Psoriasis: Can The Old Dog Benefit From New Tricks?

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Psoriasis History

- 1800s: coal tar, salicylic acid & UV therapy
- 1920s – 1950s: Goeckerman therapy (coal tar + UVB), Ingram regimen (anthralin/dithranol + UV), Hospital-based day treatments
- 1950s – 1970s: Topical corticosteroids
- 1970s – 1990s: Methotrexate, cyclosporine, systemic retinoids, PUVA photochemotherapy, calcipotriene, tazarotene
- 2000s & beyond: injectable monoclonal antibodies (biologics), advanced targeted oral & topical therapies

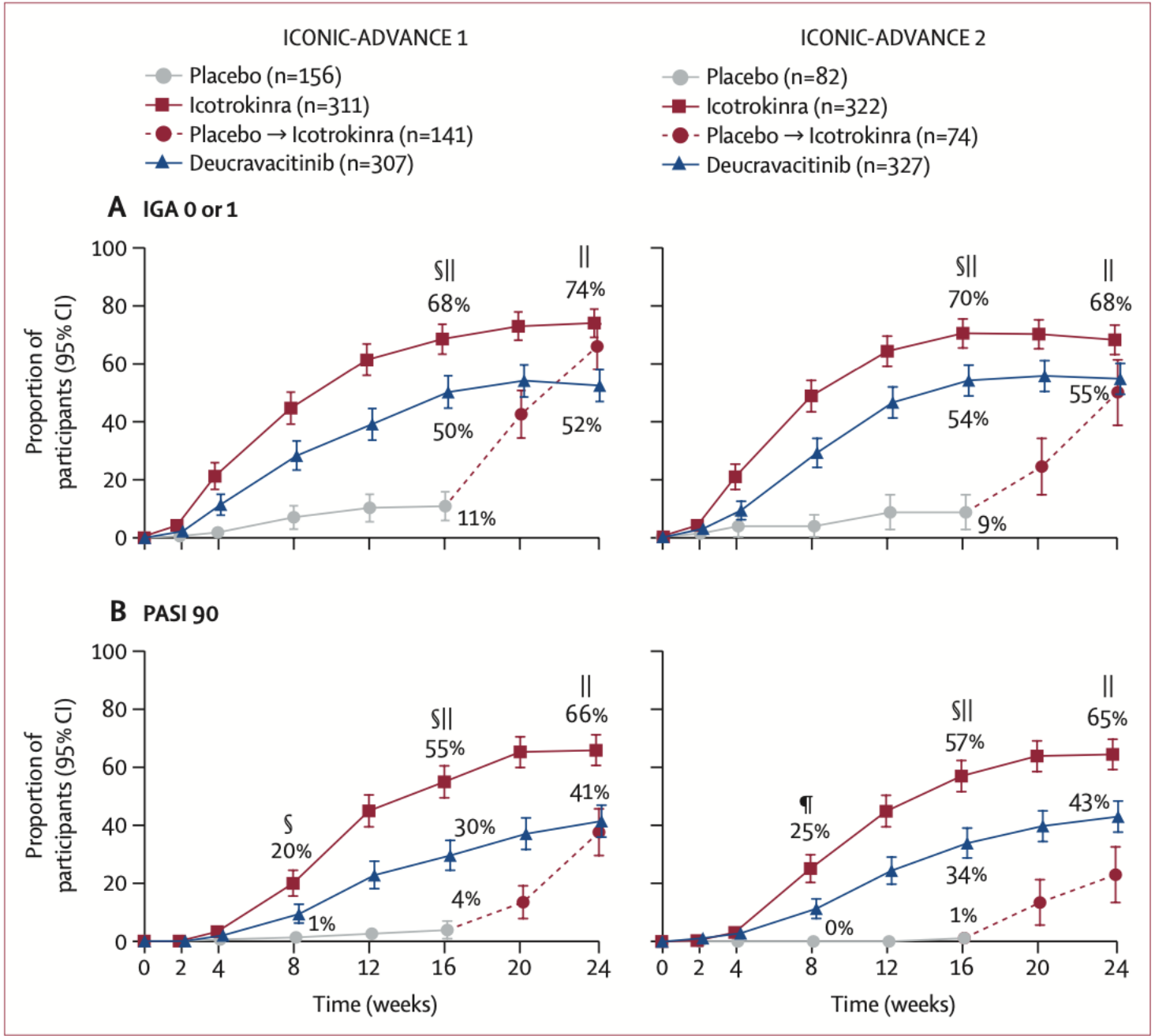
So Do We Still Need Innovation?

