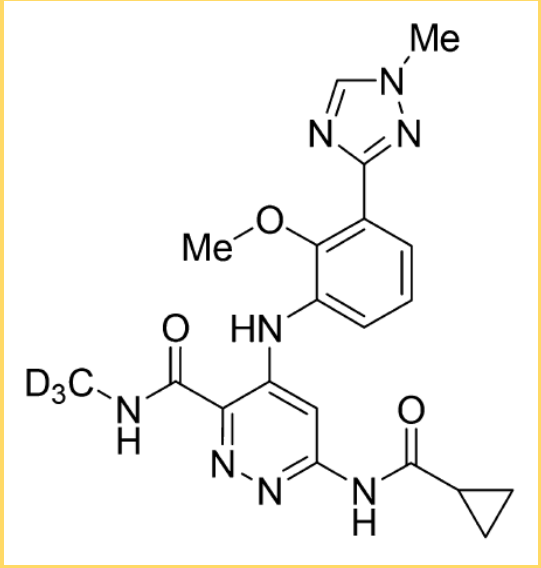
TYK2: New & Emerging

Evolution of Allosteric TYK2 Inhibitors

Less TYK2 Selective → Highly TYK2 Selective

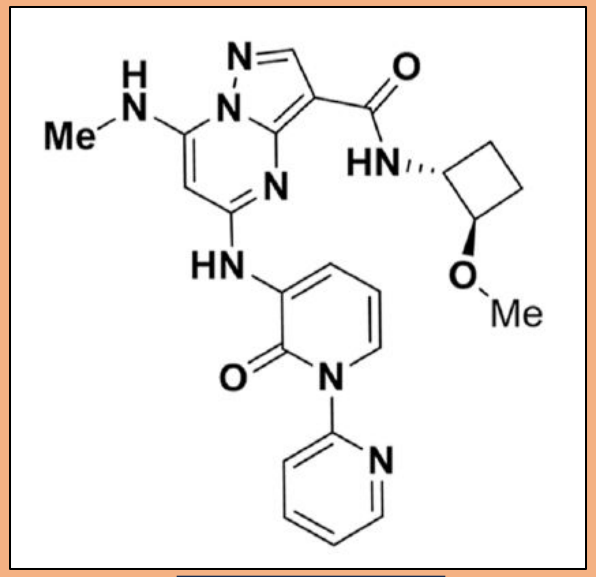
1st Generation



FDA: 2022

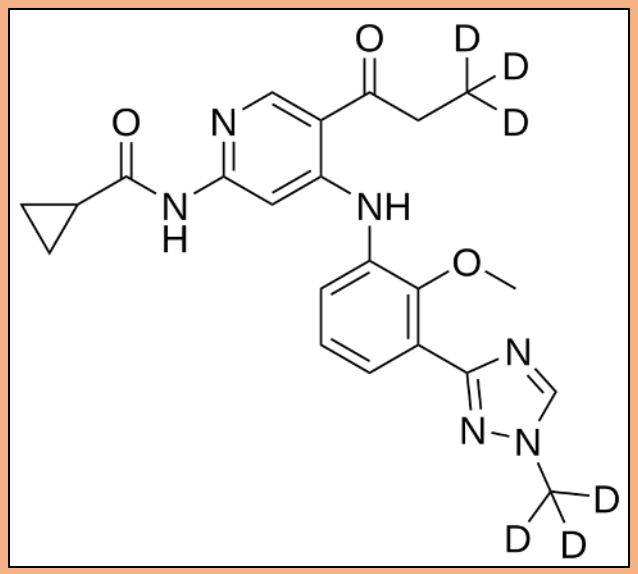
Deucravacitinib

2nd Generation



FDA: TBD

Zasocitinib



FDA: TBD

Envudeucitinib

Christopher G. Bunick, MD, PhD

Associate Professor of Yale Dermatology & Program in Translational Biomedicine

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TYK2: New & Emerging

Christopher G. Bunick, MD, PhD
Associate Professor of Dermatology & Program in Translational Biomedicine
Yale School of Medicine

DISCLOSURE OF RELATIONSHIPS WITH INDUSTRY

Investigator

AbbVie
Almirall
Apogee
Daiichi Sankyo
LEO Pharma
Ortho Dermatologics
Sun Pharma
Takeda
Timber
Palvella

Consultant

AbbVie
Almirall
Amgen
Apogee
Arcutis
Botanix
Connect BioPharma
Dermavant
Eli Lilly
EPI Health/Novan
Incyte
LEO Pharma
Novartis
OrthoDermatologics
Pfizer
Regeneron
Sanofi
Sun Pharma
Takeda
Teladoc
Triveni
UCB
Veradermics

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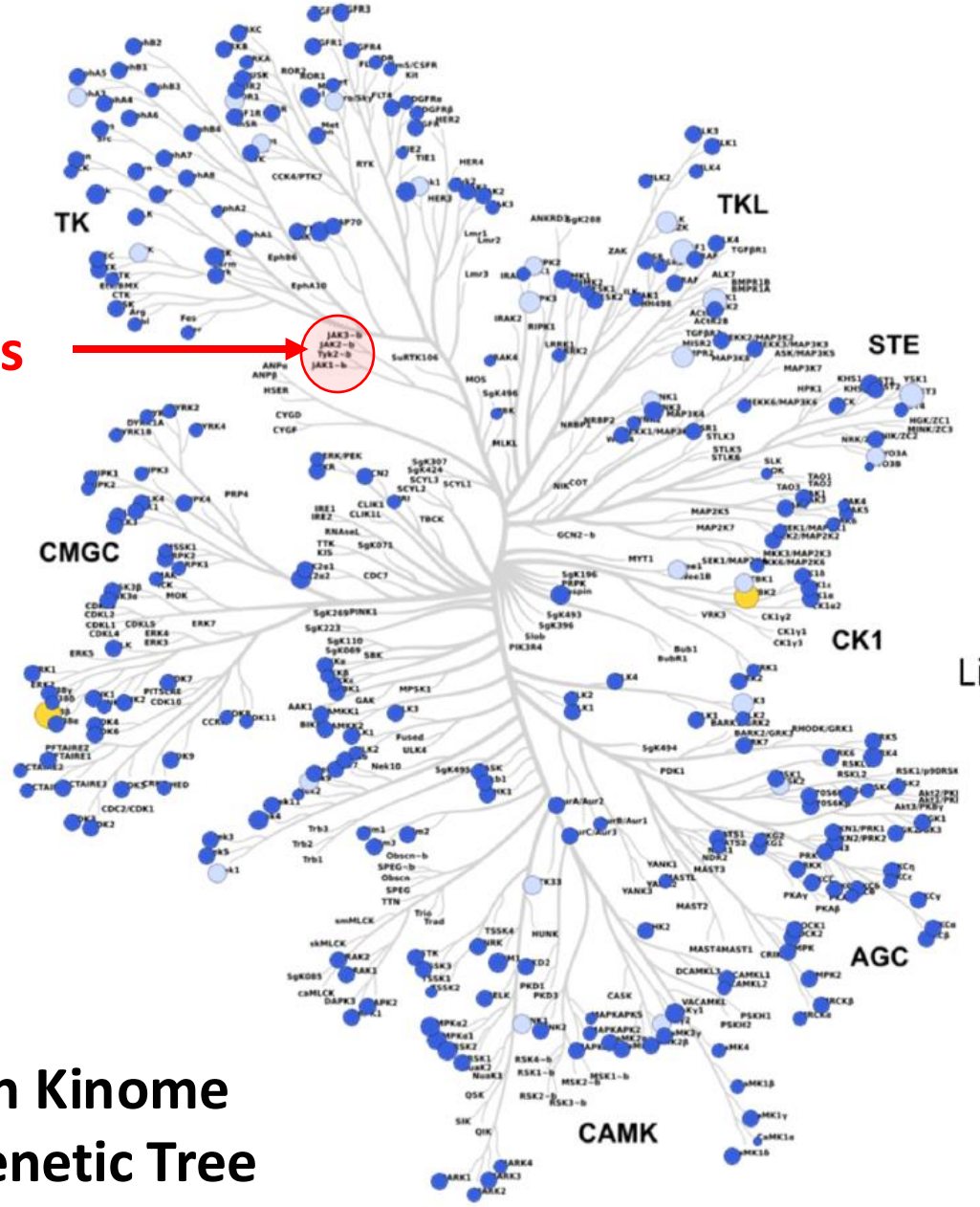
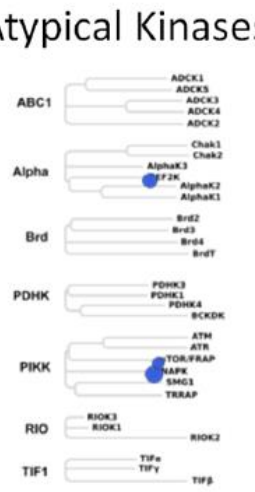
JAK family proteins are one small part of the entire human kinome

