

PSORIASIS

PEER-TO-PEER EDUCATIONAL TOOLKIT

A compilation of key content from select presentations at the 2021 South Beach Symposium Part I: Medical Dermatology Summit and the Masters of Pediatric Dermatology

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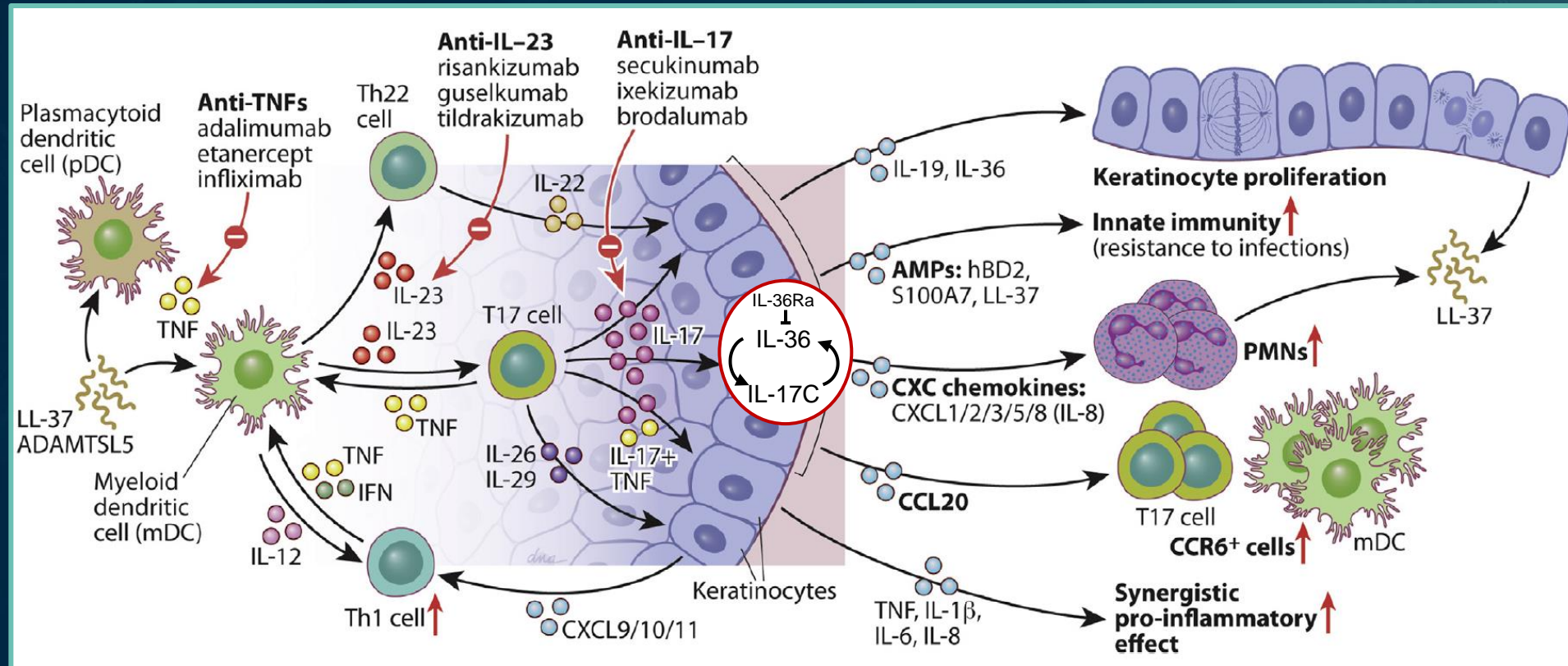
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Psoriasis Pathogenesis

IL-23/T17-mediated effects on immune cell populations and keratinocyte biology in psoriatic skin

