

Targeted Immune Modulators for Plaque Psoriasis, Psoriatic Arthritis, and Generalized Pustular Psoriasis: Clinical Evidence

Topic Brief

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Presented by Courtney Cooper, MPH



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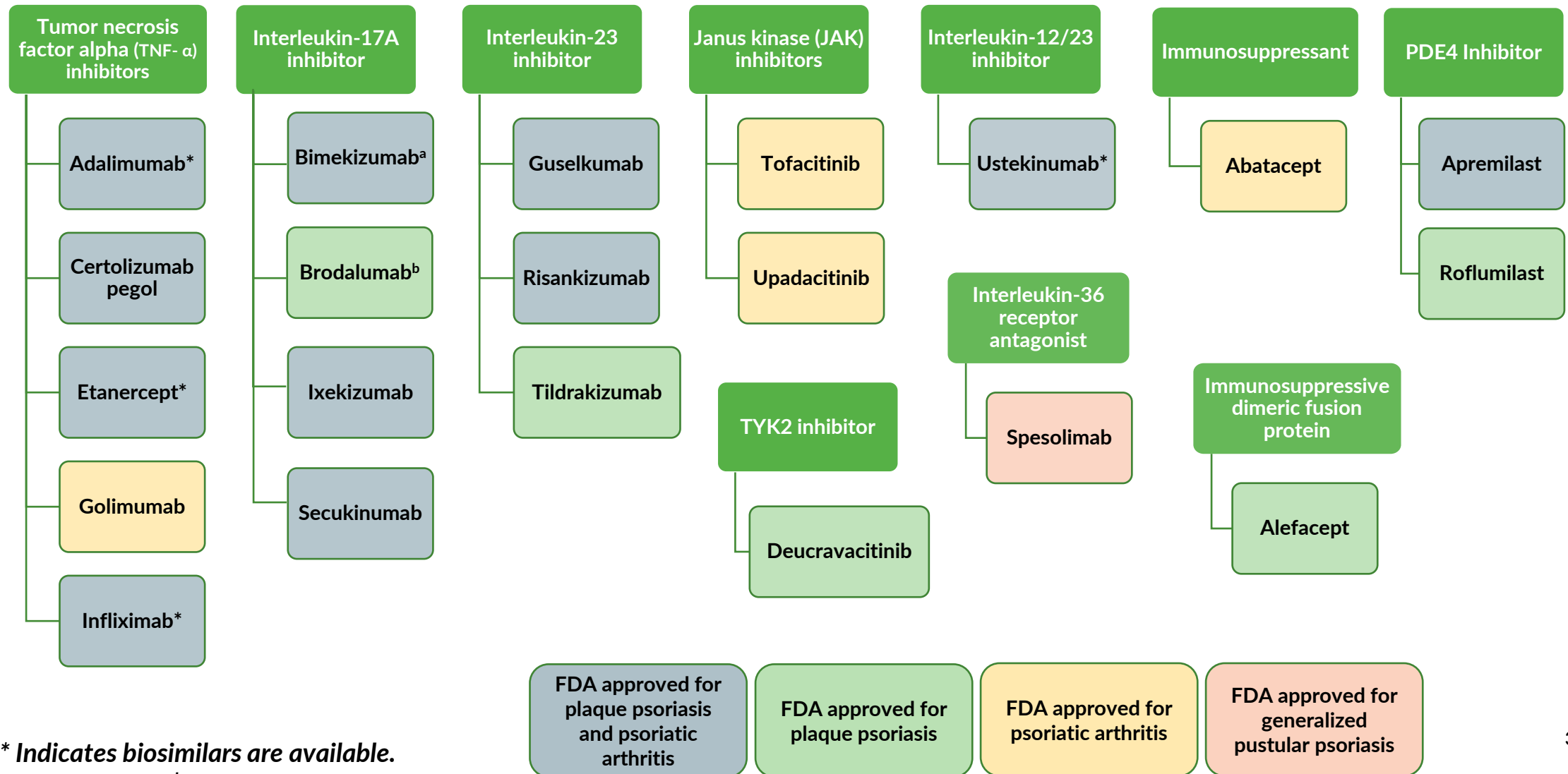
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Background

- Targeted immune modulators (TIMs) are a class of drugs that selectively block mechanisms involved in an inflammatory or immune response
- TIMs are US Food and Drug Administration (FDA) approved for a variety of conditions, including plaque psoriasis (PP), psoriatic arthritis (PsA), and generalized pustular psoriasis (GPP), which are inflammatory diseases that affect the skin or joints
- There have been 10 previous DERP reports on this topic
 - Most recent was published February 2024

TIMs for Plaque Psoriasis, Psoriatic Arthritis, and Generalized Pustular Psoriasis



Notes. * Indicates biosimilars are available.

^a Also interleukin-17F. ^b Receptor antagonist.