- Therapies have become more effective, tolerable, safe & convenient
- Yet, patients do not get clear or almost clear 100% of the time in any clinical trial so there's always room to improve
- Unmet needs:
    1. Medications with long-term clearance after initial dosing e.g. keeps you clear for a year
    2. Oral agent with efficacy that reaches the most effective biologics e.g. bimekizumab in a pill

New Kid On The Block

- Icotrokinra (oral IL-23R antagonist) currently in phase III trials
- Dosed 200mg once daily in 12+
- Peptide optimized for oral absorption
- PASI 75 of ~15% at week 4 up to ~69% at week 16 up to 81% at week 24
- PASI 90 of ~50% at week 16 up to 65% at week 24
- Data suggest safety profile mimics injectable drugs in this class

Icotrokinra



Icotrokinra

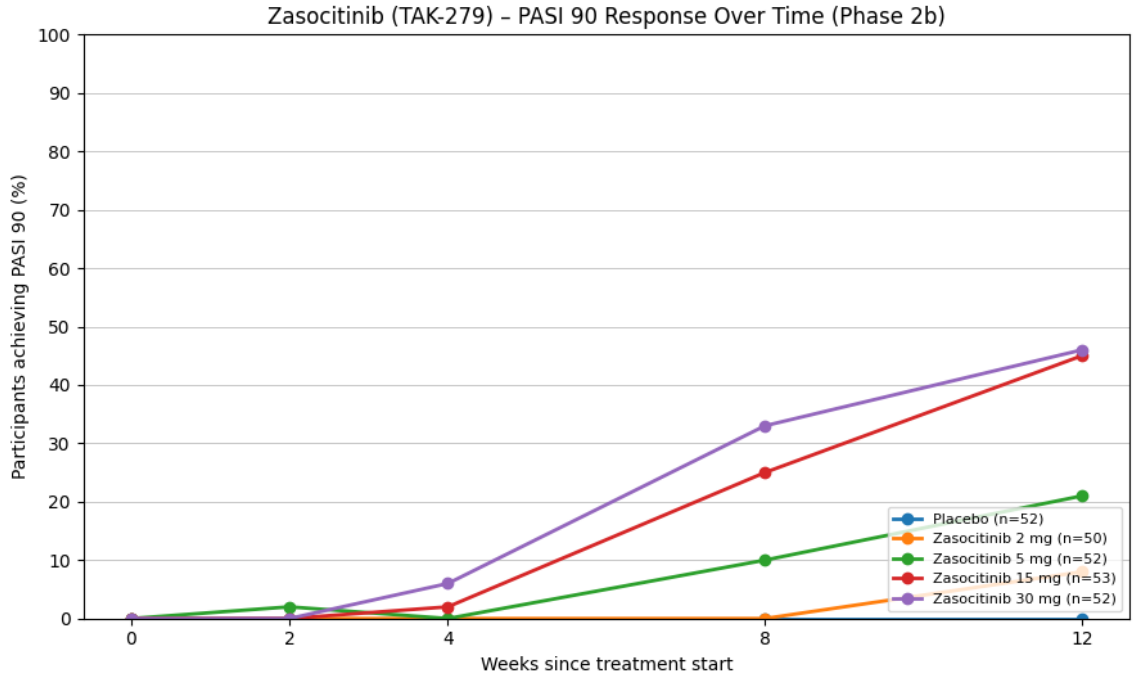
	Placebo-controlled (weeks 0–16)			Active-comparator controlled (weeks 0–24)		Crossover (weeks 16–24)
	Icotrokinra	Placebo	Deucravacitinib	Icotrokinra	Deucravacitinib	Placebo→icotrokinra
Number of participants	632	237	634	632	634	215
Mean weeks of follow-up (SD)	15·9 (1·88)	15·5 (2·69)	15·8 (2·25)	23·5 (3·26)	23·3 (3·94)	8·1 (0·58)
≥1 adverse event	303 (48%)	136 (57%)	360 (57%)	359 (57%)	411 (65%)	60 (28%)
Adverse events occurring in ≥5% of participants†						
Headache	26 (4%)	11 (5%)	19 (3%)	28 (4%)	20 (3%)	3 (1%)
Nasopharyngitis	37 (6%)	13 (5%)	58 (9%)	56 (9%)	77 (12%)	8 (4%)
Upper respiratory tract infection	23 (4%)	8 (3%)	33 (5%)	32 (5%)	49 (8%)	7 (3%)
Serious adverse event	14 (2%)	4 (2%)	14 (2%)	18 (3%)	20 (3%)	3 (1%)
Serious infection‡	1 (<1%)	1 (<1%)	4 (1%)	3 (<1%)	4 (1%)	0
Adverse event resulting in discontinuation	13 (2%)	12 (5%)	14 (2%)	15 (2%)	17 (3%)	0
Gastrointestinal adverse event	45 (7%)	15 (6%)	63 (10%)	55 (9%)	80 (13%)	5 (2%)
Malignancy§	3 (<1%)	1 (<1%)	1 (<1%)	3 (<1%)	2 (<1%)	0
Active tuberculosis	0	0	0	0	0	0

