

Blockbuster Opportunities in the Dermatology Pipeline

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A Snapshot of William Blair

Firm Overview		2019 ECM Results		2019 M&A Results		2019 Firm Results	
1935 Founded	~1,500 Employees	91 Transactions	\$41B Capital Raised	134 Transactions		~250 IB Transactions	
20 Offices Worldwide		~70% Healthcare Offerings Executed as Bookrunner		\$59B Deal Value		>\$1B Revenue	
100% Owned by Employed Partners		~20% IPO Market Share		30%+ Cross-Border Transactions		\$85B AUM ⁽¹⁾	

Locations



2019 Industry Trends

Dermatology Successes in 2019

1. Large Strategic Deals

- Abbvie + Allergan (“Abbv-Gan”) ~\$63B mega deal
- AbbVie’s plan to separate the cash pay aesthetics business into a separate business unit

2. Product Focused Deal Making Continues

- Amgen acquisition of Otezla from Celgene
- \$13.4B deal for an oral compound which I would say has pretty modest efficacy and brought in \$1.96B in revenue in 2019
- Highlights opportunity for safe compounds that can effectively slot in before biologics in psoriasis
- As a standalone deal it would have been one of the largest single asset deals in biotech
- XBiotech deal with Johnson & Johnson for bermekimab
- \$750M acquisition for Phase II asset in development for Hidradenitis Suppurativa and Atopic Dermatitis
- Eli Lilly Acquiring Dermira for \$1.1 billion (announced 1/10/2020), gaining access to lebrikizumab (IL-13) in atopic dermatitis as well as the marketed Qbrexa for hyperhidrosis

3. Strong Product Launches

- Skyrizi from AbbVie

4. Clinical successes

- Lebrikizumab (Dermira)
- Ligelizumab (Roche)
- SB206 (Novan)
- KB103 (Krystal)
- PRN1008 (Principia)

Key Questions Around Dermatology Pipeline

1. New product differentiation from standard of care

- Eskata from Aclaris had issues in the market around “real world” use and differentiation from standard of care
- Business case needs to be strong in the aesthetics world (how do you compete against the profitability of Botox?)

2. Clinical results vs. “real world” use

- Allergan had some issues with assets they acquired in the past three years with Kybella revenue of \$34 million posted in 2019 and a write down of \$1.6 billion back in January

3. How will you commercialize?

- We’ve also seen some incredibly strong launches in the dermatology space from companies with an established dermatology presence such as AbbVie’s Skyrizi
- We see potential pathways to commercial success in indications with severe unmet medical need
 - KB103, a gene therapy for dystrophic epidermolysis bullosa (“EB”)

We see Several Blockbusters in Development with Better Biologics (post TNF inhibitors), Better Orals, Better Topicals, Better Science

Innovation in Psoriasis

Psoriasis Overview

Psoriasis is a chronic inflammatory skin disease that affects ~2% of the global population (~8 million people in the US)

