TV-118-110420-01

SYLLABUS AND COURSE GUIDE

Hitting the Target with IL-23 Inhibitors in Psoriatic Arthritis

Premiere Date: Wednesday, November 4, 2020
6:30 PM - 8:00 PM ET (live)
Credit Expiration Date: Thursday, November 4, 2021

Log-in: www.cmeoutfitters.com/TargetPsA

LIVE FACULTY:
Philip J. Mease, MD
Christopher T. Ritchlin, MD, MPH

MODERATOR:
Atul A. Deodhar, MD, MRCP, DNB, FACR, FACP

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INFORMATION FOR PARTICIPANTS

Statement of Need

Psoriatic arthritis (PsA) is a chronic, inflammatory, musculoskeletal disease with a significant impact on quality of life and functional ability. Despite the data showing the overall impact of PsA, delays in diagnosis are common, which can lead to long-term joint damage and functional disability.

In this CME Outfitters Live and OnDemand activity, expert faculty will focus on assessment, treatment, and management strategies to provide patients with the best treatment aligned with evolving evidence and expert recommendations.

Learning Objectives

At the end of this CME/CE activity, participants should be able to:

- Decrease diagnostic delays through better identification of signs and symptoms of PsA.
- Apply key clinical efficacy and safety data for IL-23 inhibitors to treatment decisions in patients with PsA.
- Collaborate with patients to optimize treatment regimens across the health care continuum.

The following learning objectives pertain only to those requesting CNE or CPE credit:

- Describe ways to decrease diagnostic delays through better identification of signs and symptoms of PsA.
- Identify key clinical efficacy and safety data for IL-23 inhibitors for treatment decisions in patients with PsA.
- Summarize how to collaborate with patients to optimize treatment regimens across the health care continuum.

Target Audience

Rheumatologists, dermatologists, primary care physicians, PAs, nurse practitioners, nurses, and pharmacists

Financial Support

Supported by an educational grant from Janssen Biotech, Inc., administered by Janssen Scientific Affairs, LLC

CREDIT INFORMATION

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Universal Activity Number: Live: 0376-0000-20-112-L01-P; Enduring: 376-0000-20-112-H01-P
Type: Knowledge-based

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Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.5 MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.

Learning Formats: Live activity; Enduring material

Royal College MOC

Through an agreement between the Accreditation Council for Continuing Medical Education and the Royal College of Physicians and Surgeons of Canada, medical practitioners participating in the Royal College MOC Program may record completion of accredited activities registered under the ACCME's "CME in Support of MOC" program in Section 3 of the Royal College's MOC Program.

MIPS Improvement Activity

This activity counts towards MIPS Improvement Activity requirements under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). Clinicians should submit their improvement activities by attestation via the CMS Quality Payment Program website.

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Post-tests, credit request forms, and activity evaluations must be completed online (requires free account activation), and participants can print their certificate or statement of credit immediately (75% pass rate required). This website supports all browsers except Internet Explorer for Mac. For complete technical requirements and privacy policy, visit https://www.cmeoutfitters.com/privacy-and-confidentiality-policy.

There is no fee for participation in this activity. The estimated time for completion is 90 minutes. Questions? Please call **877.CME.PROS**.

FACULTY BIOS & DISCLOSURES

Atul A. Deodhar, MD, MRCP, DNB, FACR, FACP (Moderator)

Dr. Deodhar is Professor of Medicine and Medical Director of Rheumatology Clinics in the Division of Arthritis & Rheumatic Diseases at Oregon Health & Science University, Portland. He is board certified in internal medicine and rheumatology and is a fellow of the American College of Rheumatology (ACR) and American College of Physicians.

Dr. Deodhar is a past chair of SPARTAN (Spondyloarthritis Research and Treatment Network), an organization of North American rheumatologists dedicated to education and research in the field of axial spondyloarthritis. He serves on the steering committee of GRAPPA (Group for the Research and Assessment of Psoriasis and Psoriatic Arthritis). He served on the ACR treatment guidelines sub-committee and as the associate editor of the Advanced Rheumatology Course by Association of Health Professionals in Rheumatology (ARHP). Dr. Deodhar has served the ACR in various other capacities as a vice chair of the annual meeting planning committee, member of the peripheral MRI task force, Association of Rheumatology Health Professionals (ARHP) nominating committee, and developer of the ARHP online advanced rheumatology course. He serves on the Rheumatology Board of the American Board of Internal Medicine (ABIM).

Dr. Deodhar is the Deputy Editor of *Best Practice and Research Clinical Rheumatology* and a guest editor for *Current Opinion in Rheumatology*. He is a reviewer for *Nature Reviews in Rheumatology, Arthritis & Rheumatology, Annals of the Rheumatic Diseases*, and *Annals of Internal Medicine*, among several other journals. His research interests are axial spondyloarthritis and psoriatic arthritis. He has authored three books, over 200 peer-reviewed articles, several book chapters, and editorials. Dr. Deodhar has been a principal or co-investigator in more than 100 clinical trials mostly focused on therapies for ankylosing spondylitis, psoriatic arthritis, and rheumatoid arthritis.