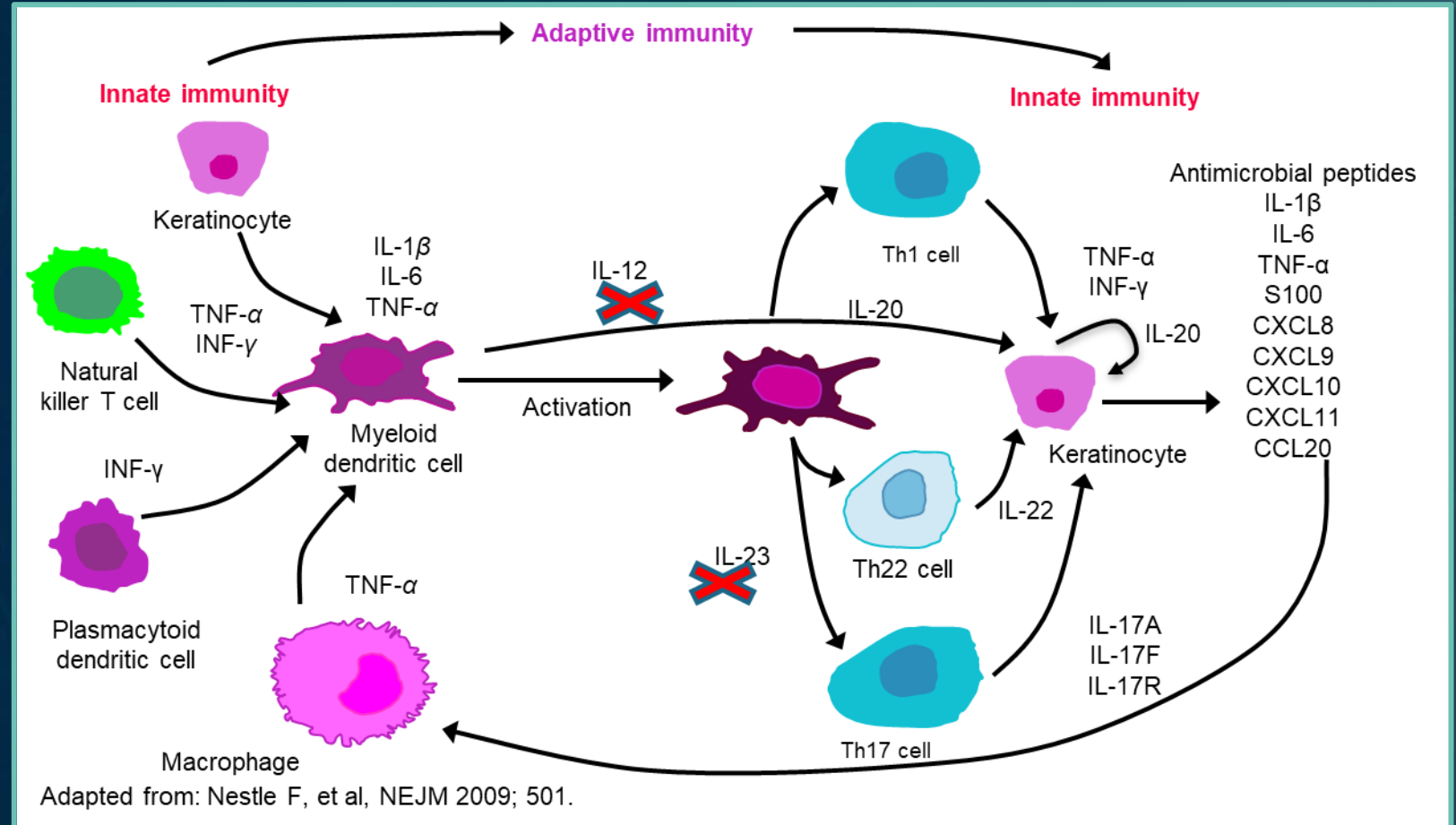


IL-36Ra = *IL36RN* (gene)

IL-12/IL-23 Inhibitors

- **Ustekinumab**

- Approved by FDA for treatment of psoriasis in 2009
- Most recently approved by FDA for pediatric psoriasis in 2020



