	The 8 categories assessed are 1) dressing and grooming, 2) arising, 3) eating, 4) walking, 5) hygiene, 6) reach, 7) grip, and 8) common daily activities. For each of these categories, patients report the amount of difficulty they have in performing 2 or 3 specific activities. There are 4 possible responses for the Disability Index questions: Without ANY difficulty = 0, With SOME difficulty = 1, With MUCH difficulty = 2, UNABLE to do = 3. The highest score reported by the patient for any component question of the 8 categories determines the score for that category: • If a component question is left blank or the response is too ambiguous to assign a score, then the score for that category is determined by the remaining completed

question(s).

- If all component questions are blank or if more than 1 answer is given, then follow-up with the respondent is required.
- If the respondent's mark is between the response columns, then move it to the closest one. If it's directly between the two, move it to the higher one.

Each of the disability items on the HAQ has a companion aids/devices variable that is used to record what type(s) of assistance, if any, the participant uses for his/her usual activities. These variables (see below) are coded as follows:

0 = No assistance is needed

1 = A special device is used by the patient in his/her usual activities

2 = The patient usually needs help from another person

3 = The patient usually needs BOTH a special device AND help from another person

Devices that are associated with each category: note that this assignment of devices to particular disability categories assumes that the devices are used only for the purpose for which they are designed. Devices written in the "Other" sections or notes written next to any component questions are considered if they would be used for any stated categories. Permanent adaptations of the person's environment (eg, changing faucets in the bedroom or kitchen, using Velcro closures on clothing) should also be counted as aids and devices.

The Standard Disability Index. "What is the disability level of this person?"

1) This question results in a new set of category scores that are computed by adjusting the score for each category, if necessary, based on the patient's use of an aid or device or assistance for that category. If either devices and/or help from another person are checked for a category, the score is set to "2," unless the score is already "3" (ie, scores of "0" or "1" are increased to "2"). For example, if the highest score for the dressing category is "1," and the patient says they use a device for dressing, the computed category score would be "2." The sum of the computed categories scores is then calculated and divided by the number of categories answered. This gives a score in the 0-3 range.

The Alternative Disability Index. "What is the disability level of this patient when using

	aids and devices to compensate for disability?” 2) The aid and device variables are not used to calculate the alternative disability index; it is calculated by adding the scores for each of the categories and dividing by the number of categories answered. This gives a score in the 0-3 range. CorEvitas reports the Standard Disability Index, taking into account a person’s assistive devices.
Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)	BASDAI consists of a 0-10 scale measuring discomfort, pain, and fatigue (0 being no problem and 10 being the worst problem) in response to 6 questions asked of the patient pertaining to the 5 major symptoms of ankylosing spondylitis: • Fatigue • Spinal pain • Arthralgia (joint pain) or swelling • Enthesitis or inflammation of tendons and ligaments (areas of localized tenderness where connective tissues insert into bone) • Morning stiffness duration • Morning stiffness severity To give each symptom equal weighting, the average of the 2 scores relating to morning stiffness is taken. The resulting 0-50 score is divided by 5 to give a final 0-10 BASDAI score. Scores of 4 or greater suggest suboptimal control of disease.
Bath Ankylosing Spondylitis Functional Index (BASFI)	BASFI consists of 10 questions. All questions are completed on numerical rating scales or on a 10 cm visual analog scale with “easy” and “impossible” as anchors. The mean of the 10 scales gives the BASFI score a value between 0 and 10. Full list of questions includes the following: 1. Putting on your socks or tights without help or aids (eg, sock aids)? 2. Bending forward from the waist to pick up a pen from the floor without an aid? 3. Reaching up to a high shelf without help or aids (eg, helping hand)?

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4. Getting up from an armless chair without using your hands or any other help?
 5. Getting up off the floor without any help from lying on your back?
 6. Standing unsupported for 10 minutes without discomfort?
 7. Climbing 12-15 steps without using a handrail or walking aid (one foot on each step)?
 8. Looking over your shoulder without turning your body?
 9. Doing physically demanding activities (eg, physiotherapy exercises, gardening, or sports)?
 10. Doing full-day activities whether it be at home or work?

Assessment of Spondylarthritis International
Society Health Index (ASAS HI)

The ASAS HI is a linear composite measure with a dichotomous response option: “I agree” and “I do not agree.” Each statement on the ASAS HI is given a score of 1=I agree or 0=I do not agree. The total sum of the ASAS HI ranges from 0-17, with a lower score indicating a better health status. Please note that items number 7 and 8 are not applicable for all patients. For those patients who ticked the response “not applicable,” the sum score is analyzed based on n=16 or n=15, respectively.

Modified Routine Assessment of Patient
Index Data 3 (RAPID3)

Modified multidimensional health assessment questionnaire (MDHAQ, 0-10)÷3 + Patient Global Assessment VAS (0-10 cm)÷3 + patient pain VAS (0-10 cm)÷3

The modified version of the RAPID3 is not the validated measure RAPID3. RAPID3 was developed for rheumatoid arthritis.

Two of the 10 items in the MDHAQ are substituted with comparable functional variables: (a) “Walk 2 miles or 3 kilometers, if you wish?” is substituted with “Climb up 5 steps?”, and (b) “Participate in recreational activities and sports as you would like, if you wish?” is substituted with “Do chores such as vacuuming or yardwork?”. Three items in the MDHAQ have relatively minor differences in wording: “Wash and dry your body?”, “Turn faucets on and off?”, and “Get in and out of a car?”

^aKiltz U, van der Heijde D, Boonen A, Cieza A, Stucki G, Khan MA, et al. Development of a health index in patients with ankylosing spondylitis (ASAS HI): final result of a global initiative based on the ICF guided by ASAS. *Ann Rheum Dis* 2015;74:830-5.
CRP, C-reactive protein; PsA, psoriatic arthritis; SpA, spondyloarthritis; VAS, visual analog scale.