He completed his fellowship in rheumatology at Oregon Health & Science University and, before that, a research fellowship in rheumatology at the Royal Cornwall Hospital, Truro, England. Dr. Deodhar completed his residency in internal medicine and geriatrics at the Royal Cornwall Hospital, Truro, as well as in the Sassoon General Hospital and King Edward Memorial Hospital, Pune, India. He received his MBBS and MD degrees from the University of Pune, India and his MRCP from the Royal College of Physicians, London, England.

Philip J. Mease, MD

Dr. Mease received undergraduate and medical degrees from Stanford University and completed residency in internal medicine and fellowship in rheumatology at the University of Washington. He directs the Rheumatology Research Division at Swedish Medical Center/Providence St. Joseph Health and is Clinical Professor of Medicine at the University of Washington in Seattle. His major research interests include psoriatic arthritis (PsA) and spondyloarthritis (SpA). His work includes research on disease state, development of outcome measures, and determining the efficacy and safety of emerging therapies for these conditions. Dr. Mease has authored over 490 journal articles, numerous abstracts, and book chapters. He is past President, founding organizer, and current Treasurer of the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and a member of its Collaborative Research Network (CRN) steering committee. He is also a member of the Assessment of Spondyloarthritis international Society (ASAS) and the Spondyloarthritis Research and Treatment Network (SPARTAN). Dr. Mease is active in the Outcome Measures in Rheumatology Clinical Trials (OMERACT) organization as co-chair of the PsA and chronic pain working groups and as a steering committee member. He is the Scientific Director of the PsA and SpA arms of the Consortium of Rheumatology Researchers of North America (CORRONA) registry. Dr. Mease is co-chair of the PsA task force of the National Psoriasis Foundation, which in 2019 awarded him a lifetime achievement award for his work in advancing the field of PsA.

Christopher T. Ritchlin, MD, MPH

Dr. Ritchlin is a Professor of Medicine and Chief of Allergy, Immunology & Rheumatology at the University of Rochester Medical Center in Rochester, New York. He attended medical school at Albany Medical College and completed his medical residency and chief residency at Mount Sinai Hospital in New York. He trained as a fellow in rheumatology at the New York University Medical Center and remained as a postdoctoral fellow for 2 years, and then spent an additional year in the lab of Dr. Robin Poole in Montreal, Canada. Dr. Ritchlin joined the faculty of the University of Rochester School of Medicine and Dentistry in 1991 and in 2009 he earned an MPH degree at the University.

Dr. Ritchlin is engaged in translational research that is centered on mechanisms of bone resorption in psoriatic arthritis and on the role of the lymphatic system in joint flares observed in both rheumatoid and psoriatic arthritis. His laboratory has a number of ongoing projects including circulating osteoclast precursors in inflammatory joint disease and psoriasis, mechanisms of inflammatory osteolysis in psoriatic arthritis, and gene activation profiles in the blood and end organs of patients with immune-mediated inflammatory disorders. The lab is also examining the contribution of circulating dendritic cells to inflammation in rheumatoid and psoriatic arthritis. His research is funded by the NIH, National Psoriasis foundation, Amgen, Centocor, and UCB. Dr. Ritchlin is also a co-investigator in the IPART and CORRONA registries and leads an effort to identify arthritis biomarkers in psoriasis patients. He is a member of the ACR Division Directors Special Committee and is leading efforts to provide basic science online teaching modules to fellows in rheumatology. Dr. Ritchlin also directs the mentoring of junior investigators in the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA). He has published over 160 manuscripts on topics related to psoriatic arthritis, lymphatic mechanisms of joint flare, and bone remodeling.

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Dr. Mease reports he receives grants from AbbVie Inc.; Amgen Inc.; Bristol Myers Squibb; Eli Lilly and Company; Galapagos, Inc.; Gilead Sciences, Inc.; Janssen Pharmaceuticals, Inc.; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Sun Pharmaceutical Industries Inc.; and UCB, Inc. He is a consultant for AbbVie Inc.; Amgen Inc.; Boehringer Ingelheim; Bristol Myers Squibb; Eli Lilly and Company; Galapagos, Inc.; Gilead Sciences, Inc.; GlaxoSmithKline; Janssen Pharmaceuticals, Inc.; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Sun Pharmaceutical Industries Inc.; and UCB, Inc. He is on the speakers bureau for: AbbVie Inc.; Amgen Inc.; Bristol Myers Squibb; Eli Lilly and Company; Genentech; Janssen Pharmaceuticals, Inc.; Novartis Pharmaceuticals Corporation; Pfizer Inc.; and UCB, Inc.