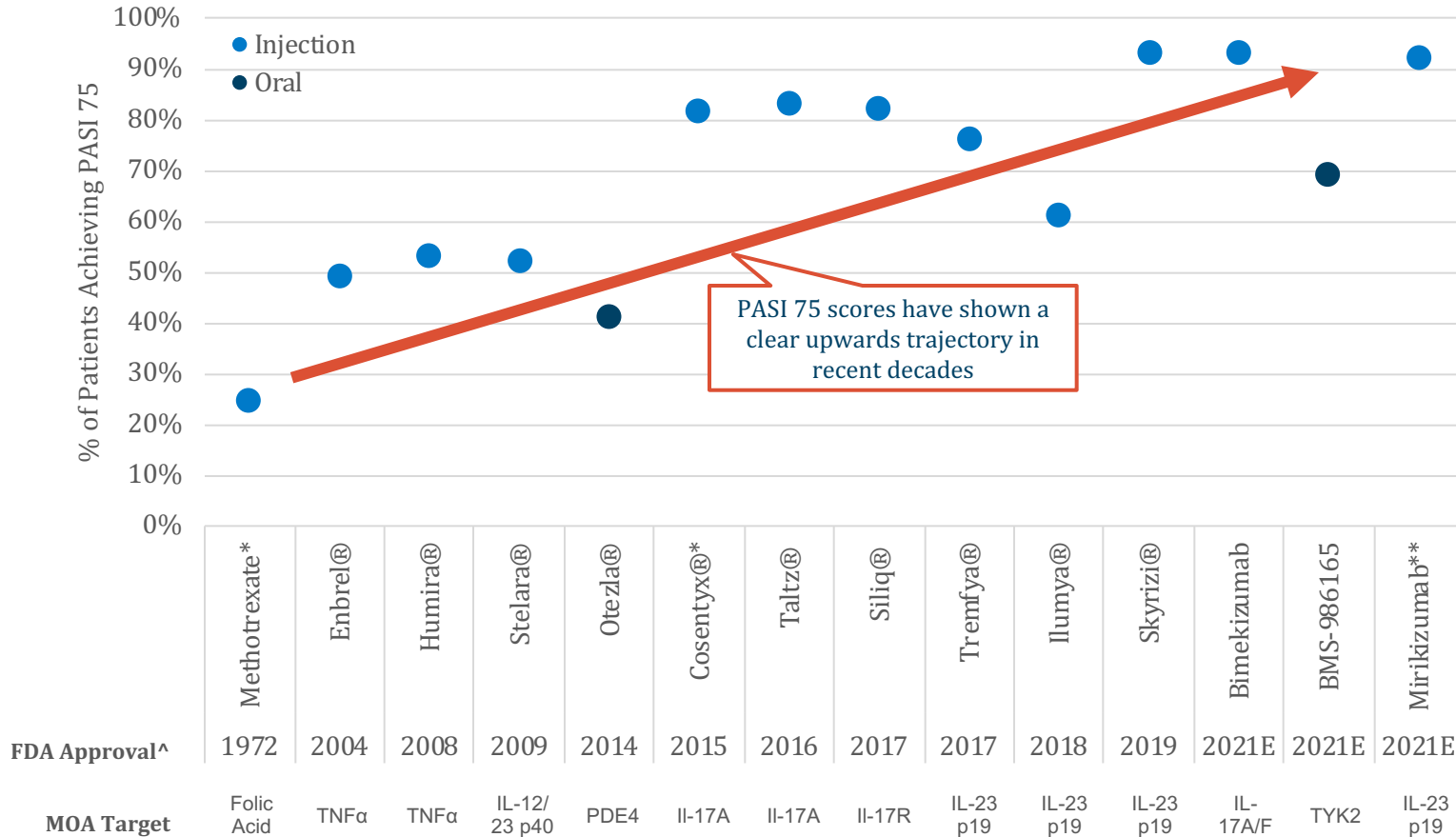
- Environmental factors trigger inflammation characterized by TNF α /IL-23/Th17 infiltrates in genetically disposed population
- Sustained inflammation leads to uncontrolled keratinocyte proliferation and dysfunctional differentiation
- Most common subtype is plaque psoriasis (psoriasis vulgaris) which accounts for ~90% of cases
- Often develops between the ages of 15 to 25, and treatment consists of topical treatments, phototherapy, and systemic therapy
 - Topical treatments account for nearly 75% of psoriasis prescriptions in the US, ~90% of which are topical corticosteroids¹
- Has seen significant development over the past couple of decades, making it a multi-billion dollar market