Dr. Mark Lebwohl

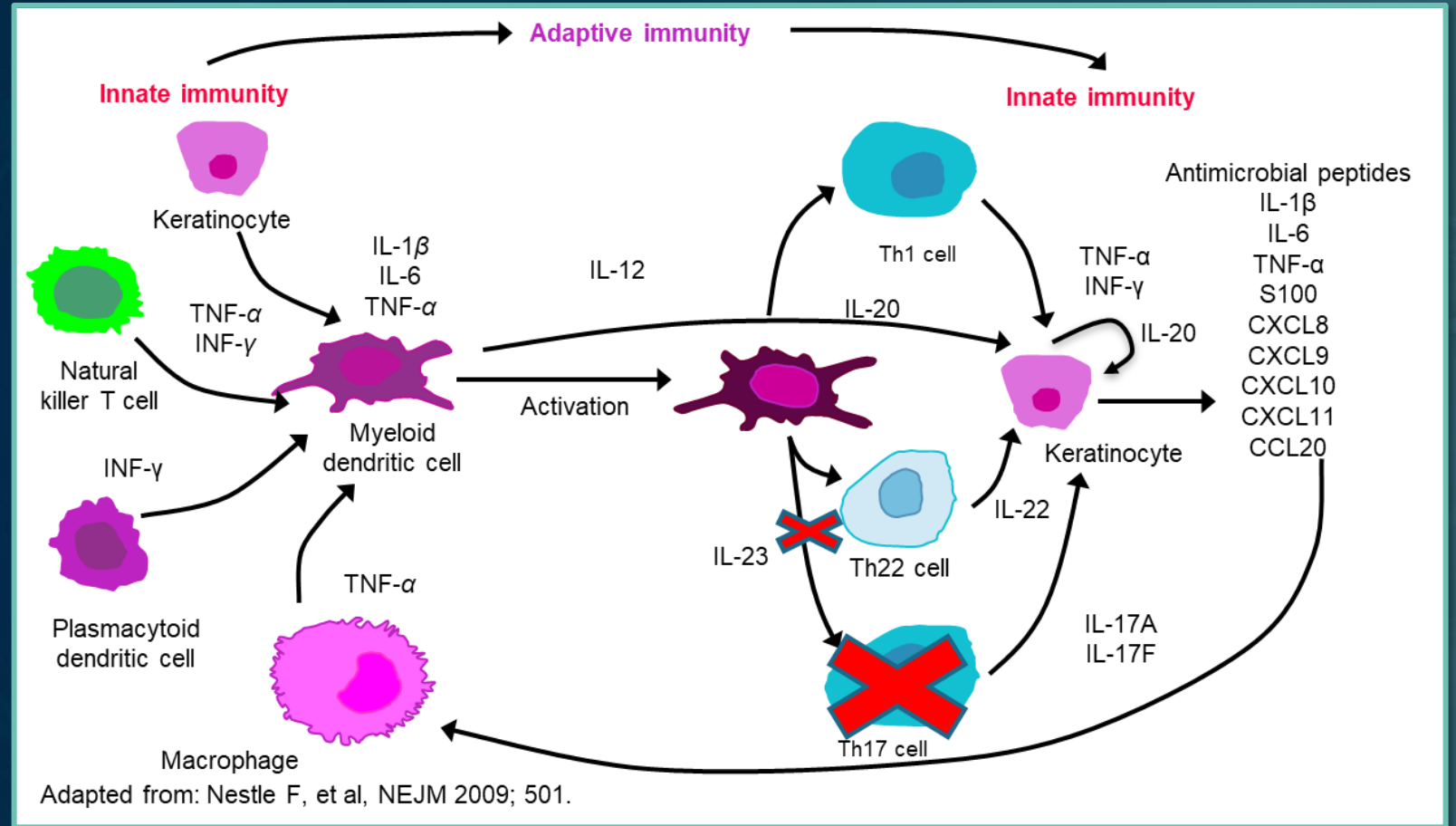
IL-23 Inhibitors

- **Guselkumab**

- Approved by FDA for treatment of plaque psoriasis in 2017
- Currently in phase 3 trials for pediatric patients aged 6 years and older

- **Tildrakizumab**

- Approved by FDA for treatment of plaque psoriasis in 2018
- Currently in phase 2/3 trials for pediatric patients aged 12 years and older