PICOS (1 of 2)

- Populations:
 - Adults with plaque psoriasis, psoriatic arthritis, or generalized pustular psoriasis
- Interventions:
 - FDA-approved TIMs and respective biosimilars
 - Select new pipeline drugs with a pending or assigned Prescription Drug User Fee Act (PDUFA) date in February 2025
- Comparators:
 - Another eligible intervention
 - Standard of care or placebo (for newly approved and pipeline therapies only)

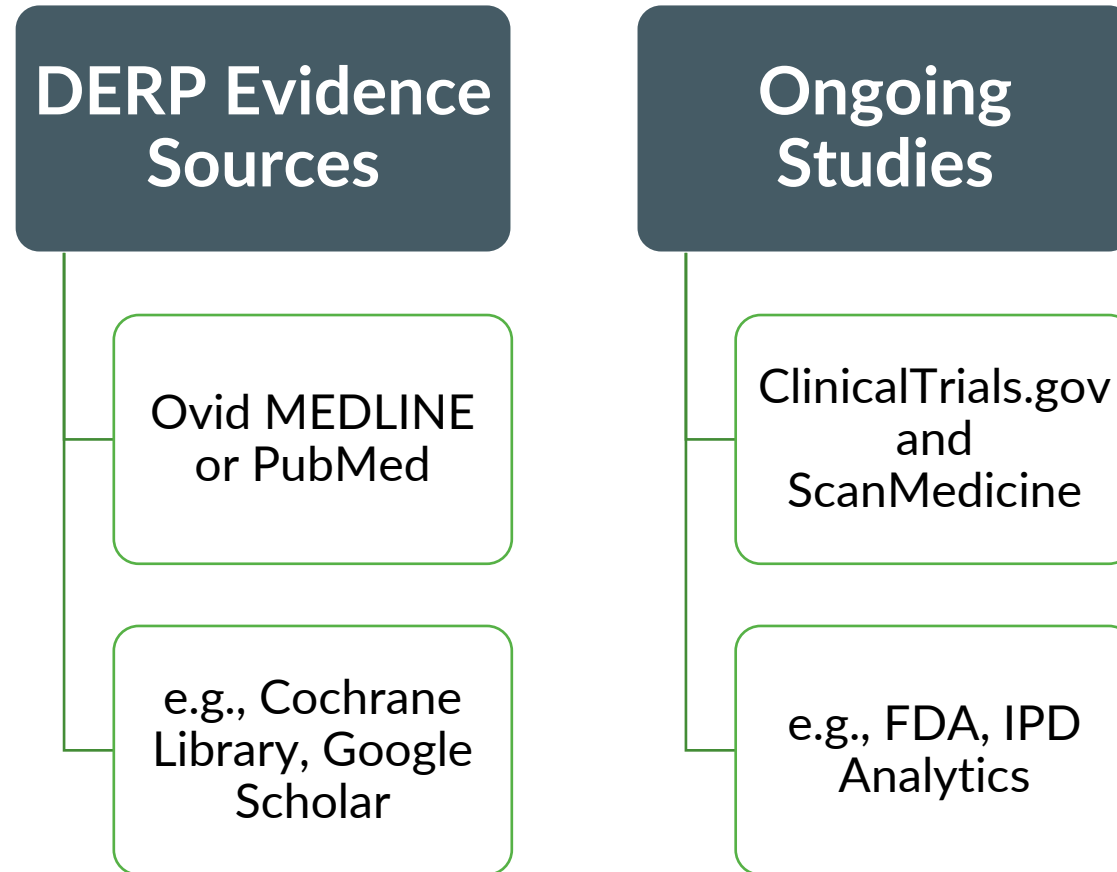
PICOS (2 of 2)

- Outcomes:
 - ❑ Treatment response (e.g., Investigator's Global Assessment)
 - ❑ Disease symptoms (e.g., Psoriasis Area and Severity Index)
 - ❑ Quality of life
 - ❑ Adverse events
 - ❑ Serious adverse events
- Study Designs:
 - ❑ Randomized controlled trials (RCTs)
 - ❑ ≥ 12 weeks in duration
 - ❑ Conducted in the US or other countries considered *very-high* on the United Nations Human Development Index

Key Questions

1. Effectiveness of the listed interventions for PP, PsA, and GPP
2. Harms of the listed interventions for PP, PsA, and GPP
3. Differences by patient or disease characteristics for PP, PsA, and GPP
4. Characteristics of ongoing studies and pipeline therapies for PP, PsA, and GPP

Methods



We included only studies conducted in countries categorized as *very high* on the United Nations Human Development Index

Findings



Overview of Newly Identified and Previously Included Evidence

Total	46 total RCTs		
Status	6 new in update	40 previously included	
Condition	36 for PP (6 new)	10 for PsA (0 new)	0 for GPP

Abbreviations. GPP: generalized pustular psoriasis; PsA: psoriatic arthritis; PP: plaque psoriasis; RCTs: randomized controlled trials.