Significant Improvements in Treatment in Recent Years

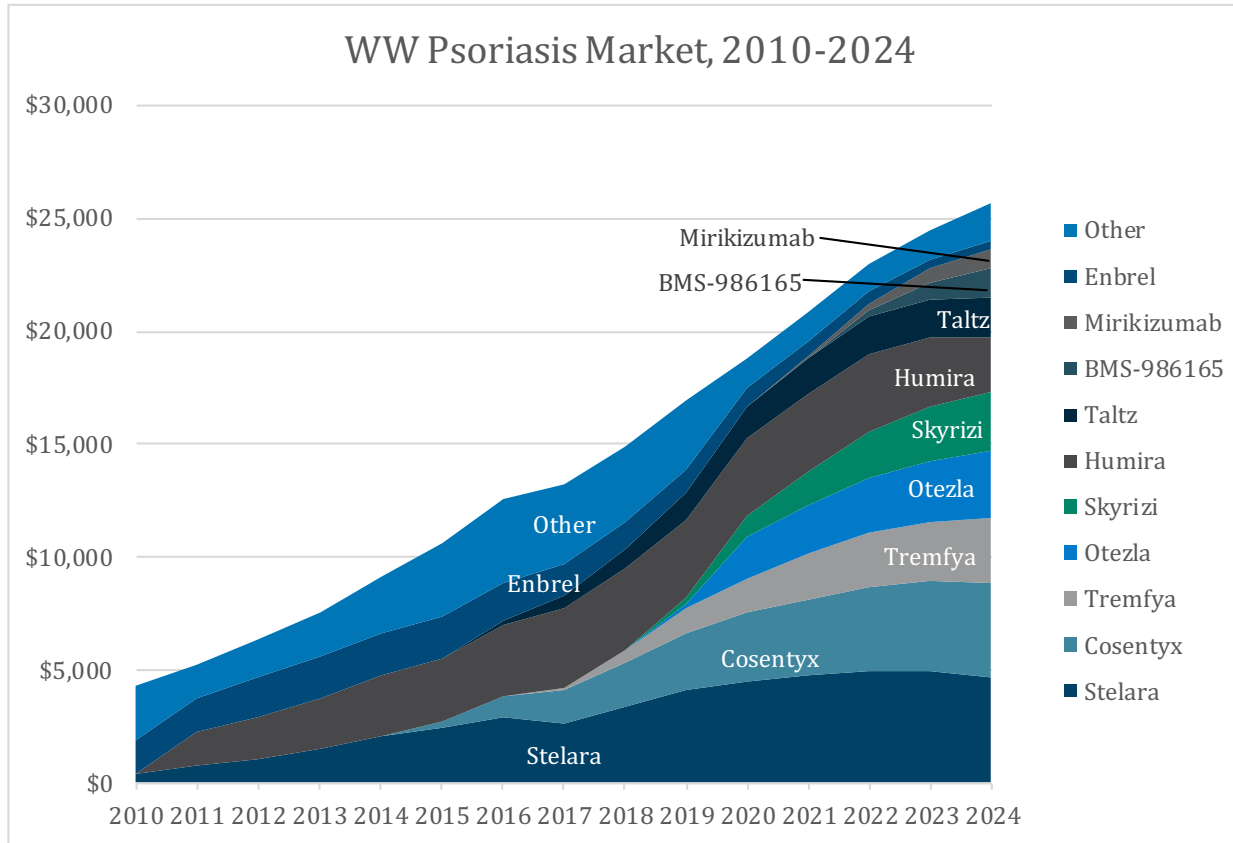
Advancements in our understanding of disease biology have lead to significant improvements in treatment efficacy, as evidenced by PASI 75 scores in clinical trials

PASI 75 Scores from Phase IIb Trials Over The Years



Psoriasis Represents a Large and Growing Market

Psoriasis is a large market, driven primarily by highly effective biologics, with significant growth expected over the coming years