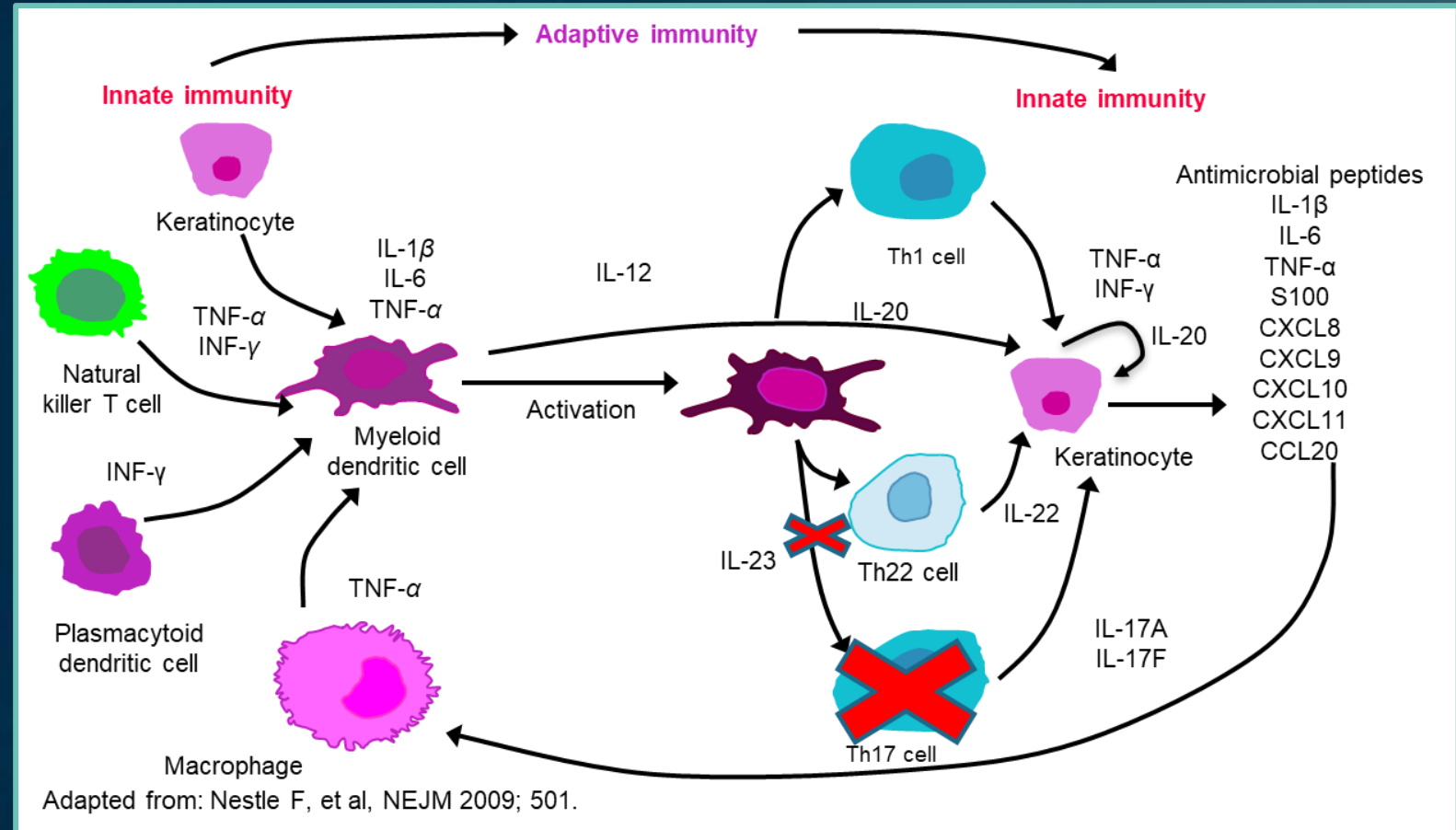
IL-23 Inhibitors

- **Risankizumab**

- Approved by FDA for treatment of plaque psoriasis in 2019
- Currently in phase 3 trials for pediatric patients aged 6 years and older

- **Mirikizumab**

- Recently completed phase 3 studies in adult patients with moderate-to-severe plaque psoriasis with favorable results