Dr. Ritchlin reports he receives grants from AbbVie Inc.; Amgen Inc.; and UCB, Inc. He is a consultant for AbbVie Inc.; Amgen Inc.; Eli Lilly and Company; Janssen Pharmaceuticals, Inc.; Novartis Pharmaceuticals Corporation; Pfizer Inc.; Regeneron Pharmaceuticals Inc.; Sun Pharmaceutical Industries Inc.; and UCB, Inc.

Jeffrey Helfand, DO (peer reviewer) has no disclosures to report.

Mae Ochoa, RPh (peer reviewer) has no disclosures to report.

Poshala Tish Aluwihare, PhD (planning committee) has no disclosures to report.

Susan Perry (planning committee) has no disclosures to report.

Jan Perez (planning committee) has no disclosures to report.

Sharon Tordoff (planning committee) has no disclosures to report.

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Hitting the Target with IL-23 Inhibitors in Psoriatic Arthritis

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2. Complete your post-test and evaluation at the conclusion of the webcast
3. Be sure to fill in your **ABIM ID number** and **DOB** (MM/DD) on the evaluation so we can submit your credit to ABIM

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- Over the next 90 days, actively work to incorporate improvements in your clinical practice from this presentation
- Complete the follow-up survey from CME Outfitters in approximately 3 months

CME Outfitters will send you confirmation of your participation to submit to CMS attesting to your completion of a CME for MIPS Improvement Activity

CME for MIPS IMPROVEMENT ACTIVITY

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CONTINUING MEDICAL EDUCATION

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Learning Objective 1

Decrease diagnostic delays through better identification of signs and symptoms of psoriatic arthritis (PsA).

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Learning Objective 2

Apply key clinical efficacy and safety data for IL-23 inhibitors to treatment decisions in patients with PsA.

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Learning Objective 3

Collaborate with patients to optimize treatment regimens across the health care continuum.

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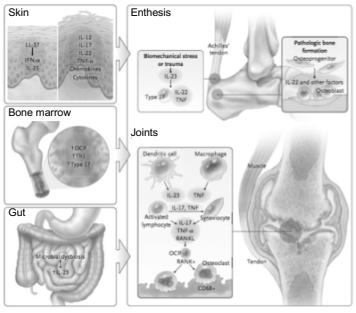
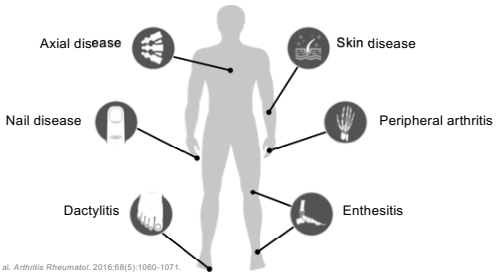
Pathogenic Pathways in PsA



Ritchlin C, et al. *N Engl J Med*. 2017;376:957-970.

Clinical Domains of PsA



Coates LC, et al. *Arthritis Rheumatol*. 2016;68(5):1060-1071.

Differentiating Axial PsA from AS

- Axial PsA and AS are part of the spectrum of spondyloarthritis
  - Overlapping features but different genetic, clinical, radiographic, and prognostic characteristics
- HLA-B*27 occurs less frequently in axial PsA but is a genetic risk factor for both diseases
- Axial PsA develops at older age, is less symptomatic, and is associated with distinct radiographic features
- Lack of universally accepted definition of axial PsA
- True comparison of two diseases is challenging

AS = ankylosing spondylosis

Feld J, et al. *Nat Rev Rheumatol*. 2018;14(6):363-371.

Common Comorbidities in PsA

Ocular inflammation[1]
(eg, uveitis/iritis)

Inflammatory bowel disease[2]

Psychosocial burden[3,4]
- Anxiety
- Depression
- Suicidal ideation
- Substance use

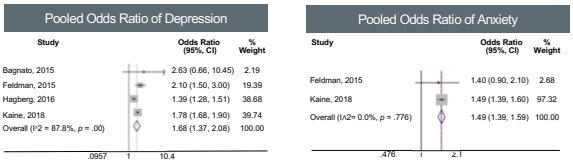
Increased risk of CVD[5-8]
- Hyperlipidemia
- Hypertension
- Insulin resistance
- Diabetes
- Obesity

CVD = cardiovascular disease

1. Au S, et al. *Psoriasis Forum*. 2011;17:169-179. 2. Li WQ, et al. *Ann Rheum Dis*. 2013;72(7):1200-1205. 3. Husni E, et al. *Semin Arthritis Rheum*. 2017;47:351-360. 4. Chisholm A, et al. *Rheumatology (Oxford)*. 2016;55(6):1047-1052. 5. Egeberg E, et al. *Rheumatology Advances in Practice*. 2018;0:1-5. 6. Mallbris L, et al. *Curr Rheumatol Rep*. 2006;8(5):355-363. 7. Neimann AI, et al. *J Am Acad Dermatol*. 2006;55(5):829-835. 8. Tam LS, et al. *Rheumatology (Oxford)*. 2008;47(5):718-723.