>\$14 B

2018 global sales of top 10 psoriasis therapies

>\$9 B

2019 global sales for top-5 post-TNF biologics†

>\$16 B

consensus 2024 global sales for top 5 post-TNF biologics

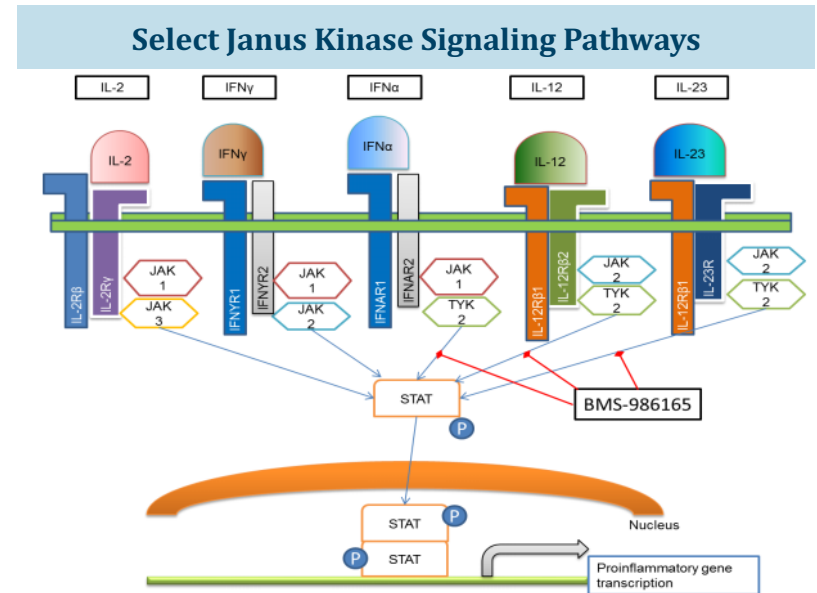
>\$23 B

Estimated 2024 global sales of top 10 psoriasis therapies

TYK2: A New Target for Th17 Driven Diseases

Tyrosine Kinase 2 (TYK2) is a member of the Janus Associated Kinase (JAK) family of signaling kinases that plays an important role in pro-inflammatory signal propagation

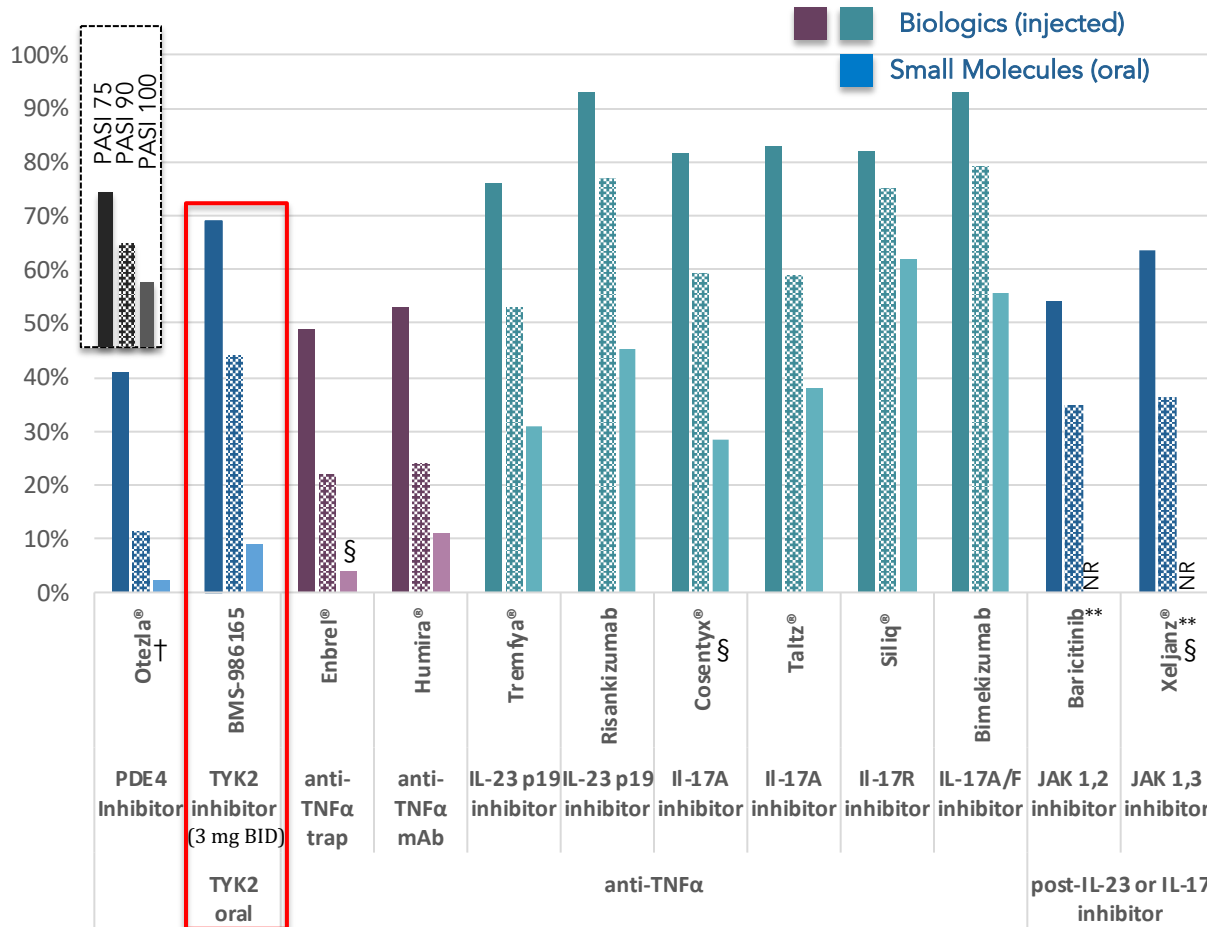
- TYK2 functions as a heterodimer with JAK1 or JAK2
 - Inhibition of either member of the dimer blocks receptor signaling
- Strong genetic association with multiple autoimmune disorders in humans
- Potential to replicate efficacy of Th17 biologics while also inhibiting Type-I interferons (IFN) (α and β) with a small molecule
 - Key target for several challenging auto-immune disorders
- Not inhibited by current JAK inhibitors like tofacitinib at clinical doses
- Potentially safer to inhibit compared with JAK1/2/3*
- Outstanding concerns: JAK class labelling? Will we see JAK-like side effects?