Values are n (%) unless otherwise noted. *The safety analysis set included all randomly assigned and treated participants. †In any treatment group. ‡Serious infections included bacterial arthritis (placebo group), campylobacter colitis (deucravacitinib group), viral infection (deucravacitinib group), infection exacerbated by chronic obstructive airways disease (icotrokinra group), lower respiratory tract infection (deucravacitinib group), viral upper respiratory tract infection (deucravacitinib group), and pneumonia (icotrokinra group). §Details on malignancies reported through week 24 of both studies are provided in the appendix (pp 2–3).

Table 2: **Combined adverse events from the ICONIC-ADVANCE 1 and ICONIC-ADVANCE 2 safety analysis sets***

Zasocitinib

- Highly selective TYK2 inhibitor
- Binds the JH2 pseudokinase domain locking the kinase in inactive conformation
- Inhibits IL-23/Th17 signaling & also mitigates type I interferon & IL-12
- The 30 mg qd in phase III: PASI90 over 50% and PASI100 at 30% at 16 weeks



Psoriasis Therapy Beyond Biologics

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ABSTRACT

Although psoriasis patients have benefited from the advent of biologic treatments over the past two decades, these medications are not appropriate for all patients and can be augmented by additional therapy. Differences among the manifold options can be difficult to parse, though essential for matching treatment with an individual patient. UV-light therapies, including both UV-B and psoralen with UV-A light, continue to play an important role in treatment, as do non-biologic systemic options including methotrexate, cyclosporine, apremilast, and acitretin. Recent years have seen a dramatic expansion in available topical therapies, the most common modality for the treatment of psoriasis, including new foam, spray, lotion, and cream formulations of topical corticosteroids (TCS) and new fixed-dose combination offerings of TCS with tazarotene and calcipotriene. Newer advances, including the oral tyrosine kinase 2 inhibitor deucravacitinib and non-steroidal topicals such as roflumilast, a PDE-4 inhibitor, and tapinarof, a first-in-class non-steroidal small-molecule, will soon provide even more options for treatment. It is vital for clinicians to remain aware of this ever-expanding armamentarium, allowing for more productive shared decision-making with patients, improved satisfaction, and better disease control.