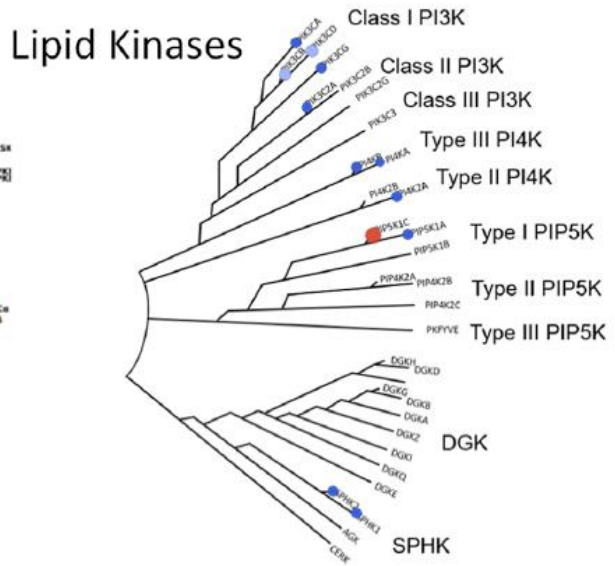
4 Derm JAKs



Human Kinome Phylogenetic Tree



JAK1, JAK2, JAK3, and TYK2 are closely related phylogenetically



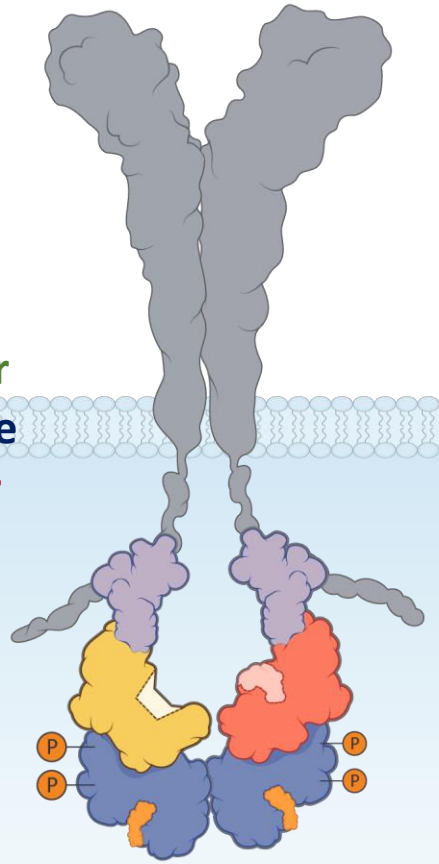
Leit S, et al. Discovery of a Potent and Selective Tyrosine Kinase 2 Inhibitor: TAK-279. J Med Chem. 2023 Aug 10;66(15):10473-10496.

JAK1, JAK2, JAK3, and TYK2 signal intracellularly, distinguishing themselves from extracellular receptors and ligands

Extracellular Psoriasis Pathway Targets

Secreted cytokines circulating in the extracellular space or cell-surface receptors

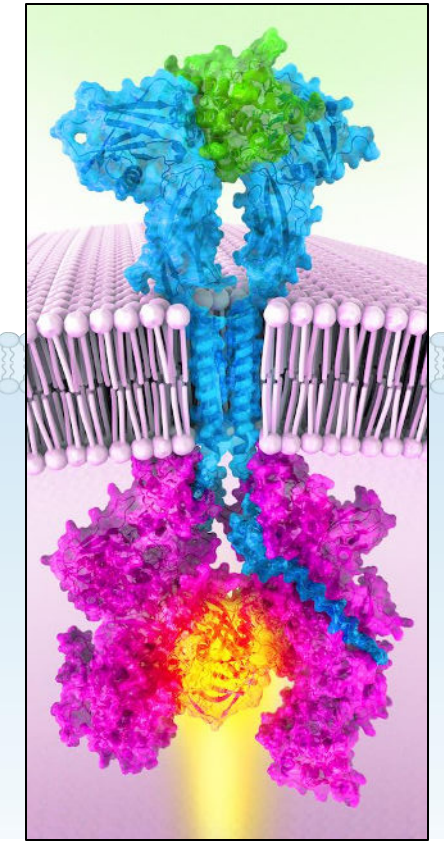
- IL-23
- IL-17A
- IL-17A/F
- IL-17RA
- TNF-α



Intracellular Psoriasis Pathway Targets

Kinases and signaling proteins inside cells that act downstream of multiple cytokines to drive transcriptional programs in the cell nucleus

- TYK2
- PDE4
- RORγt
- JAK1 (PsA)



Conceptual framework for JAK and TYK2 Inhibition

JAK family of kinases

TYK2
JAK1
JAK2
JAK3

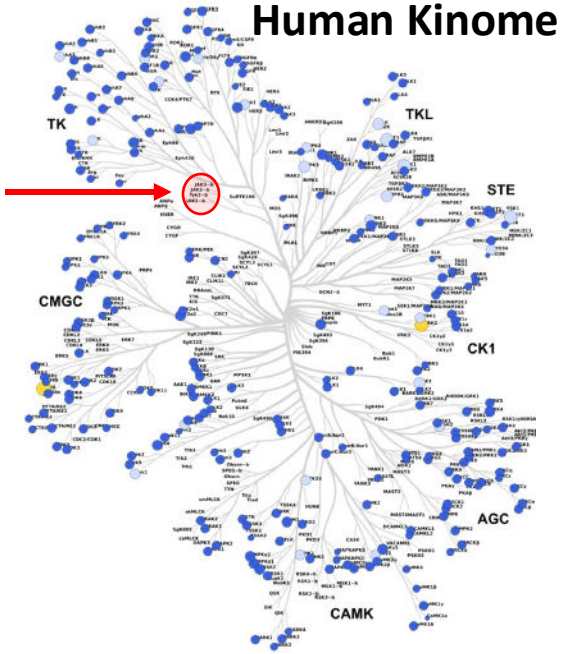
4 phylogenetically related proteins

Shared structural homology

Regulatory or allosteric domain

Active phosphorylation domain

Human Kinome



Leit S, et al. Discovery of a Potent and Selective Tyrosine Kinase 2 Inhibitor: TAK-279. J Med Chem. 2023 Aug 10;66(15):10473-10496.

Regulatory Domain or Allosteric Domain Inhibitors

"TYK2 inhibitors"

deucravacitinib, zasocitinib, envudeucitinib

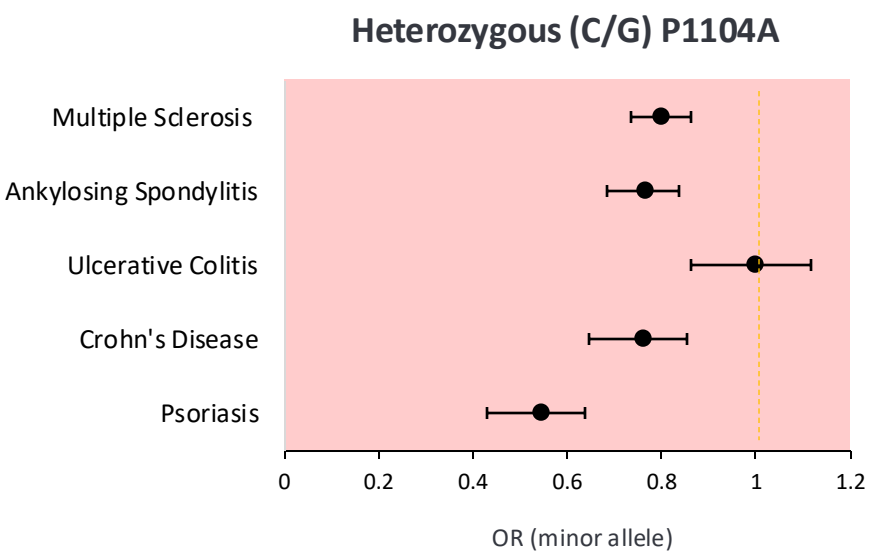
Kinase Domain Inhibitors

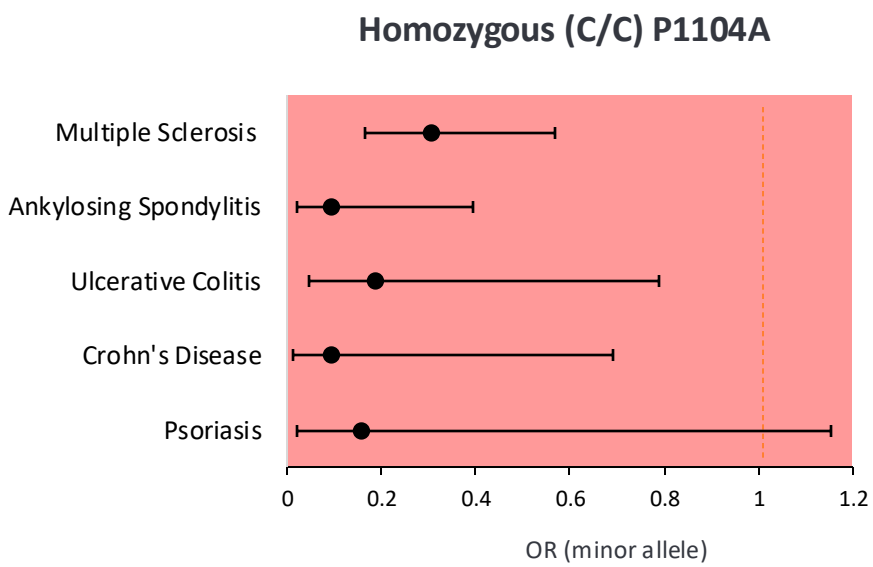
"JAK inhibitors"