>\$1.2 B Consensus 2024 sales for BMS-986165 (lead TYK2)[^]

TYK2: Best-in-Class Oral Approaching Biologic Efficacy

PASI 75/90/100 Comparison at 12 Weeks, reported at Phase IIb



2018 WW Psoriasis Sales by Product (USD millions)*

1,374	N/A	1,180	3,643	544	N/A	2,002	831	32	N/A	N/A	N/A**
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Select TYK2 Inhibitors

BMS-986165

- Allosteric TYK2 inhibitor with low affinity for JAK1/2/3
- Phase II trial demonstrated highest PASI 75 score for an oral to-date, with no SAEs
- Phase III trials vs. Otezla ongoing with readout expected in 2020
- Ongoing Phase II trials in psoriatic arthritis, lupus, Crohn's disease, ulcerative colitis

Nimbus' TYK2 Drug Candidate

- Potent allosteric inhibitors with marked TYK2 functional selectivity (>1,000x that of other JAKs and >100x that of BMS-986165)
- First-in-human Phase I initiated
- Had partnership with Celgene: TBD if BMJ keep it after acquisition

[†] Efficacy data from week 16; [§] Efficacy data from Phase III report; NR: Not reported; *Annual sales and indication-specific estimates from EvaluatePharma; **Development in psoriasis terminated