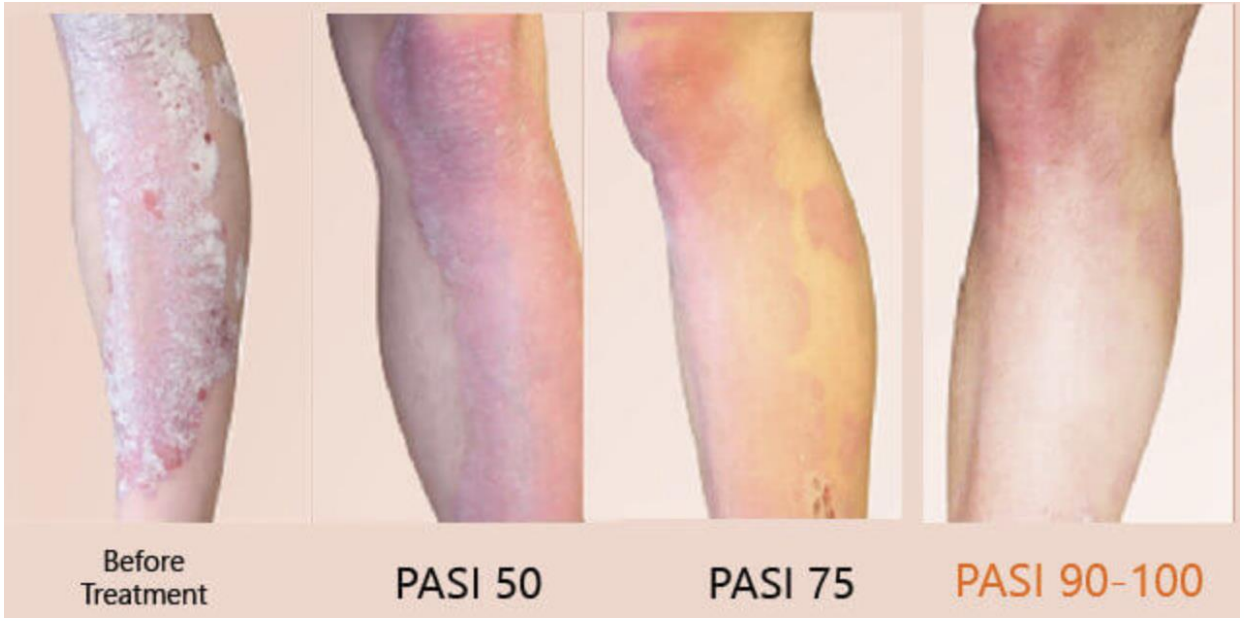
Of note Apremilast is only systemic approved for mild disease

Table 1. Non-biologic systemic therapies for plaque psoriasis

Medication	Treatment success rates*	Advantages
Methotrexate	45.2% at week 12 or 16[3]	Highly effective therapy at low cost
Acitretin	47% at week 12[46]	No immune suppression
Cyclosporine	50-97% at week 10-16[47]	Excellent bridge to alternative therapy for control of severe disease
Apremilast	30-40% at week 16[11-13]	No monitoring needed
Deucravacitinib†	50.3%-53.6% at week 16[16]	Oral dosing with efficacy approaching injectable biologics

*Based on reported PASI75 over multiple studies
†Phase III trials ongoing, application for regulatory approval pending

Primary Endpoint – Week 16



Early Safety – Week 16

- RKZ with serious TEAE of 2.4% (lower than placebo 4%)
- Serious infection of 0.4% (similar to placebo 0.3%)
- Candida of 0.2% (placebo 0%)
- BKZ with serious TEAE of 1.6% (lower than placebo 2.4%)
- Serious infection of 0.3% (placebo 0%)
- Candida of 9.1% (placebo 0%)

Early Safety – Week 16

- Apremilast with nausea/diarrhea of 17% (placebo 6%)
- URI of 9% (placebo 6%)
- Depression of 1% (placebo 0%)
- Folliculitis 1% (placebo 0%)
- Deucravacitinib with nausea/diarrhea of 1.7-4.4%
- URI of 19.2% (placebo 14.8%)
- Folliculitis of 1.7% (placebo 0%)
- HSV of 2% (placebo 0.2%)