abrocitinib, upadacitinib, ruxolitinib, delgocitinib

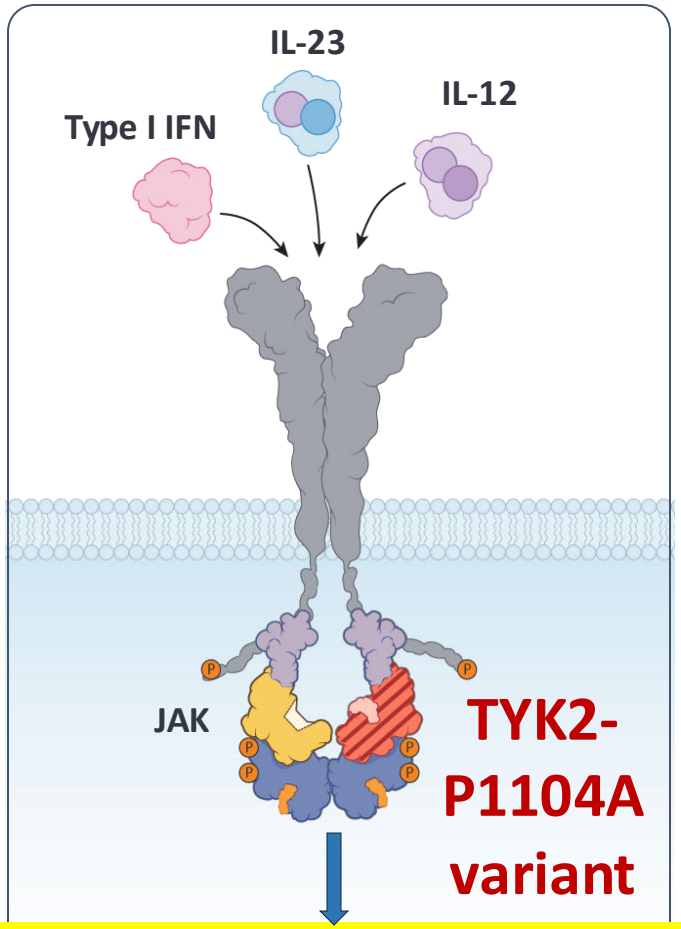
The TYK2 P1104A Variant Provides Nature's Model of Selective Immune Modulation

Individuals carrying heterozygous and homozygous SNPs in P1104A are protected against immune-mediated inflammatory diseases with no observed detrimental effects.





Protection Against Inflammatory Diseases by TYK2-P1104A

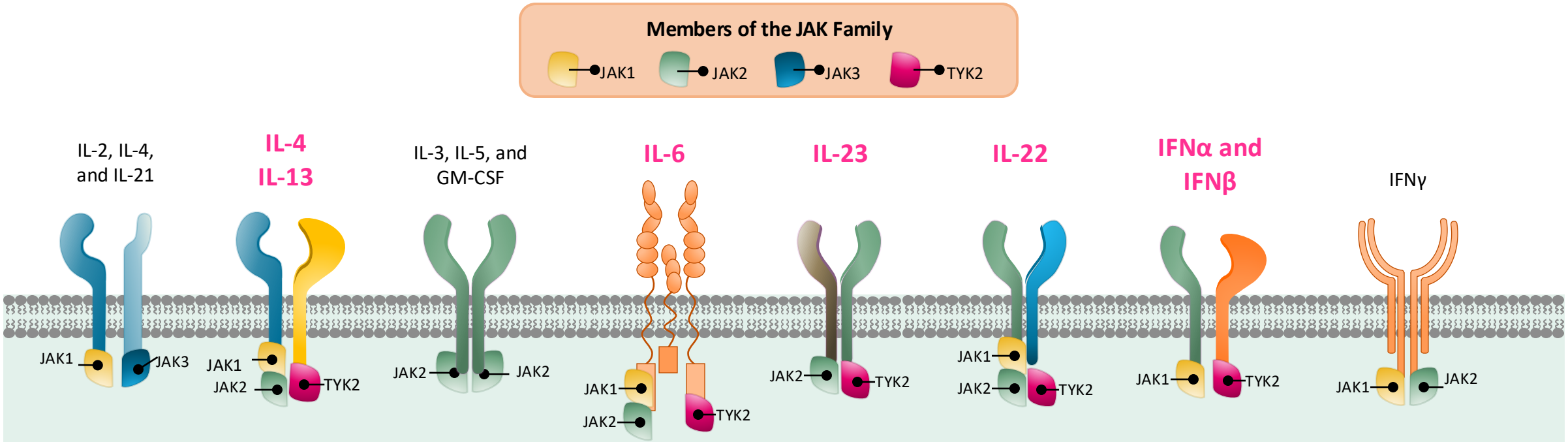


TYK2 signaling reduced by 70-80% by nature's natural variant

IFN, interferon; IL, interleukin; JAK, Janus kinase; OR, odd ratio; pSTAT, phosphorylated signal transducer and activation of transcription; SNP, single nucleotide polymorphism; TYK, tyrosine kinase; T_H, T helper.

Dendrou CA, et al. *Sci Transl Med*. 2016;8(363):363ra149.

Extracellular cytokine signaling is linked to intracellular JAK/STAT signaling



Different combinations of JAKs and TYK2 associate with different cytokine receptors, thereby mediating distinct immunomodulatory and inflammatory signals

*The **JAK-STAT pathway** is implicated in the activation of keratinocytes and immune cells. This may lead to increased cytokine secretion, which in turn **promotes further inflammation** and amplifies the immune response.*[2,7,8]

GM-CSF, granulocyte–macrophage colony-stimulating factor; IL, interleukin; IFN, interferon; JAK, Janus kinase; TYK, tyrosine kinase.
Adapted from Schwartz DM et al. Nat Rev Drug Discov. 2017;16:843–62.

1. Schwartz DM et al. Nat Rev Drug Discov. 2017;16:843–62. 2. Lee GR, et al. *Dermatol Ther* 2019;e12840:1–12; 3. Tanimoto A, et al. *Inflamm Res* 2015;64:41–51; 4. Dubin C, et al. *Ther Clin Risk Manag* 2020;16:1319–1332. Erratum in: *Ther Clin Risk Manag* 2021;17:233; 5. Virtanen AT, et al. *BioDrugs* 2019;33:15–32. 6. Junttila, S Iikka. Frontiers in Immunology 2018(9);1-6, 7. Weidinger S, et al. *Nat Rev Dis Primers* 2018;4:1; 8. Gittler JK, et al. *J Allergy Clin Immunol* 2013;131:300–313.

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Table 1 Jaks and STATs that are activated by cytokines