Depression and Anxiety in PsA

Individuals with PsA have 66% higher odds of having prevalent depression and 49% higher odds of having prevalent anxiety, compared to individuals without PsA



CI = confidence interval

Zusman EZ, et al. *Semin Arthritis Rheum*. 2020 Feb 13. pii: S0049-0172(20)30020-2. [Epub ahead of print].

CASPAR Criteria for the Classification of PsA

Inflammatory musculoskeletal disease (arthritis, spondylitis, enthesitis) with ≥ 3 points from the following:	
Evidence of PsO:	
Current PsO	2
Personal history of PsO	1
Family history of PsO	1
Psoriatic nail dystrophy	
Negative rheumatoid factor	1
Dactylitis (current or recorded by a rheumatologist)	1
Radiographic evidence of juxta-articular new bone formation	1

CASPAR = **C**lassification Criteria for **P**soriatic **Ar**thritis

Taylor W, et al. *Arthritis Rheum*.2006;54:2665-2673.

Workup

- Lab testing
  - Complete blood count with differential
  - Blood urea nitrogen, creatinine, uric acid, and urinalysis
  - ESR and CRP
  - RF, anti-CCP antibody, and ANA
  - HLA-B27 testing in patients with psoriasis who present with arthritis and if PsA is suspected despite absence of psoriasiform skin lesions
- Arthrocentesis and synovial fluid analysis
- Radiographs of involved joints (e.g., hands, feet, sacroiliac joints)

ANA = antinuclear antibody; anti-CCP = anti–cyclic citrullinated peptide; CRP = C-reactive protein; ESR = erythrocyte sedimentation rate; RF = rheumatoid factor

Rida MA, Chandran V. *Clin Immunol*. 2020;214:108390.

Defining Conditions and Considerations: Examples of Severe Disease

Severe PsA	Severe PsO
• Erosive disease • Elevated markers of inflammation (ESR, CRP) attributable to PsA • Long-term damage that interferes with function (i.e., joint deformities) • Highly active disease that causes a major impairment in quality of life (QoL) • Active PsA at many sites including dactylitis, enthesitis • Function-limiting PsA at a few sites • Rapidly progressive disease	• PASI ≥ 12 • BSA ≥ 5%-10% • Significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp) where disease burden causes significant disability • Impairment of physical or mental functioning can warrant a designation of moderate-to-severe disease despite the lower amount of skin surface area involved

BSA = body surface area; PASI = Psoriasis Area and Severity Index
Singh JA, et al. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.

Minimal Disease Activity (MDA) Criteria

A patient is classified as having MDA when he/she meets 5 of the following 7 criteria:

- Tender joint count ≤ 1
- Swollen joint count ≤ 1
- PASI ≤ 1 or BSA ≤ 3
- Patient pain VAS ≤ 15
- Patient global activity VAS ≤ 20
- HAQ ≤ 0.5
- Tender entheseal points ≤ 1

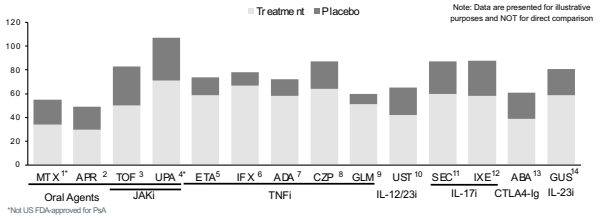
HAQ = health assessment questionnaire; VAS = visual analog scale
Coates LC, et al. *Lancet.* 2015;386(10012):2489-2498.

PsA Therapies

Nonpharmacologic therapies	Physical therapy, occupational therapy, smoking cessation, weight loss, massage therapy, exercise	
Symptomatic treatments	Nonsteroidal anti-inflammatory drugs, local glucocorticoid injections	
Oral small molecule	Methotrexate*, sulfasalazine*, cyclosporine*, leflunomide*, apremilast	
TNF inhibitor (TNFi)	Etanercept, infliximab, adalimumab, golimumab, certolizumab pegol	AxSpA
IL-12/23i	Ustekinumab	
IL-17i	Secukinumab, ixekizumab	AxSpA
CTLA4-Ig	Abatacept	
JAK inhibitor	Tofacitinib, upadacitinib*	
IL-23i	Guselkumab, risankizumab*, tildrakizumab*	

*Not FDA-approved for PsA
AxSpA = axial spondyloarthritis; IL = interleukin; JAK = Janus kinase
Singh JA, et al. *Arthritis Care Res (Hoboken).* 2019;71(1):2-29.