Skyrizi: Potentially Best-in-Class anti-IL-23 Inhibitor

FDA Approval
April 23, 2019

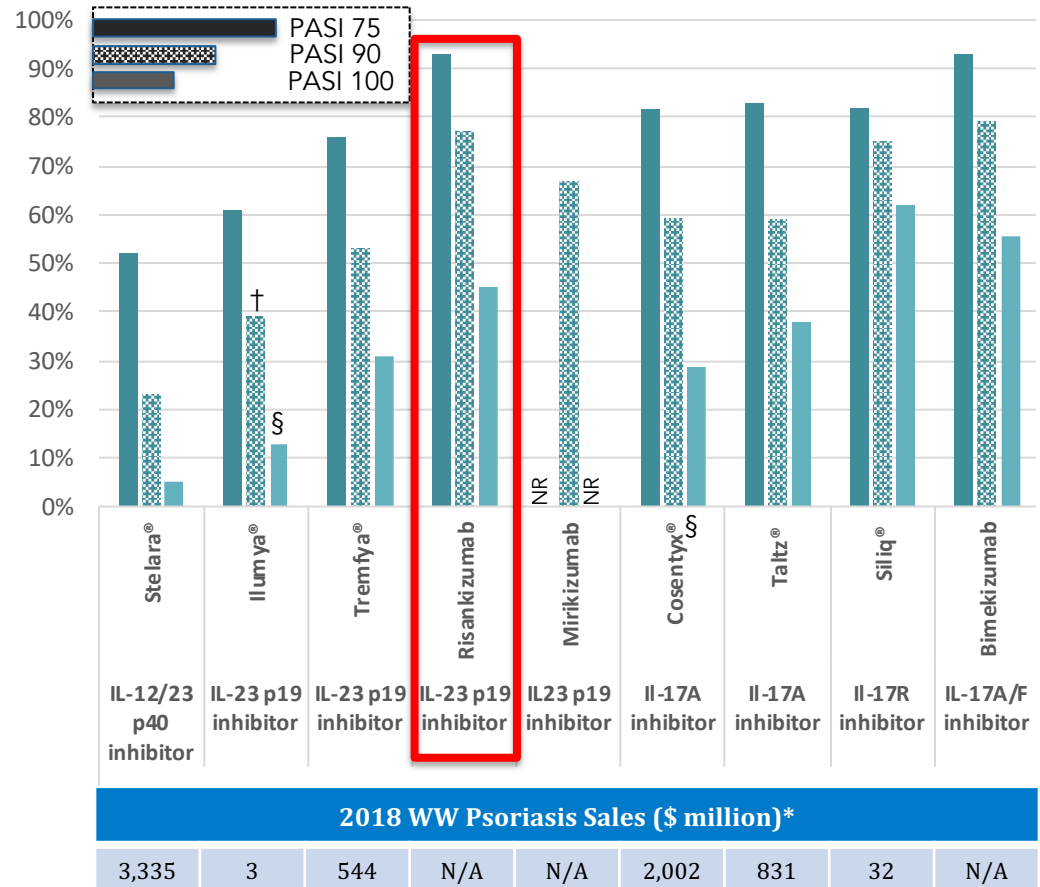
Mechanism
IL-23 p19 antagonist

Administration
SubQ injection (q12w)