Safety profile through Week 16 (≥5%)[2]

AES OCCURRING IN ≥5% OF PATIENTS IN ANY ACTIVE TREATMENT GROUP WEEKS 0-16 FROM POOLED CLINICAL TRIALS (PSO-1 AND PSO-2)[2]

AE category, %	SOTYKTU (n=842)*	Apremilast (n=422)	Placebo (n=419)
Nasopharyngitis	9.0%	8.8%	8.6%
Upper respiratory tract infection	5.5%	4.0%	4.1%
Headache	4.5%	10.7%	4.5%
Diarrhea	4.4%	11.8%	6.0%
Nausea	1.7%	10.0%	1.7%

Monitoring In The "Old Days"

- Biologics: TNF inhibitors, IL-12/23, IL-17, IL-23
- CBC, CMP, TB, hepatitis, HIV at baseline; CBC/CMP q3m & TB yearly
- This resulted from the study/label of etanercept as the original biologic & has carried forward with numerous newer/safer agents despite lack of evidence

What's The Big Deal?

- Routine lab monitoring expense in the USA is up to 4.9 billion dollars annually (though precise numbers are not available and are variable)
- Beyond cost, the risks of false positive & non-relevant abnormalities are very real; the downside may include:

Scaring the patient unnecessarily & causing health anxiety

Having to stop an effective medication (sometimes permanently)

Additional follow-up tests that could lead down the road to more morbidity e.g. leukopenia leading to bone marrow biopsy and chemotherapy (& perhaps due to a benign viral phenomenon)

Monitoring in 2025 & Beyond

CHIEF MEDICAL EDITOR MESSAGE

What Routine Lab Monitoring Is Needed for Biologics?

Steve R. Feldman, MD, PhD

December 2016

- Summary: "there isn't strong evidence to say you should do regular lab monitoring for patients on biologics. There is also not strong evidence to say that you shouldn't"
- Therefore we can tailor our monitoring based on patient characteristics including health, lifestyle & personality

Monitoring in 2025 & Beyond

Br J Dermatol. 2011 Aug;165(2):375-82. doi: 10.1111/j.1365-2133.2011.10329.x.

Relevance of laboratory investigations in monitoring patients with psoriasis on etanercept or adalimumab

P P M van Lümig [1], R J B Driessen, M A M A Roelofs-Thijssen, J B M Boezeman, P C M van de Kerkhof, E M G J de Jong

Abstract

Background: Guidelines concerning biological treatment of patients with psoriasis recommend different pretreatment and monitoring laboratory panels in variable frequencies to monitor treatment.

Objectives: To investigate the relevance of laboratory investigations in monitoring patients with psoriasis on etanercept or adalimumab.

Methods: A prospective cohort study over 5 years was conducted in all consecutive patients with psoriasis on etanercept or adalimumab. All laboratory investigations performed for monitoring treatment were analysed. Laboratory abnormalities were graded according to the Common Terminology Criteria for Adverse Events v4.03. The primary endpoint was the percentage of patients with a grade 3 or grade 4 laboratory abnormality. The secondary endpoints were defined as: (i) significant changes in laboratory parameters during etanercept or adalimumab treatment and (ii) the percentage of patients having a laboratory abnormality requiring discontinuation of etanercept or adalimumab treatment.

Results: Laboratory parameters were available for 162 patients treated with etanercept and/or adalimumab. The number of treatment episodes was 155 for etanercept and 58 for adalimumab. Follow-up was 316 patient-years for etanercept and 54 patient-years for adalimumab. Thirty-eight of 146 patients treated with etanercept (26%) had one or more grade 3 and/or grade 4 laboratory abnormalities. For adalimumab, this was eight of 58 (14%). These were predominantly considered unrelated to biologic therapy. For both biologics, significant changes were observed in mean laboratory parameters during treatment compared with pretreatment as well as significant trends. However, mean values during treatment remained within normal ranges. Laboratory abnormalities did not lead to permanent discontinuation of biologic treatment in any patient.