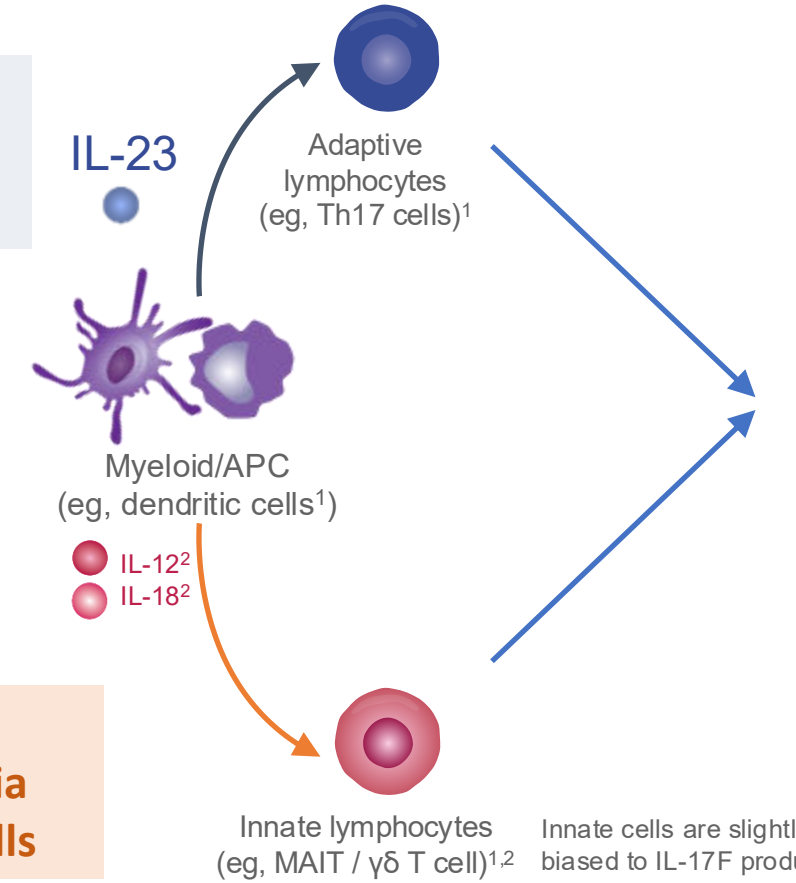
Type I Cytokines	Jaks	STATs
Cytokines whose receptors share γ_c		
IL-2, IL-7, IL-9, IL-15	Jak1, Jak3	Stat5a, Stat5b, Stat3
IL-4	Jak1, Jak3	Stat6
IL-13*	Jak1, Jak2, Tyk2	Stat6
Cytokines whose receptors share β_c		
IL-3, IL-5, GM-CSF	Jak2	Stat5a, Stat5b
Cytokines whose receptors share gp130		
IL-6, IL-11, OSM, CNTF, LIF, CT-1	Jak1, Jak2, Tyk2	Stat3
IL-12+	Jak2, Tyk2	Stat4
Leptin+		Stat3
Cytokines with homodimeric receptors		
Growth hormone	Jak2	Stat5a, Stat5b, Stat3
Prolactin	Jak2	Stat5a, Stat5b
Erythropoietin	Jak2	Stat5a, Stat5b
Thrombopoietin	Jak2	Stat5a, Stat5b
Type II Cytokines		
Interferons		
IFNα, IFNβ	Jak1, Tyk2	Stat1, Stat2
IFNγ	Jak1, Jak2	Stat1
IL-10‡	Jak1, Tyk2	Stat3

*IL-13 does not share γ_c but uses IL-4Rα.
+IL-12 and leptin do not share gp130, but their receptors are related to gp130.
‡IL-10 is not an interferon, but its receptor is a type II cytokine receptor.

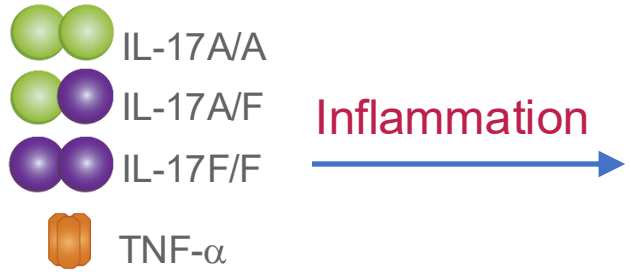
The IL-23/IL-17 Axis: A Central Part of the Pathophysiology of Psoriasis

TYK2 is involved in IL-23 dependent and independent pathways in PsO

IL-23–dependent IL-17A/F production via adaptive immune cells



IL-23–independent IL-17A/F production via innate-like immune cells



IL-17F Has Overlapping Biology With IL-17A and Forms Hetero- and Homodimers Secreted by Adaptive and Innate Immune Cells

Keratinocytes, in turn, produce cytokines and chemokines, driving an inflammatory feedback loop

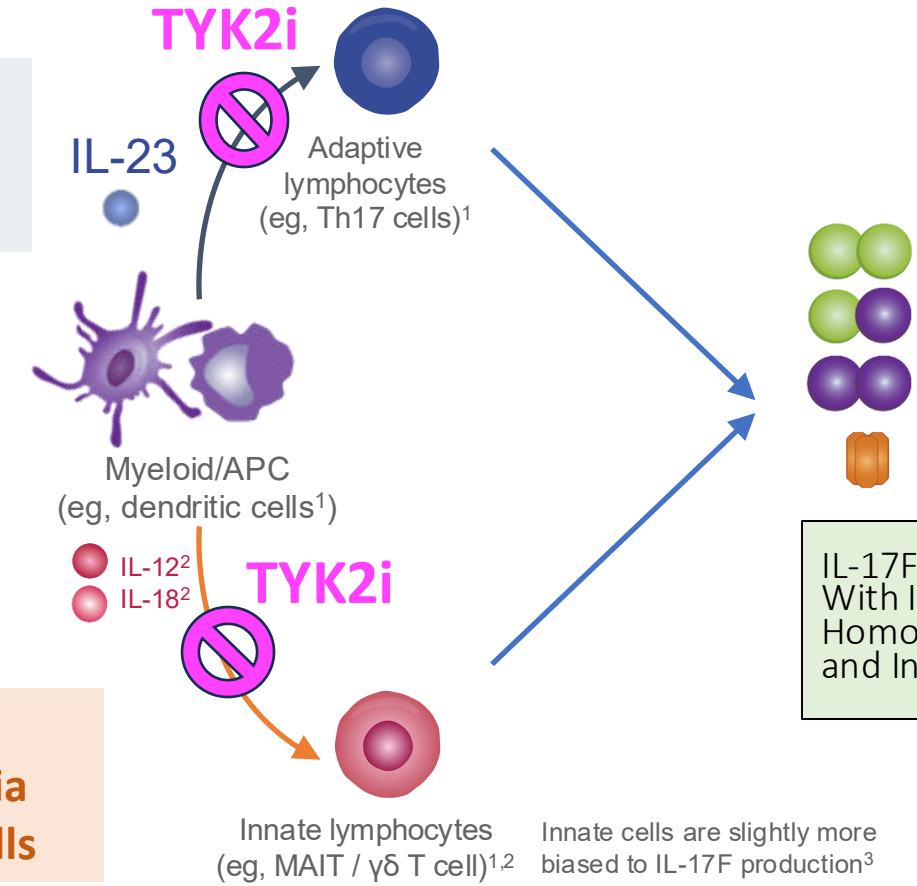
APC, antigen-presenting cell; γδ, gamma delta; IL, interleukin; ILC, innate lymphoid cell; MAIT, mucosal-associated invariant T cell; Th, T helper; TNF, tumor necrosis factor.

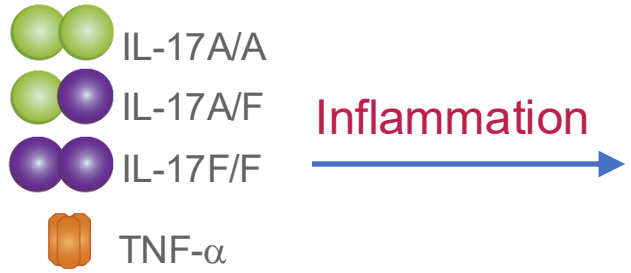
1. Tsukazaki H, Kaito T. *Int J Mol Sci.* 2020;21(17):6401. **2.** Rosine N, Miceli-Richard C. *Front Immunol.* 2021;11:553742. **3.** Cole S, et al. *Front Immunol*. 2020;11:585134. **4.** Blanco P, et al. *Cytokine Growth Factor Rev*. 2008;19(1):41-52. **5.** Lynde CW, et al. *J Am Acad Dermatol*. 2014;71(1):141-150. **6.** Oliver R, et al. *Br J Dermatol*. 2021;10.1111/bjd.20827.

The IL-23/IL-17 Axis: A Central Part of the Pathophysiology of Psoriasis

TYK2 is involved in IL-23 dependent and independent pathways in PsO

IL-23–dependent IL-17A/F production via adaptive immune cells





IL-17F Has Overlapping Biology With IL-17A and Forms Hetero- and Homodimers Secreted by Adaptive and Innate Immune Cells

Keratinocytes, in turn, produce cytokines and chemokines, driving an inflammatory feedback loop

IL-23–independent IL-17A/F production via innate-like immune cells

APC, antigen-presenting cell; γδ, gamma delta; IL, interleukin; ILC, innate lymphoid cell; MAIT, mucosal-associated invariant T cell; Th, T helper; TNF, tumor necrosis factor.