Efficacy of PsA Treatments: ACR20

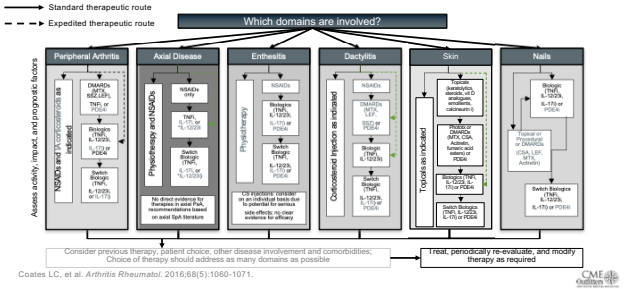


*Not US FDA-approved for PsA

MTX: 15 mg every week (qw) x 6 months; APR (apremilast): 20 mg twice a day (bid) x 24 weeks; TOF (tofacitinib): 5 mg bid x 12 weeks; UPA (upadacitinib): 15 mg every 2 weeks (q2w) x 12 weeks; ETA (etanercept): 25 mg twice a week x 24 weeks; IFX (infliximab): I5 mg/kg at weeks 0, 2, 6, and 14 x 16 weeks; ADA (adalimumab): 40 mg every 2 weeks (q2w) x 12 weeks; CZP (certolizumab): loading dose of 400 mg at week 0, 2, and 4, then 200 mg q2w x 24 weeks); GLM (golimumab): 50 mg x 14 weeks;
UST (ustekinumab): 45 mg x 24 weeks; SEC (secukinumab): 150 mg baseline, weeks 1, 2, and 3 and then every 4 weeks from week 4 x 16 weeks; IXE (ixekizumab): 80 mg q4w x 24 weeks;
ABA (abatacept): 125 mg qw x 24 weeks; GUS (gusellkumab): 100 mg q4w x 24 weeks.

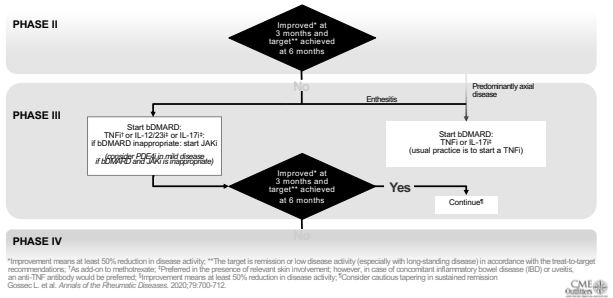
1. Kingsley GH, et al. *Rheumatology*. 2012;51(6):1368-1377. 2. Kavanaugh A, et al. *Ann Rheum Dis*. 2014;73(8):1020-1026. 3 Mease P, et al. *New Engl J Med*. 2017;377(16):1537-1550. 4. Mease P, et al. *Arthritis Rheumatol*. 2019;Suppl 71:45-6. 5. Mease PJ, et al. *Arthritis Rheum*. 2004;50(7):2264-2272. 6. Antoni CE, et al. *Arthritis Rheum*. 2005;52(4):1227-1236.
7. Mease PJ, et al. *Arthritis Rheum*. 2005;52(10):3279-3289. 8. Mease PJ, et al. *Ann Rheum Dis*. 2013;73(1):48-55. 9. Kavanaugh A, et al. *Ann Rheum Dis*. 2013;72(11):1777-1785.
10. McInnes IB, et al. *Lancet*. 2013;382(9894):780-779. 11. Mease P, et al. *Ann Rheum Dis*. 2018;77(6):890-897. 12. Mease PJ, et al. *Ann Rheum Dis*. 2017;76(1):79-87.
13. Mease PJ, et al. *Ann Rheum Dis*. 2017;76(9):1550-1558. 14. Mease PJ, et al. *Lancet*. 2020;395(10230):1126-1136.

GRAPPA Treatment Recommendations



Coates LC, et al. *Arthritis Rheumatol*. 2016;68(5):1060-1071.

EULAR Recommendations: 2019 Update



*Improvement means at least 50% reduction in disease activity; **The target is remission or low disease activity (especially with long-standing disease) in accordance with the treat-to-target recommendations; †As add-on to methotrexate; ‡Preferred in the presence of relevant skin involvement; however, in case of concomitant inflammatory bowel disease (IBD) or uveitis, an anti-TNF antibody would be preferred; §Improvement means at least 50% reduction in disease activity; ¶Consider cautious tapering in sustained remission

Gossec L. et al. *Annals of the Rheumatic Diseases*. 2020;79:700-712.