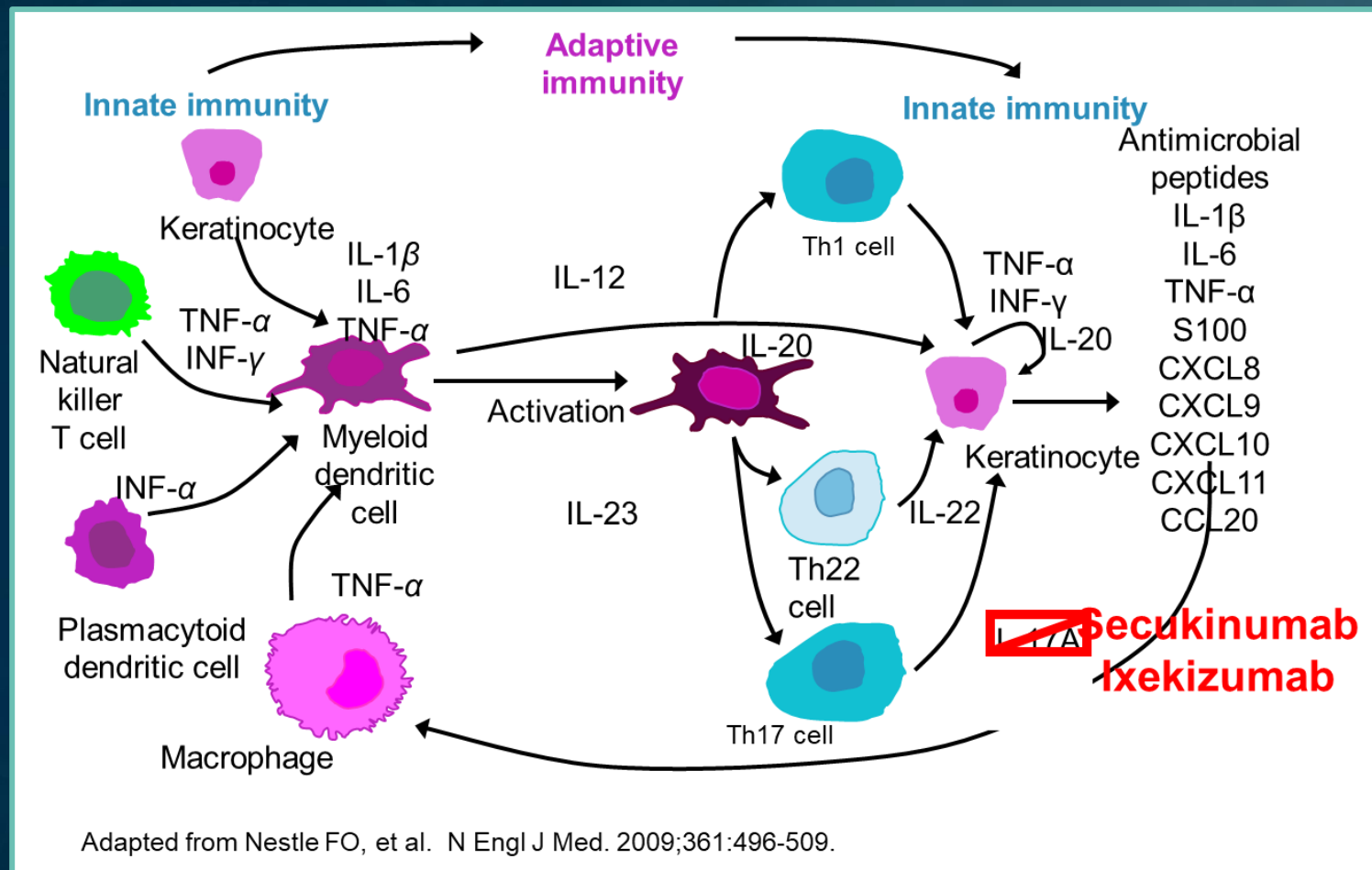
IL-17A Inhibitors

- **Ixekizumab**

- Approved by FDA for treatment of plaque psoriasis in 2016
- Most recently approved by FDA for pediatric psoriasis in 2020