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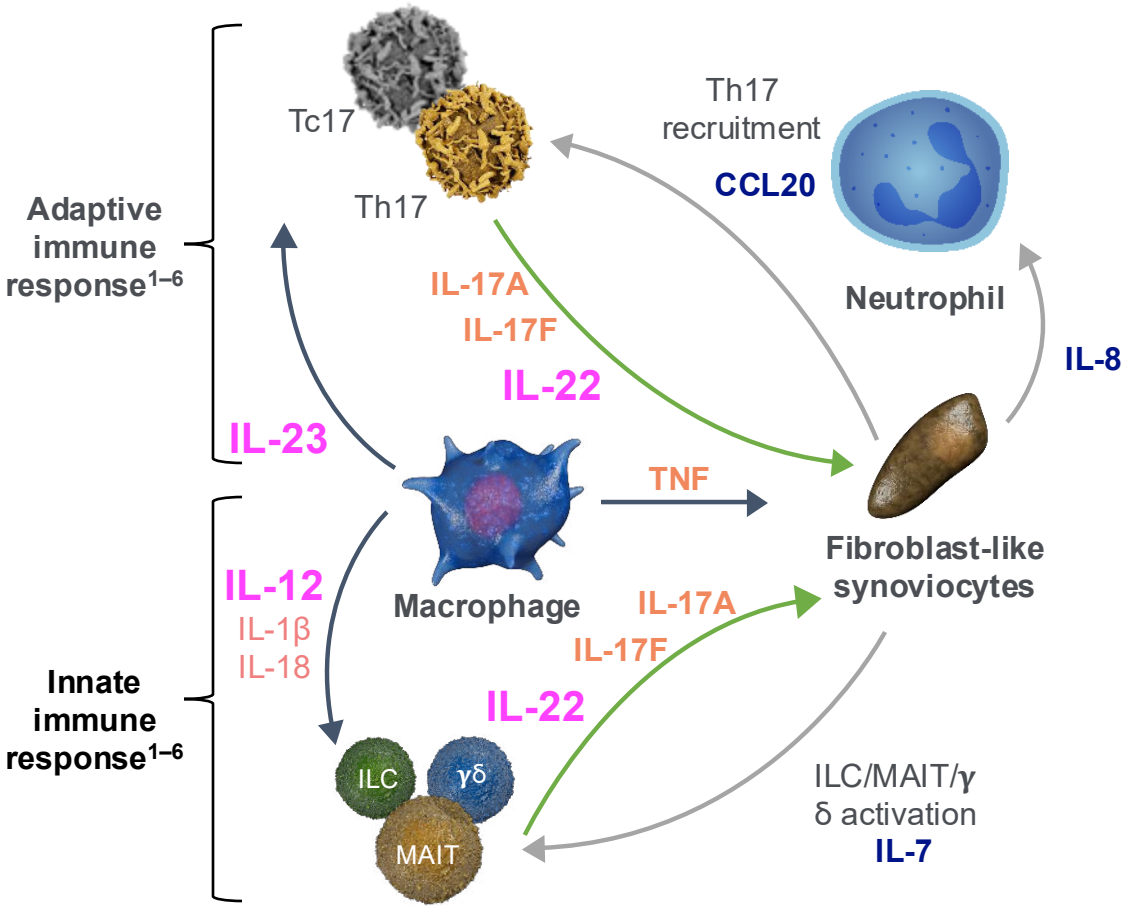
Key Inflammatory Pathways Are Involved In the Pathobiology of Psoriatic Arthritis

TYK2 is involved in adaptive and innate immune pathways in PsA

TYK2-mediated pathways ripe for therapeutic inhibition in PsA



Pathobiology figure adapted from Smith J and Colbert R. *Arthritis Rheumatol*. 2014;66:231–241. *Image reproduced from Soldati E, et al. *PLoS One*. 2021;16(5):e0251788 under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/); †Image used with permission of the author from Nicolaes J, et al. ACR Convergence 2021. Poster 0157. ‡Image reproduced from Laloo F, et al. *Insights Imaging*. 2019;10(1):67 under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/). §Reproduced from Gottlieb A, et al. *PLoS One*. 2015;10:e0134703 under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/)

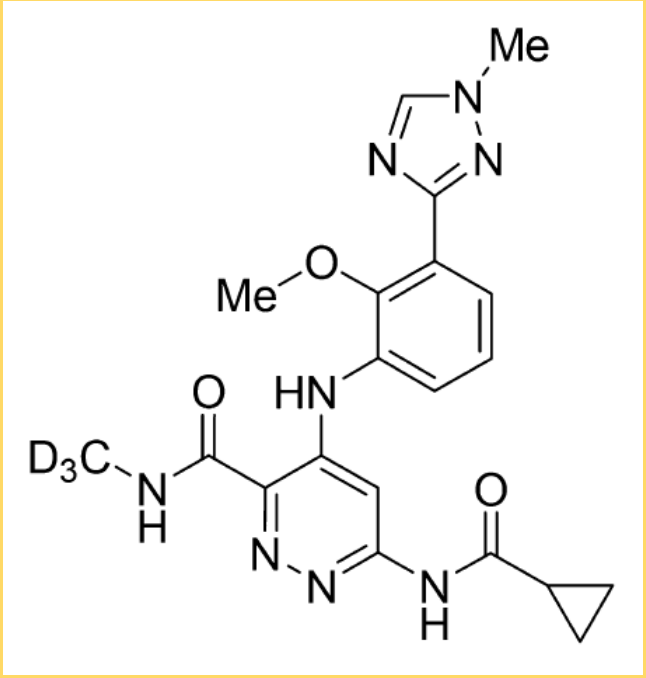
axSpA, axial spondyloarthritis; CCL, C-C motif chemokine ligand; IL, interleukin; ILC, innate lymphoid cell; MAIT, mucosal-associated invariant T cells; PsA, psoriatic arthritis; SI, sacroiliac; Tc, CD8+ T cell; Th, T helper; TNF, tumor necrosis factor

1. Tsukazaki H and Kaito T. Int *J Mol Sci*. 2020;21:6401. 2. Smith JA and Colbert RA. *Arthritis Rheumatol*. 2014;66(2):231–241. 3. Blanco P, et al. *Cytokine Growth Factor Rev*. 2008;19:41–52. 4. Rosine N and Miceli-Richard C. *Front Immunol*. 2021;11:553742. 5. Cole S, et al. *Front Immunol*. 2020;11:585134. 6. Taams L, et al. *Nat Rev Rheum*. 2018;14:453–466. 7. Shah M, et al. *RMD Open*. 2020;6(2):e001306. 8. Fassio A, et al. *Int J Mol Sci*. 2023;24(19):14924. 9. Soldati E, et al. *PLoS One*. 2021;16(5):e0251788. 10. Nicolaes J, et al. ACR Convergence 2021. Poster 0157. 11. Laloo F, et al. *Insights Imaging*. 2019;10(1):67. 12. Gottlieb A, et al. *PLoS One*. 2015;10:e0134703.