2018 ACR/NPF Guidelines: Strong Recommendations

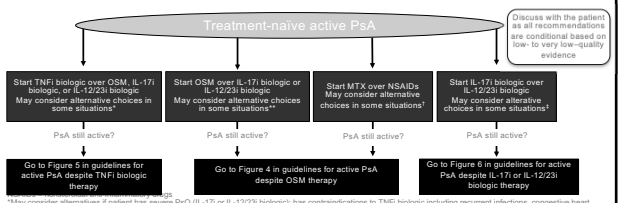
- Agents with no efficacy in IBD should not be used in patients with IBD
- Heed box warnings
- Smoking cessation

	Level of Evidence
In active PsA + IBD despite OSM, switch to a TNFi monoclonal antibody biologic over a TNFi biologic soluble receptor biologic (i.e., etanercept) (PICO 58)	Moderate
In active PsA + IBD despite OSM, switch to a TNFi monoclonal antibody biologic over an IL-17i biologic (PICO 59)	Moderate
In active PsA + IBD despite OSM, switch to an IL-12/23i biologic over switching to an IL-17i biologic (PICO 60)	Moderate
In adult patients with active PsA and frequent serious infections who are treatment-naïve, start an OSM over a TNFi biologic (PICO 64)	Moderate
In adult patients with active PsA, recommend smoking cessation over no smoking cessation (PICO 6)	Moderate

ACR = American College of Rheumatology; NPF = National Psoriasis Foundation; OSM = oral small molecule

Singh JA, et al. *Arthritis Care Res (Hoboken)*. 2019;71(1):2-29.

2018 ACR/NPF Guidelines: Recommendations

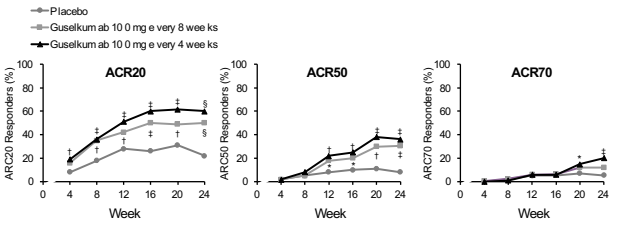


*May consider alternatives if patient has severe PsO (IL-17i or IL-12/23i biologic); has contraindications to TNFi biologic including recurrent infections, congestive heart failure, or demyelinating disease (OSM, IL-17i biologic, or IL-12/23i biologic); prefers oral medications (OSM) or less frequent administrations (IL-12/23i biologic); has concern over starting biologic as the first therapy (OSM); or does not have severe PsO or severe PsA (OSM)
**May consider alternatives if patient has severe PsO or severe PsA (IL-12/23i biologic or IL-17i biologic); has concomitant active IBD (IL-12/23i biologic); or prefers less frequent administrations (IL-12/23i biologic)
†May consider NSAIDS in patients with less active disease, after careful consideration of cardiovascular risks and renal risks of NSAIDs
‡May consider IL-12/23i biologic if patient has concomitant IBD or desires less frequent drug administration
The order of listing of various conditional recommendations or of different treatment choices within a conditional statement does not indicate any sequence in which treatment options would be chosen; each conditional statement stands on its own

Singh JA, et al. *Arthritis Care Res (Hoboken)*. 2019;71(1):2-29.

IL-23 Inhibitors in PsA

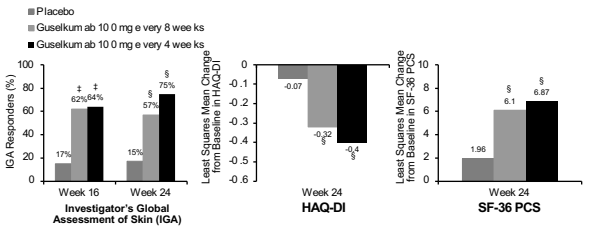
DISCOVER-1: Efficacy



*Unadjusted $p < .05$; †$p < .01$; ‡$p < .001$; §Adjusted $p < .0001$

Deodhar A, et al. *Lancet*. 2020;395(10230):1115-1125.

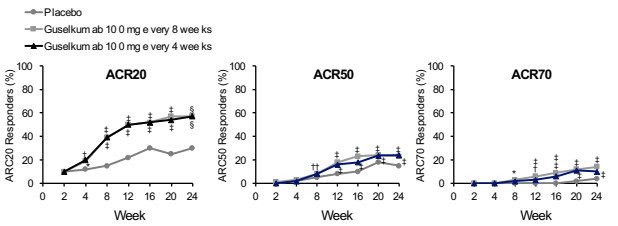
DISCOVER-1: Efficacy



‡$p < .001$; §Adjusted $p < .0001$

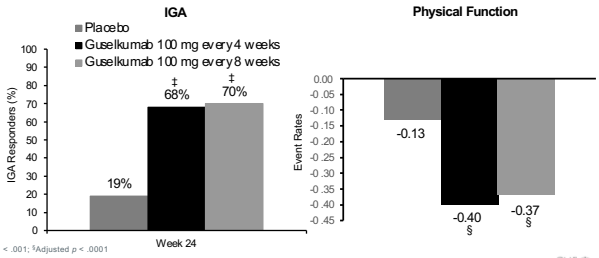
Deodhar A, et al. *Lancet*. 2020;395(10230):1115-1125.