Conclusions: In this cohort, the incidence of biologic therapy-related serious laboratory abnormalities was low. Our findings do not support a need for routine laboratory testing in patients with psoriasis on etanercept or adalimumab beyond the laboratory testing required for concomitant therapies or comorbidities.

Monitoring in 2025 & Beyond

Letter from the Editor: Cost-effectiveness of tuberculosis screening in patients already on biologic therapy

Dirk M. Elston, MD

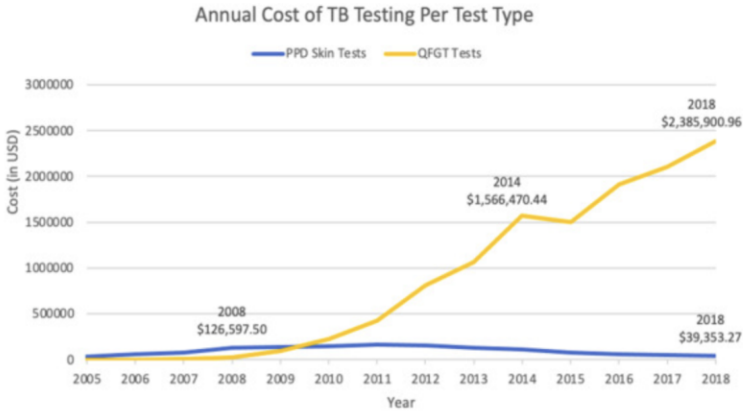
- Summary:
- Given the risk of false positives and false negatives, lab testing can never replace clinical evaluation of signs and symptoms
- The literature suggests a higher TB risk with TNFi and a low risk of other targeted biologics
- Decisions regarding repeat screening should be individualized

Monitoring in 2025 & Beyond

BRIEF REPORT · Volume 92, Issue 3, P556-557, March 2025

Annual tuberculosis screening in patients on biologics has questionable value

Madison N. Kist, BS [a] · Ryan Svoboda, MD, MS [b] · Steven Maczuga, MS [c] · Li Wang, PhD [d] · Galen T. Foulke, MD [c,d] · Matthew F. Helm, MD [c] ✉



- Even when TNF agents are used, routine screening in the absence of risk factors may result in unnecessary risk of chemoprophylaxis-induced hepatitis, increased costs, and a delay in early TNFi
- Serial testing with quant gold, particularly among low-risk populations without any new exposures, is unreliable with frequent reversions and conversions
- In a study, 15 of 50 patients with negative baseline developed conversion during biologic treatment(typically transient)
- Of the 10 who were positive at the rescreening, 5 received isoniazid preventive therapy: an equal number of patients reverted to negative with or without treatment and none of the patients developed active TB during follow-up (6.9 ± 1.0 years)

Monitoring in 2025 & Beyond

- Biologics: TNF inhibitors, IL-12/23, IL-17, IL-23

- CBC, CMP, TB, hepatitis, HIV at baseline
- TNFi: CBC/CMP q3m & TB yearly
- All others: Yearly TB ROS

- Even amongst the TNFi class, clinically significant lab abnormalities are rare & even more so in the others
- I prescribed psoriasis biologics to ~500 patients in 2024 with 0 serious adverse events

Final Thoughts

- These new advanced systemic oral medications are superior to apremilast and deucravacitinib
- Some patients will want to start with an oral option
- Icotrokinra appears poised to be most effective, tolerable, and safe oral therapy in the near future (adoption TBD based on the label)
- The most effective biologic agents still have much higher peak efficacy than these new MOAs

Final Thoughts Continued

- SAEs (MACE, malignancy, infection, SIB, liver injury) are fairly equivalent between the most commonly used drugs despite differing warnings in the package inserts

- We must continue to let data drive our monitoring with newer MOAs, not legacy

- We are clearly in a golden age of the management of psoriatic disease

Thank you