- **Secukinumab**

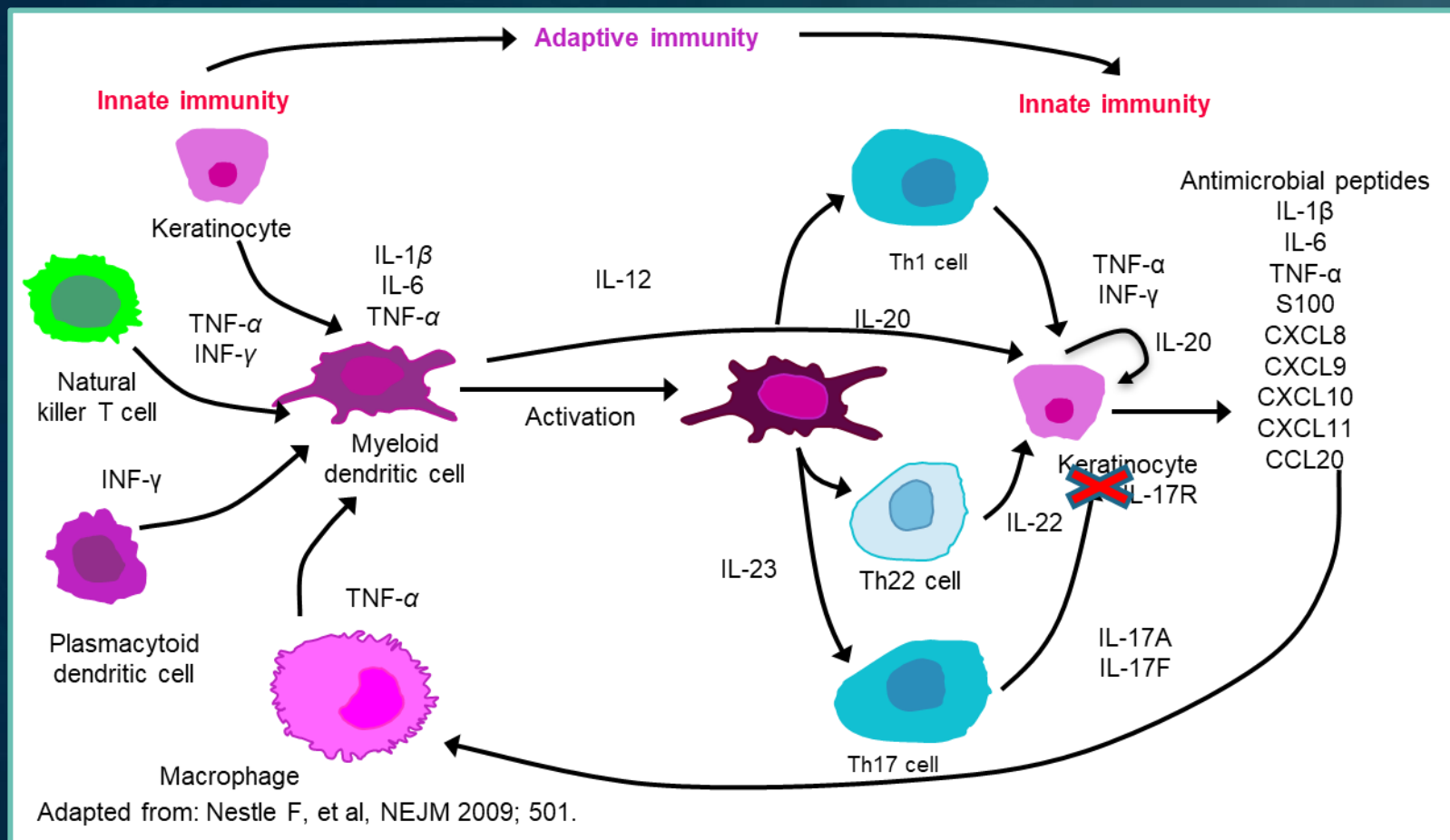
- Approved by FDA for treatment of plaque psoriasis in 2016
- Currently in phase 3 trials studying safety and efficacy in pediatric patients aged 6 years and older



IL-17 Inhibitors

- **Brodalumab**

- Approved by FDA for treatment of psoriasis in 2017
- Currently in phase 3 trials studying safety and efficacy in pediatric patients aged 12 years and older