Evolution of Allosteric TYK2 Inhibitors

Less TYK2 Selective → **Highly TYK2 Selective**

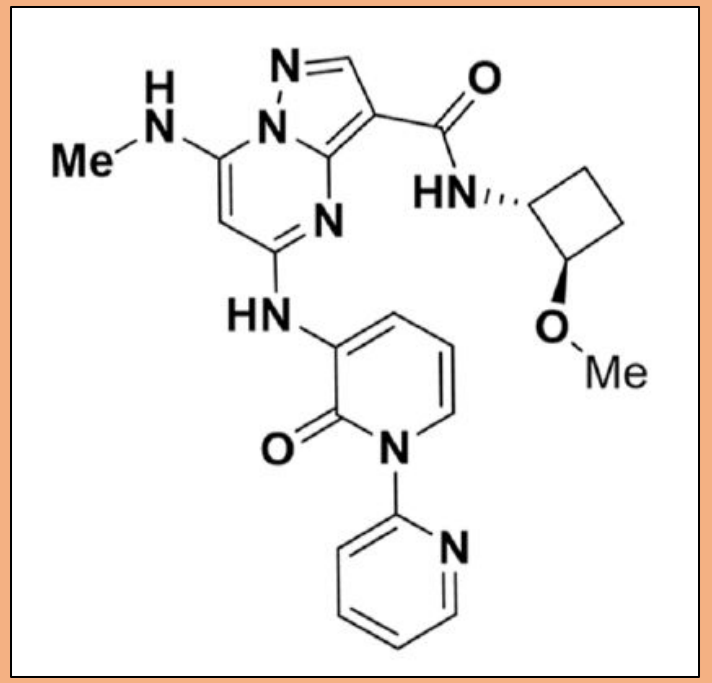
1st Generation



FDA: 2022

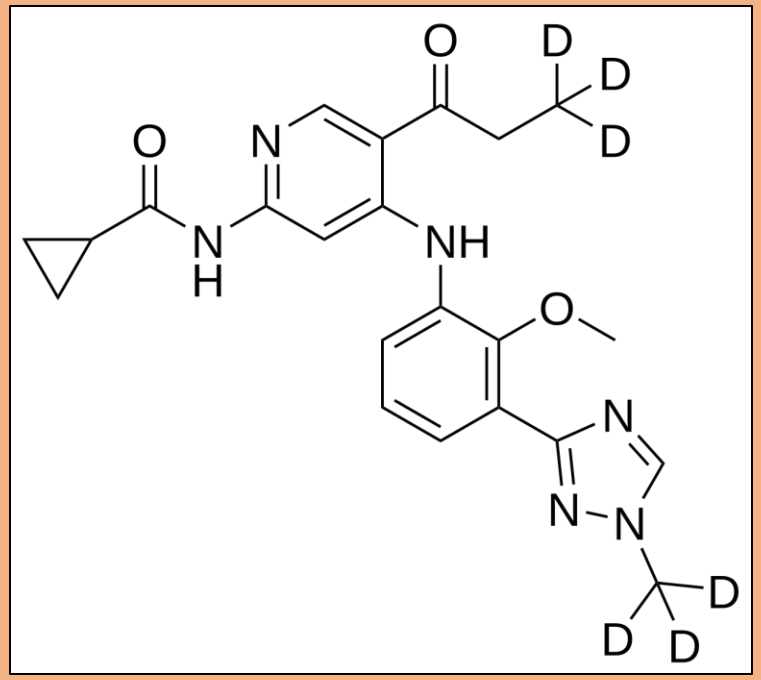
Deucravacitinib

2nd Generation



FDA: TBD

Zasocitinib



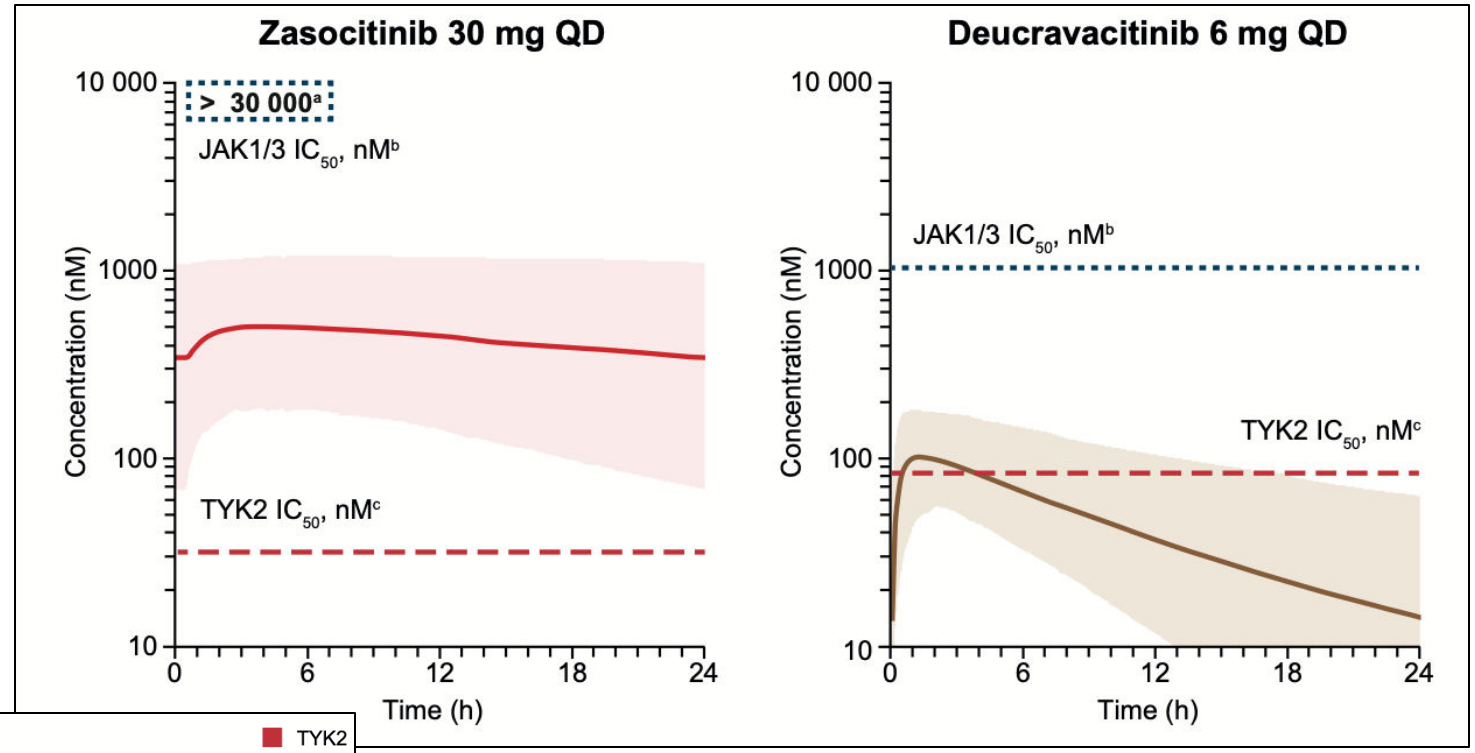
FDA: TBD

Envudeucitinib

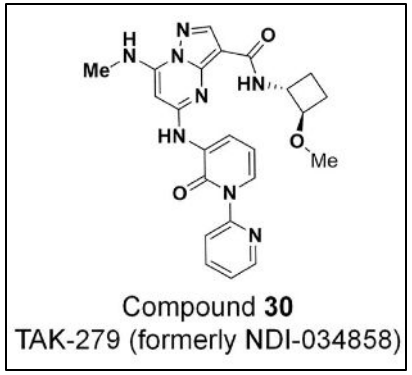
Zasocitinib: next-generation TYK2 Inhibitor

	K_i from HTRF assay	
	Zasocitinib	**Deucravacitinib**
JAK1 JH2 (nM)[a]	> 15 000	1
TYK2 JH2 (pM)[b]	8.7	11.5
Biochemical selectivity (fold)	> 1.7 × 10^6	87

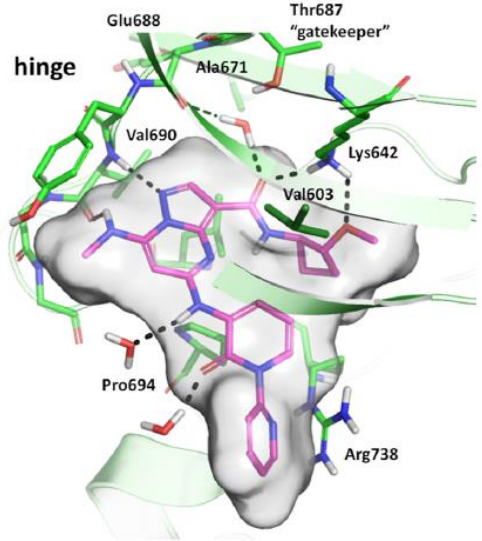
[a]Geometric mean of three samples; z-score ≥ 0.9, JAK1 JH2 (tracer) = 1 nM (K_D), JAK1 JH2 = 300 pM for both inhibitors.
[b]Geometric mean of three samples; z-score ≥ 0.8, TYK2 (tracer) = 225 nM (50 × K_D) for zasocitinib and 4.5 nM (K_D) for deucravacitinib, TYK2 = 200 pM for both inhibitors.



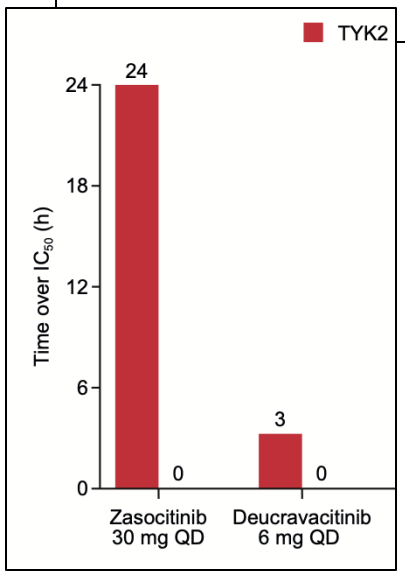
zasocitinib



Compound **30**
TAK-279 (formerly NDI-034858)



Compound **30**, TYK2 JH2 Kd = 0.0038 nM



Shailly Mehrotra,Yasuyo Sano, Petro Halkowycz, Elizabeth Wilson, Chandra Durairaj, Kok-Fai Kong, Guliang Xia, Faith Dunbar, Taylor Spector, Christopher Bunick, Iain B McInnes. Zasocitinib (TAK-279) displays high TYK2 inhibition and no inhibition of JAK1/3 versus licensed inhibitors. Poster presented at the European Society for Dermatological Research (ESDR) Conference 2024; 4–7 September 2024; Lisbon, Portugal.