DISCOVER-2: Efficacy



Mease PJ, et al. *Lancet*. 2020;395(10230):1126-1136.

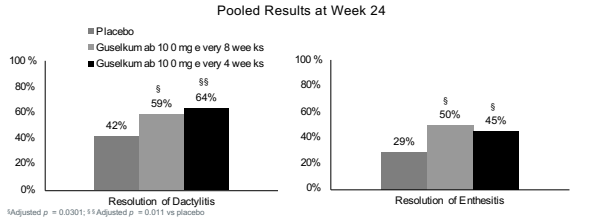
DISCOVER-2: Efficacy



‡p < .001; §Adjusted p < .0001

Mease PJ, et al. *Lancet*. 2020;395(10230):1126-1136. Schattner A. *Ann Intern Med*. 2020 21;173(2).

DISCOVER-1 and DISCOVER-2: Dactylitis and Enthesitis

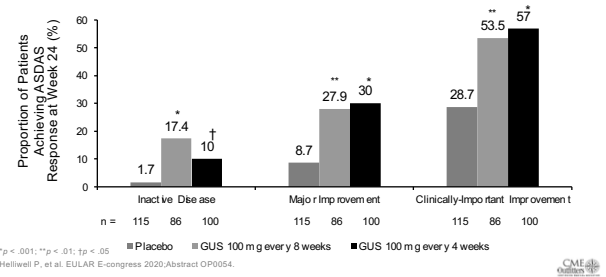


§Adjusted p = 0.0301; §§Adjusted p = 0.011 vs placebo

Unadjusted (nominal) p values are not controlled for multiplicity and should be interpreted only as supportive.
*Per the preplanned statistical analysis plan, resolution of dactylitis and enthesitis data were combined across DISCOVER-1 and DISCOVER-2 as major secondary endpoints in the U.S. testing procedure

Mease PJ, et al. *Lancet*. 2020;395:1126-1136.

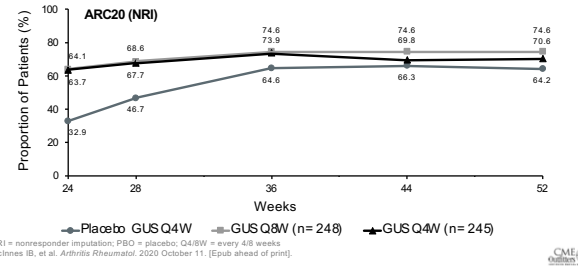
DISCOVER-1 and -2: Axial Outcome Measures



*p < .001; **p < .01; †p < .05

Helliwell P, et al. EULAR E-congress 2020;Abstract OP0054.

DISCOVER-2: 1-Year Findings



NRI = nonresponder imputation; PBO = placebo; Q4/8W = every 4/8 weeks
McInnes IB, et al. *Arthritis Rheumatol*. 2020 October 11. [Epub ahead of print].

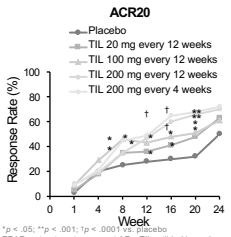
DISCOVER-1 and DISCOVER-2: AEs

- Few AEs resulted in study drug discontinuation
- No deaths in GUS arms
- Minimal elevation of liver enzymes in GUS vs. PBO
- No serious infections
- No IBD
- No malignancy signal

AEs = adverse events
1. Deodhar A, et al. *Lancet*. 2020;395(10230):1115-1125. 2. Mease PJ, et al. *Lancet*. 2020;395:1126-1136.

Tildrakizumab in Active PsA: Efficacy and AEs

Randomized, Double-Blind, Placebo-Controlled, Multiple-Dose, Phase IIb Study (N = 391)

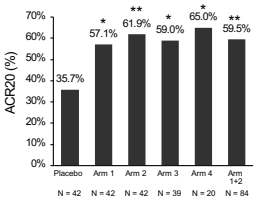


- Most frequent TEAEs through week 24
  - Nasopharyngitis (pooled TIL arms: 5.4% [17/312]; placebo: 6.3% [5/79])
  - Diarrhea (TIL: 1.3% [4/312]; placebo: 0)
- No reports of candidiasis, IBD, major adverse cardiac events, or malignancy
- No patients discontinued treatment due to TEAEs
- No deaths reported
- Serious TEAEs occurred in 2.2% (7/312) of patients treated with TIL vs. 2.5% (2/79) in patients treated with placebo