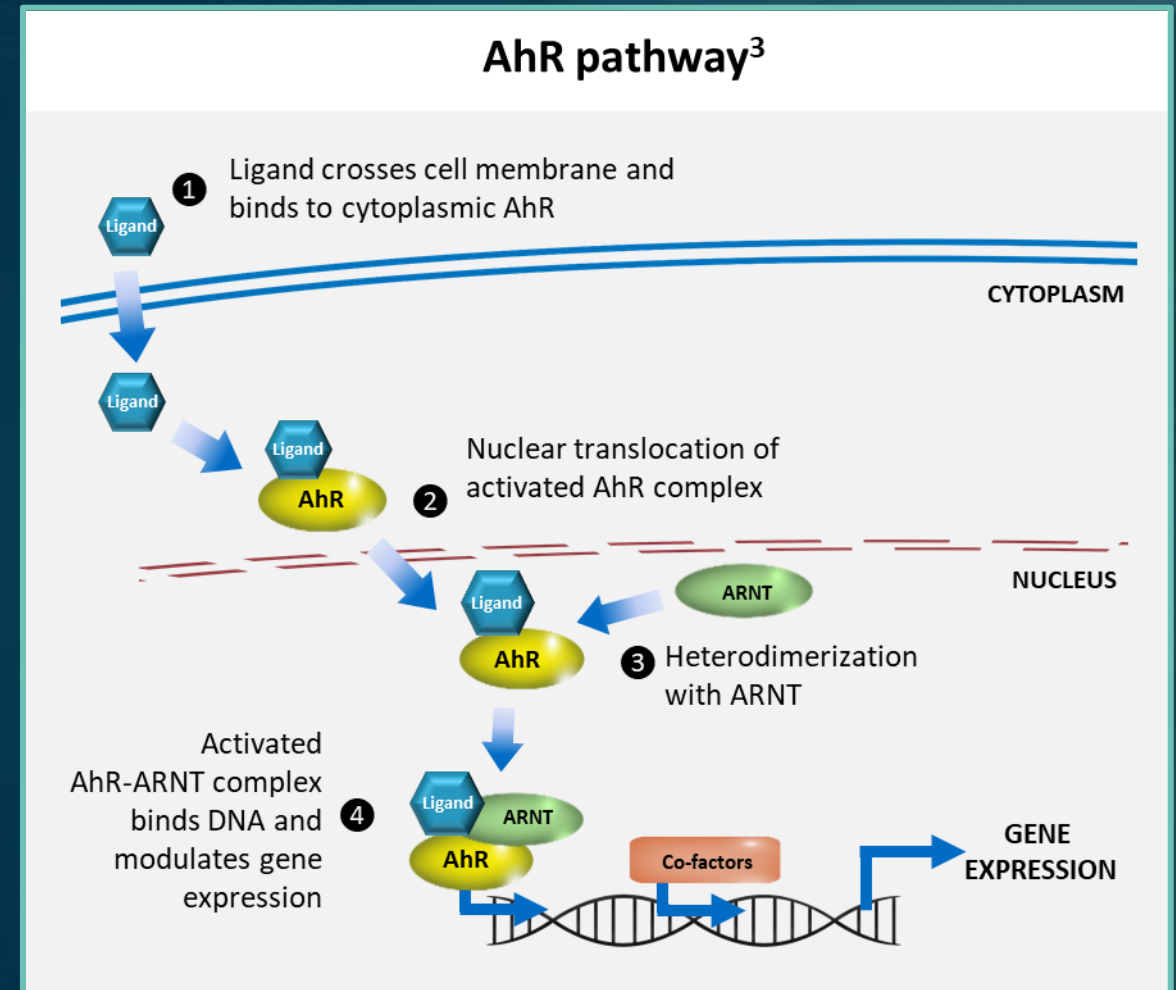


Dr. Mark Lebwohl

Tapinarof

- **Tapinarof**

- Topical, small molecular TAMA that directly binds to and activates AhR transcription factor
- AhR activation via tapinarof *in vitro* and animal models leads to:
 - Reduction of Th17 cytokine expression
 - Reduction of Th2 cytokine expression
 - Decreased oxidative stress
 - Increased skin barrier proteins
- Recently completed phase 3 clinical trials with positive results reported



Roflumilast

- **Roflumilast (ARQ-151)**
 - Topical cream, a potent, selective PDE-4 inhibitor
 - Demonstrates ~25 to >300-fold higher potency than currently available PDE-4 inhibitors
 - Recently hit primary endpoints in pair of Phase 3 clinical trials, and seeking FDA approval for late 2021

ARQ-151, Roflumilast Cream, Improved Chronic Plaque Psoriasis in Phase 2b Study

Mark G. Lebwohl¹, Kim A. Papp², Linda Stein Gold³, Melinda J. Gooderham⁴, Leon H. Kircik⁵, Zoe D. Draelos⁶, Steven E. Kempers⁷, Mathew Zirwas⁸, Kathleen Smith⁹, David W. Osborne⁹, Marie-Louise Trotman¹⁰, Lynn Navale⁹, Charlotte Merritt⁹, David R. Berk⁹, Howard Welgus⁹

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Dr. Leon Kircik

Pediatric Psoriasis: Treatment Landscape

- Only **6 FDA medications approved** for pediatric patients
- **Biologics:**
 - Etanercept: ≥ 6 years
 - Ustekinumab : ≥ 12 years
 - Ixekizumab: ≥ 6 years
- **Topicals:**
 - Calcipotriene Foam 0.005%: ≥ 4 years scalp and body
 - Calcipotriene 0.005% and betamethasone 0.064% **foam**:
 ≥ 12 years: mild to severe plaque psoriasis
 - Calcipotriene 0.005% and betamethasone 0.064% **suspension**:
scalp and body: ≥ 12 years