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Zasocitinib: next-generation TYK2 Inhibitor

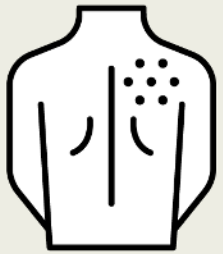
JAMA Dermatology

Phase 2b results

RCT: Tyrosine Kinase 2 Inhibition With Zasocitinib (TAK-279) in Psoriasis

POPULATION

177 Men, 82 Women



Adults with moderate to severe psoriasis for ≥6 mo covering ≥10% of total body surface area

Mean (SD [range]) age, 47 (13 [18-70]) y

INTERVENTION

259 Patients randomized and analyzed

52 Placebo
Matching oral placebo

50 Zasocitinib, 2 mg, daily

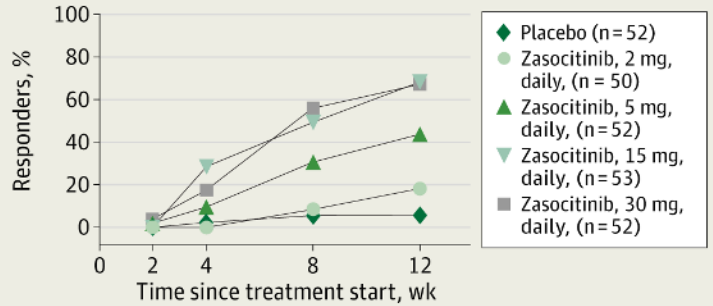
52 Zasocitinib, 5 mg, daily

53 Zasocitinib, 15 mg, daily

52 Zasocitinib, 30 mg, daily

FINDINGS

PASI 75 response rates were statistically significantly greater among patients receiving zasocitinib 5, 15, or 30 mg, daily, than receiving placebo (all $P < .001$)



PASI 75 response rate

Placebo: 6%
Zasocitinib, 2 mg: 18%, difference vs placebo: 12% (95% CI, 0-25; $P = .05$)
Zasocitinib, 5 mg: 44%, difference vs placebo: 39% (95% CI, 24-53; $P < .001$)
Zasocitinib, 15 mg: 68%, difference vs placebo: 62% (95% CI, 48-76; $P < .001$)
Zasocitinib, 30 mg: 67%, difference vs placebo: 62% (95% CI, 47-76; $P < .001$)

SETTINGS / LOCATIONS

55 Sites in North America

PRIMARY OUTCOME

Proportion of patients achieving ≥75% improvement in Psoriasis Area and Severity Index (PASI) score from baseline (PASI 75) to wk 12

Armstrong AW, Gooderham M, Lynde C, et al. Tyrosine kinase 2 inhibition with zasocitinib in psoriasis: a randomized clinical trial. *JAMA Dermatol*. Published online August 21, 2024. doi:10.1001/jamadermatol.2024.2701

JAMA Dermatol. 2024;160(10):1066-1074. doi:10.1001/jamadermatol.2024.2701

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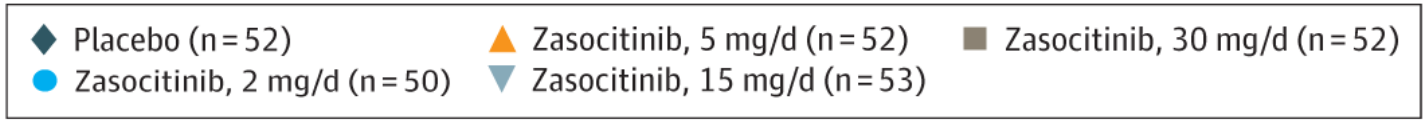
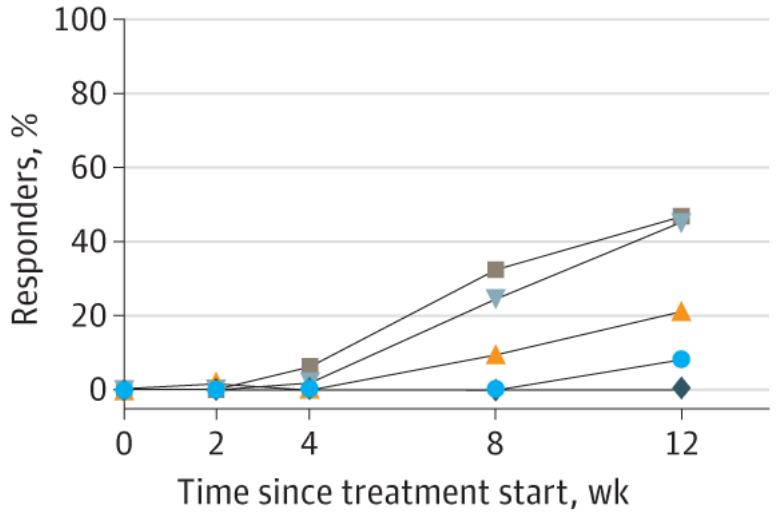
Zasocitinib: next-generation TYK2 Inhibitor

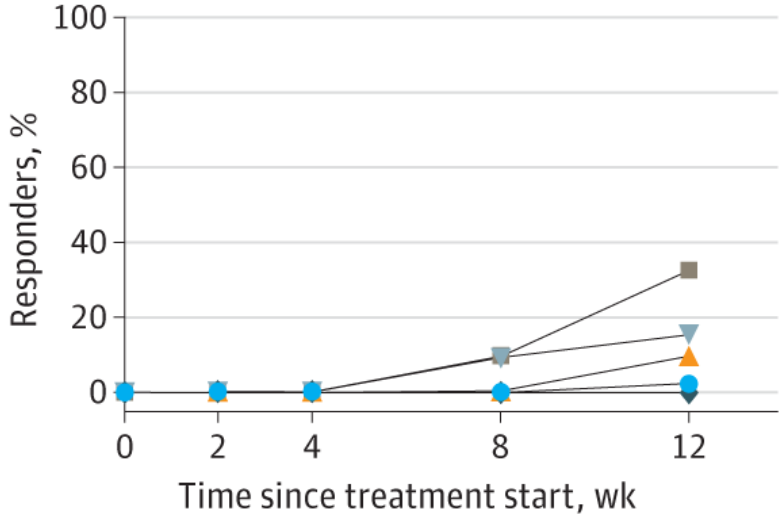


PASI 90



Response rate, No. (%)				
Placebo	0	0	0	0
Zasocitinib				
2 mg	0	0	0	4 (8)
5 mg	1 (2)	0	5 (10)	11 (21)
15 mg	0	1 (2)	13 (25)	24 (45)
30 mg	0	3 (6)	17 (33)	24 (46)

PASI 100

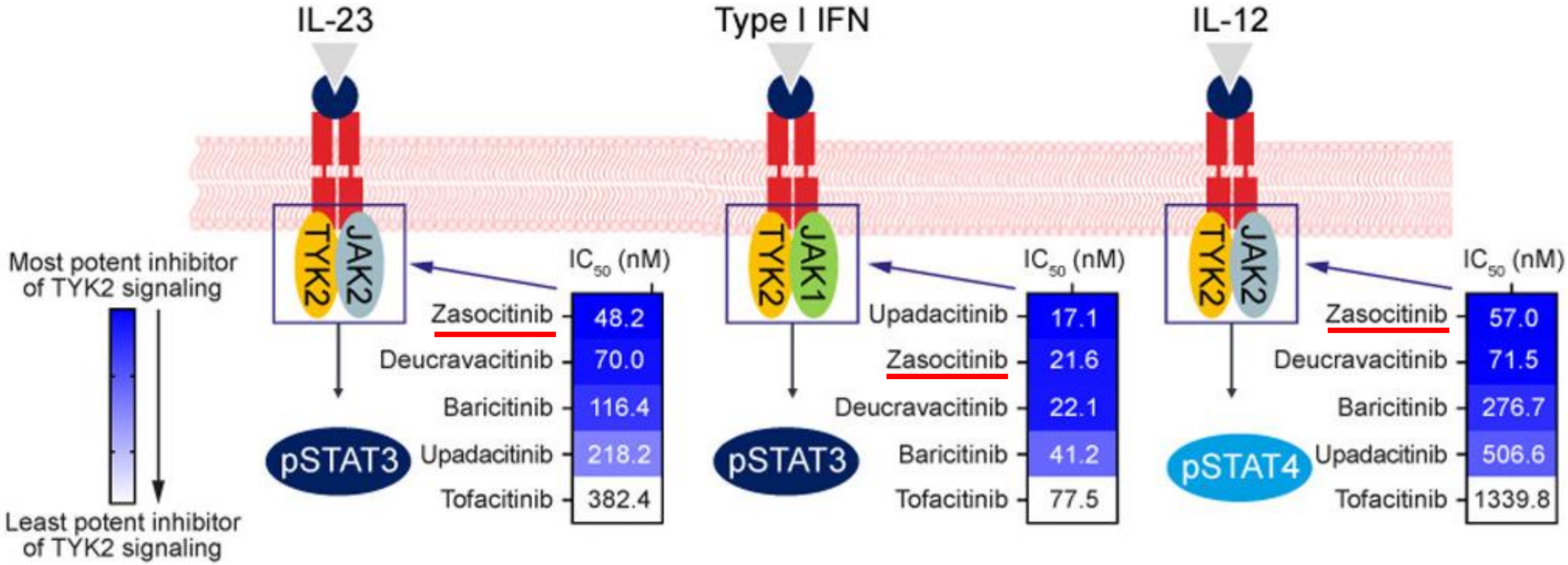


Response rate, No. (%)				
Placebo	0	0	0	0
Zasocitinib				
2 mg	0	0	0	1 (2)
5 mg	0	0	0	5 (10)
15 mg	0	0	5 (9)	8 (15)
30 mg	0	0	5 (10)	17 (33)

Deucra: PASI 100
wk 16 = 14%
wk 52 = 19%

JAMA Dermatol. 2024;160(10):1066-1074. doi:10.1001/jamadermatol.2024.2701

Next-Generation TYK2 Inhibition by Zasocitinib



Mehrotra S, Sano Y, Halkowycz P, Wilson E, Durairaj C, Kong KF, Xia G, Dunbar F, Spector T, Heap GA, Bunick CG, McInnes IB. Pharmacological Characterization of Zasocitinib (TAK-279): An Oral, Highly Selective, and Potent Allosteric TYK2 Inhibitor. J Invest Dermatol. 2025 May 27:S0022-202X(25)00531-7.