*$p < .05$; **$p < .001$; †$p < .0001$ vs. placebo
TEAEs = treatment-emergent AEs; TIL = tildrakizumab
Mease P, et al. ACR/ARP Annual Meeting; 2019. Abstract No. 2878. https://acrabstracts.org/abstract/randomized-double-blind-placebo-controlled-multiple-dose-phase-2b-study-to-demonstrate-the-safety-and-efficacy-of-tildrakizumab-a-high-affinity-anti-interleukin-23p19-monoclonal-antibody/

Risankizumab in Active PsA: Efficacy and AEs

Double-Blind, Parallel-Design, Dose-Ranging Phase II Trial (N = 185); Efficacy Results at Week 16[a]



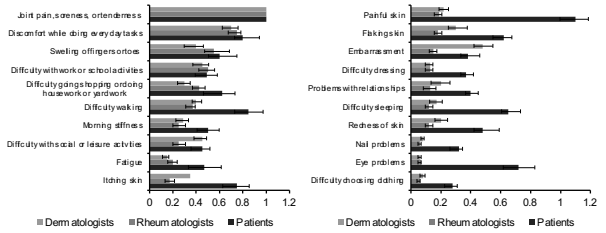
- Most frequent TEAEs through week 16
  - Infection (pooled arms): 35.6% (51/143); placebo: 28.6 % (12/42)
  - Most reported AE: upper respiratory tract infection
- No reports of tuberculosis
- Adverse cardiac events: 1/143 in treatment arm
- Malignancy: 1/143 possible case in treatment arm
- Patients discontinued treatment due to AEs: 2.8% (4/143) vs. 4.8% (2/42)
- No treatment-related deaths reported
- Serious TEAEs occurred in 2.8% (4/143) of patients treated with risankizumab vs. 0.0% (0/42) in patients treated with placebo

[a]Results for categorical endpoints are based on NRI analyses; results for continuous variables are based on MMRM analyses; *p < .05; **p < .01

Mease P, et al. ACR/ARHP Annual Meeting; 2017. Abstract No. 2L. https://acrabstracts.org/abstract/efficacy-and-safety-results-from-a-phase-2-trial-of-risankizumab-a-selective-il-23p19-inhibitor-in-patients-with-active-psoriatic-arthritis/.

Partner with Patients

Patient, Rheumatologist, and Dermatologist Perceptions of Psoriatic Disease Symptoms: DISCONNECT Study

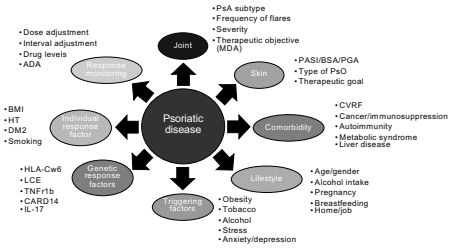


Husni ME, et al. *Arthritis Res Ther.* 2018;20(1):102.

Multidisciplinary Approach for the Management of PsA

Visalli E, et al. *Adv Ther*. 2019;36(4):806-810.

Co-management of PsA in Combined Clinics Facilitates Holistic Treatment



BMI = body mass index; CARD14 = CAspase Recruitment Domain family member 14; CVRF = cardiovascular risk factor; DM2 = diabetes mellitus 2; HT = hypertension; LCE = late cornified envelope gen cluster; PASI: Psoriasis Area and Severity Index; PGA = physician global assessment; TNFr1B = TNF receptor 1B
Queiro R, Coto P. *Rheumatology (Oxford)*. 2017;56(11):1829-1831.

Conclusions

- Advances in the understanding of the pathogenesis of PsA, have led to a significant increase in pharmacologic treatment options
- Guselkumab, targeting IL-23, is the most recent approval for PsA
- A more holistic, patient-centered approach that addresses all aspects of the disease and provides comprehensive care, is essential

SMART Goals

Specific, **M**easurable, **A**ttainable, **R**elevant, **T**imely

- Accurately diagnose PsA by utilizing simple and easy-to-administer screening questionnaires
- Reduce delay from symptom onset to rheumatology referral by identifying symptoms that might suggest referral
- Utilize clinical evidence for targeted agents when creating treatment plans
- Collaborate with patients and other clinicians to provide optimal care

To Ask a Question

Please click on the *Ask Question* tab and type your question. Please include the faculty member's name if the question is specifically for him/her.

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Hitting the Target with IL-23 Inhibitors in Psoriatic Arthritis

with Atul A. Deodhar, MD, MRCP, DNB, FACR, FACP (Moderator); Philip J. Mease, MD; and Christopher T. Ritchlin, MD, MPH

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