Dr. Adelaide Hebert

Pediatric Psoriasis: Therapeutic Outlook

BIOLOGICS:

- Secukinumab : IL 23 inhibitor: 6 to 17 years of age
- Brodalumab: anti IL 17: 6 to 17 years of age
- Tildrakizumab: IL 23 inhibitor : 12 to 17 years of age

TOPICALS:

- Halobetasol 0.01%/ tazarotene 0.045% lotion
- Roflumilast: PDE 4 inhibitor: 2 to adulthood
 - used systemically in COPD in adults

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Treating Psoriasis in Pediatric Patients

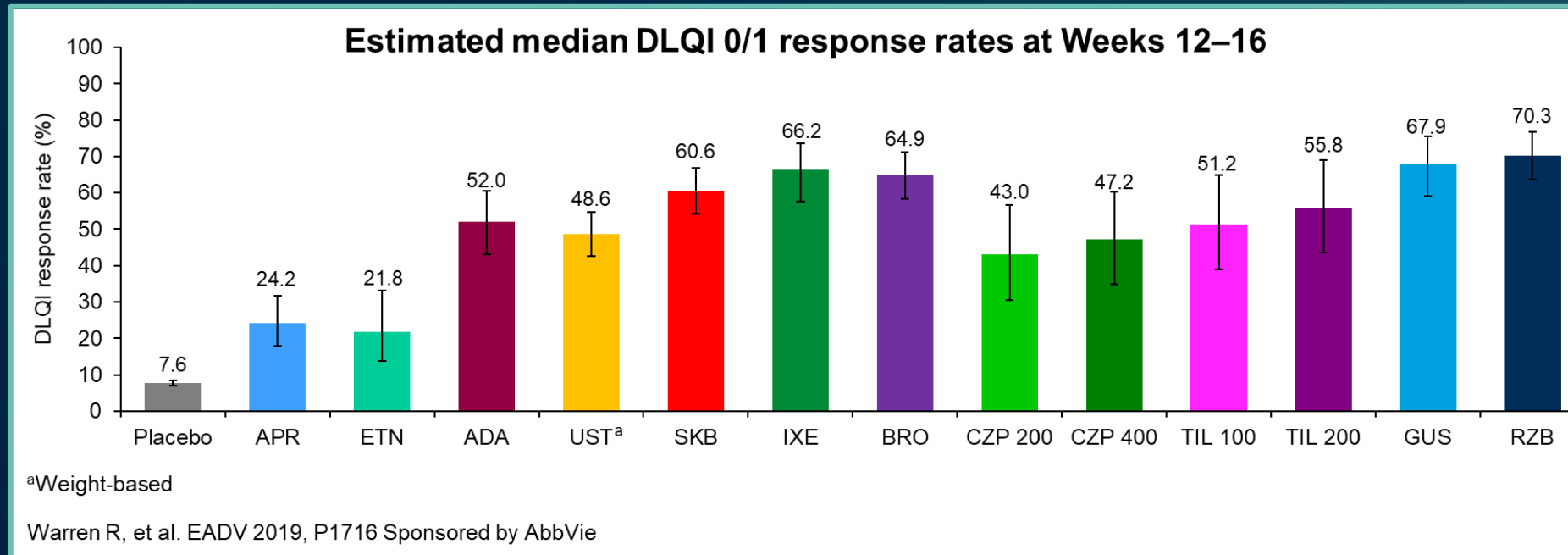
- **Younger children**
 - Consider strep throat
 - Coal tar topical
 - Topical steroids
 - Topical calcineurin inhibitors (inverse psoriasis)
 - Phototherapy
- **Older children**
 - Topical steroids/other topicals
 - Phototherapy / laser
 - Methotrexate
 - Cyclosporin
 - Topical/oral retinoids
 - Biologics

Dr. Adelaide Hebert

Quality of Life Across Therapeutic Agents

Network meta-analysis: Quality of life with novel treatments of moderate to severe plaque psoriasis

- Phase 2 and 3 clinical trials all anchored on placebo
- Interventions studied:
 - Anti-TNF agents: adalimumab, etanercept, infliximab, certolizumab pegol
 - Anti-IL agents: ustekinumab, secukinumab, ixekizumab, brodalumab, risankizumab, guselkumab, tildrakizumab
 - Anti-PDE4: apremilast
 - Fumaric acid esters: dimethyl fumarate



Dr. Adelaide Hebert