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Next-Gen TYK2i vs Icotrokinra: Comparison of Available Clinical Trial Data

TYK2i

Agent	Trial Phase	Study Name	Timepoint	PASI-75	PASI-90	PASI-100	IGA 0/1	Placebo PASI-75	Placebo PASI-90	References
Zasocitinib 15 mg QD	Phase 2b	NCT04999839	Week 12	68%	45%	15%	49%	6%	0%	[1]
Zasocitinib 30 mg QD	Phase 2b	NCT04999839	Week 12	67%	46%	33%	52%	6%	0%	[1]
Zasocitinib 30 mg QD	Phase 3	LATITUDE	Week 16	Seen as early as week 4	>50%	~30%	>50%	N/A	N/A	Takeda press release
Envudeucitinib 40 mg BID	Phase 2	STRIDE	Week 12	64%	Not reported	Not reported	Not reported	0%	Not reported	[2]
Envudeucitinib 40 mg BID	Phase 2 OLE	STRIDE	Week 52	78%	61%	39%	Not reported	N/A	N/A	[3]
Envudeucitinib 40 mg BID	Phase 3	Onward 1/2	Week 16/24	74% (16)	65% (24)	>40% (24)	59% (16)	N/A	N/A	Alumis press release
Icotrokinra 200 mg QD	Phase 3	ICONIC-LEAD	Week 16	Not reported	50%	27%	65%	Not reported	4%	[4]
Icotrokinra 200 mg QD	Phase 3	ICONIC-ADVANCE 1	Week 16	Not reported	62.5%	33.3%	64.8%	Not reported	3.7%	[5]
Icotrokinra 200 mg QD	Phase 3	ICONIC-ADVANCE 2	Week 16	Not reported	60.9%	30.4%	63.0%	Not reported	3.7%	[5]

1. Tyrosine Kinase 2 Inhibition With Zasocitinib (TAK-279) in Psoriasis: A Randomized Clinical Trial. JAMA Dermatology. 2024. Armstrong AW, Gooderham M, Lynde C, et al.
2. Highly Selective, Allosteric Inhibition of TYK2 With Oral ESK-001 in Patients With Moderate-to-Severe Plaque Psoriasis: Results From STRIDE, a 12-Week, Randomized, Double-Blinded, Placebo-Controlled, Dose-Ranging Phase 2 Study. Journal of the American Academy of Dermatology. 2025. Blauvelt A, Arenberger P, Sauder MB, et al.
3. Safety and Efficacy of Envudeucitinib, a Highly Selective, Oral Allosteric TYK2 Inhibitor, in Patients With Moderate-to-Severe Plaque Psoriasis: Results From the 52-Week Open-Label Extension Period of the Phase 2 STRIDE Study. Journal of the American Academy of Dermatology. 2025. Papp KA, Jacobs S, Sofen H, et al.
4. Oral Icotrokinra for Plaque Psoriasis in Adults and Adolescents. The New England Journal of Medicine. 2025. Bissonnette R, Soung J, Hebert AA, et al.
5. Once-Daily Oral Icotrokinra Versus Placebo and Once-Daily Oral Deucravacitinib in Participants With Moderate-to-Severe Plaque Psoriasis (ICONIC-ADVANCE 1 & 2): Two Phase 3, Randomised, Placebo-Controlled and Active-Comparator-Controlled Trials. Lancet. 2025. Gold LS, Armstrong AW, Bissonnette R, et al.

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4-year Safety Summary of Deucravacitinib (as treated population)

1 year 2 years 4 years

AE category	Cumulative through 1 year[1] (POETYK PSO-1 + PSO-2) Deucravacitinib 6 mg QD (N = 1364) Total PY = 969.0		Cumulative through 2 years[1,2,a] (POETYK PSO-1 + PSO-2 + LTE) Deucravacitinib 6 mg QD (N = 1519) Total PY = 2482.0		Cumulative through 4 years[3,4,b] (POETYK PSO-1 + PSO-2 + LTE) Deucravacitinib 6 mg QD (N = 1519) Total PY = 4392.8	
	n	EAIR/100 PY	n	EAIR/100 PY	n	EAIR/100 PY
AEs	995	229.2	1214	154.4	1301	131.7
SAEs	55	5.7	145	6.1	205	5.0
Discontinued treatment due to AEs	43	4.4	69	2.8	97	2.2
Deaths[c]	2	0.2	10[c]	0.4	11[d]	0.3
Most common AEs (EAIR/100 PY ≥5)						
Nasopharyngitis	229	26.1	271	12.9	343	9.7
COVID-19[e]	5	0.5	124	5.1	321	8.3
Upper respiratory tract infection	124	13.4	150	6.5	240	6.1
Headache	80	8.5	99	4.2	117	2.8
Arthralgia	55	5.7	85	3.5	117	2.8
Diarrhea	69	7.3	84	3.5	99	2.4

1. Warren RB et al. Poster presentation at the EADV Spring Symposium 2022; May 12-14, 2022; Ljubljana, Slovenia. Poster P465. 2. Armstrong AW et al. Poster presentation at WCDC-Hawaii 2024; January 12-17, 2024; Honolulu, HI. 3. Data on file. BMS-REF-DEU-0127. Princeton, NJ: Bristol-Myers Squibb Company; 2024. 4. Armstrong AW et al. Oral presentation at the EADV Spring Symposium 2024; May 16-18, 2024; St. Julian's, Malta.

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4-year Safety Summary of Deucravacitinib (AESI)

	1 year		2 years		4 years	
	Cumulative through 1 year[1,2] (POETYK PSO-1 + PSO-2) Deucravacitinib 6 mg QD (N = 1364) Total PY = 969.0		Cumulative through 2 years[1,3,a] (POETYK PSO-1 + PSO-2 + LTE) Deucravacitinib 6 mg QD (N = 1519) Total PY = 2482.0		Cumulative through 4 years[4,5,b] (POETYK PSO-1 + PSO-2 + LTE) Deucravacitinib 6 mg QD (N = 1519) Total PY = 4392.8	
AE category	n	EAIR/100 PY	n	EAIR/100 PY	n	EAIR/100 PY
Serious infections	17	1.7	64	2.6	85	2.0
Serious COVID-19 infection	2	0.2	30	1.2	38	0.9
Serious COVID-19 pneumonia	0	0.0	13	0.5	16	0.4
Herpes zoster infection[c]	9	0.9	18	0.7	25	0.6
MACE[d]	3	0.3	9	0.4	14	0.3
VTE[e]	2	0.2	3	0.1	3	0.1
Total malignancies	10	1.0	22	0.9	39	0.9
NMSC[f]	7	0.7	11	0.4	18	0.4
Malignancies excluding NMSC	3	0.3	12	0.5	22[g]	0.5
Lymphoma	1	0.1	3	0.1	3	0.1
Acne[h]	30	3.1	38	1.6	45	1.0
Folliculitis	27	2.8	32	1.3	35	0.8
Mouth ulcers[i]	27	2.8	34	1.4	40	0.9

1. Warren RB et al. Poster presentation at the EADV Spring Symposium 2022; May 12-14, 2022; Ljubljana, Slovenia. Poster P465. 2. Armstrong AW et al. Poster presentation at WCDC-Hawaii 2024; January 12-17, 2024; Honolulu, HI. 3. Data on file. BMS-REF-DEU-0127. Princeton, NJ: Bristol-Myers Squibb Company; 2024. 4. Armstrong AW et al. Oral presentation at the EADV Spring Symposium 2024; May 16-18, 2024; St. Julian's, Malta.

Courtesy Bristol Myers Squibb

TYK2: New & Emerging

Thank you!

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