Study Characteristics of Newly Identified Trials *(1 of 3)*

Comparators	Number of RCTs	Study Size Range	Setting ^a	Study Duration (weeks)
Brodalumab vs. guselkumab	1	113	Multisite international	28
Ustekinumab biosimilar vs. ustekinumab	5	392 to 581	Multisite international	52

Notes. All identified trials evaluated adults with moderate-to-severe plaque psoriasis. ^a None of the trials were conducted in the US.
Abbreviations. RCTs: randomized controlled trials; vs.: versus.

Study Characteristics of Newly Identified Trials *(2 of 3)*

- The 5 new biosimilar-to-reference comparisons evaluated the following ustekinumab biosimilars:
 - ❑ Otulfi (approved September 2024)
 - ❑ Pyzchiva (approved June 2024)
 - ❑ Selarsdi (approved April 2024)
 - ❑ Steqeyma (approved December 2024)
 - ❑ BAT2206 (pipeline, PDUFA date: May 2025)

Study Characteristics of Newly Identified Trials *(3 of 3)*

- All 6 newly identified trials reported on all outcomes of interest (adverse events, disease symptoms, quality of life, serious adverse events, treatment response), with 1 exception:
 - ▣ 1 study did not provide results on quality of life although it was specified as an outcome of interest

Ongoing RCT for Adults With Plaque Psoriasis

- We identified 1 eligible, ongoing RCT on TIMs for adults with plaque psoriasis

Study Name; NCT Number Location(s)	Estimated Enrollment	Intervention(s)	Relevant Outcomes	Trial Status Completion Date
IMMpactful; NCT06333860 Multisite international (including US)	N = 393 (actual)	<ul style="list-style-type: none">• Deucravacitinib• Ustekinumab	<ul style="list-style-type: none">• Disease symptoms• Treatment response	Active, not recruiting March 2026 (estimated)

Abbreviation. NCT: National Clinical Trials (number).

Ongoing RCTs for Adults With Psoriatic Arthritis (1 of 2)

- We identified 4 eligible, ongoing RCTs on TIMs for adults with psoriatic arthritis

Study Name; NCT Number Location(s)	Estimated Enrollment	Intervention(s)	Relevant Outcomes	Trial Status Completion Date
AFFINITY; NCT05071664 Multisite international (including US)	N = 91 (actual)	<ul style="list-style-type: none">• Golimumab and guselkumab• Guselkumab and placebo	<ul style="list-style-type: none">• AEs• Disease symptoms• QoL• SAEs• Treatment response	Completed August 2024 (actual)
AgAIN; NCT04632927 NR	N = 119 (actual)	<ul style="list-style-type: none">• Secukinumab• Ustekinumab	<ul style="list-style-type: none">• AEs• Disease symptoms• QoL• Treatment response	Completed October 2024 (actual)

Abbreviations. AEs: adverse events; NCT: National Clinical Trials (number); NR: not reported; QoL: quality of life; SAEs: serious adverse events.

Ongoing RCTs for Adults With Psoriatic Arthritis (2 of 2)

- We identified 4 eligible, ongoing RCTs on TIMs for adults with psoriatic arthritis

Study Name; NCT Number Location(s)	Estimated Enrollment	Intervention(s)	Relevant Outcomes	Trial Status Completion Date
EVOLUTION; NCT05669833 Multisite US	N = 150 (estimated)	<ul style="list-style-type: none">• Golimumab• Guselkumab	<ul style="list-style-type: none">• Disease symptoms• QoL• Treatment response	Recruiting June 2026 (estimated)
NCT06624228 Multisite international (including US)	N = 550 (estimated)	<ul style="list-style-type: none">• Bimekizumab• Risankizumab	<ul style="list-style-type: none">• AEs• Disease symptoms• SAEs• Treatment response	Recruiting July 2026 (estimated)

Abbreviations. AEs: adverse events; NCT: National Clinical Trials (number); QoL: quality of life; SAEs: serious adverse events.

Ongoing RCTs for Adults With Generalized Pustular Psoriasis

- No eligible, ongoing RCTs were identified on TIMs for adults with generalized pustular psoriasis

Pipeline Therapies

- At the time of our search in IPD Analytics (February 2025), we identified 2 new pipeline TIMs with a pending PDUFA date for adults with plaque psoriasis, psoriatic arthritis, or generalized pustular psoriasis:
 - ▣ Pefcalcitol (CLS008) for psoriasis
 - PDUFA date: pending
 - ▣ Ustekinumab biosimilar (BAT2206) for plaque psoriasis and psoriatic arthritis
 - PDUFA date: May 2025

Questions?