Additional opportunities

- Crohn's disease
- Psoriatic arthritis
- Ulcerative colitis
- Atopic dermatitis

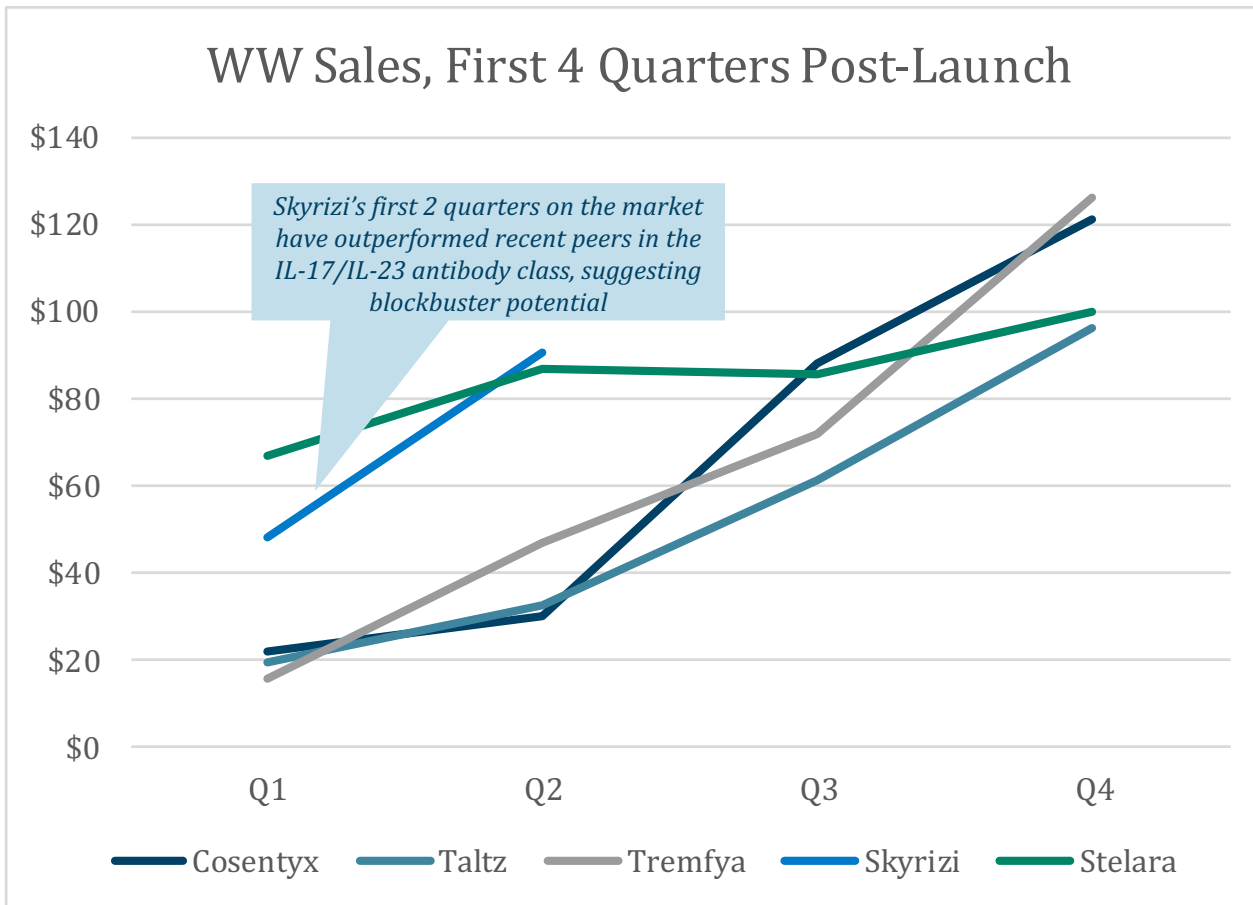
Comparison of PASI 75/90/100 at 12 Weeks From Phase IIb Trials Demonstrates Promising Efficacy



Stelara and Cosentyx illustrate significant opportunity in post-TNF market

Skyrizi Off To a Strong Start in Post-TNF PsO Market

Early launch metrics show that Skyrizi is off to a strong start in the post-TNF psoriasis market, suggesting it will hold a commanding position in this large and growing market



After 2 quarters on the market...

~3,500
prescribing physicians

>9,000
patients treated*

>80%
commercial access

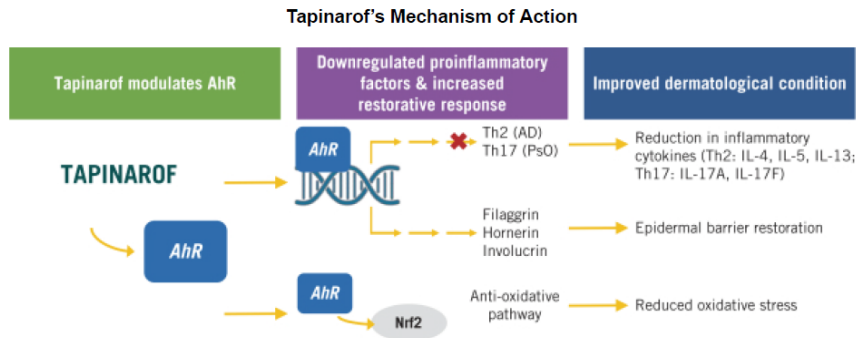
>20%
market share of in-play
psoriasis patients

Tapinarof: AhR Agonist for Plaque Psoriasis

Dermavant's tapinarof is a topical aryl hydrocarbon receptor (AhR) agonist in Phase III trials for plaque psoriasis, with potential to expand into atopic dermatitis following a successful Phase IIb trial

Mechanism of Action

- Binding to AhR downregulates pro-inflammatory factors AND increases restorative responses:
 - Downregulation of Th17 and Th2 inflammatory cytokines
 - Restores epithelial barrier function by inducing transcription of filaggrin
 - Increases production of Nrf-2 to reduce oxidative stress



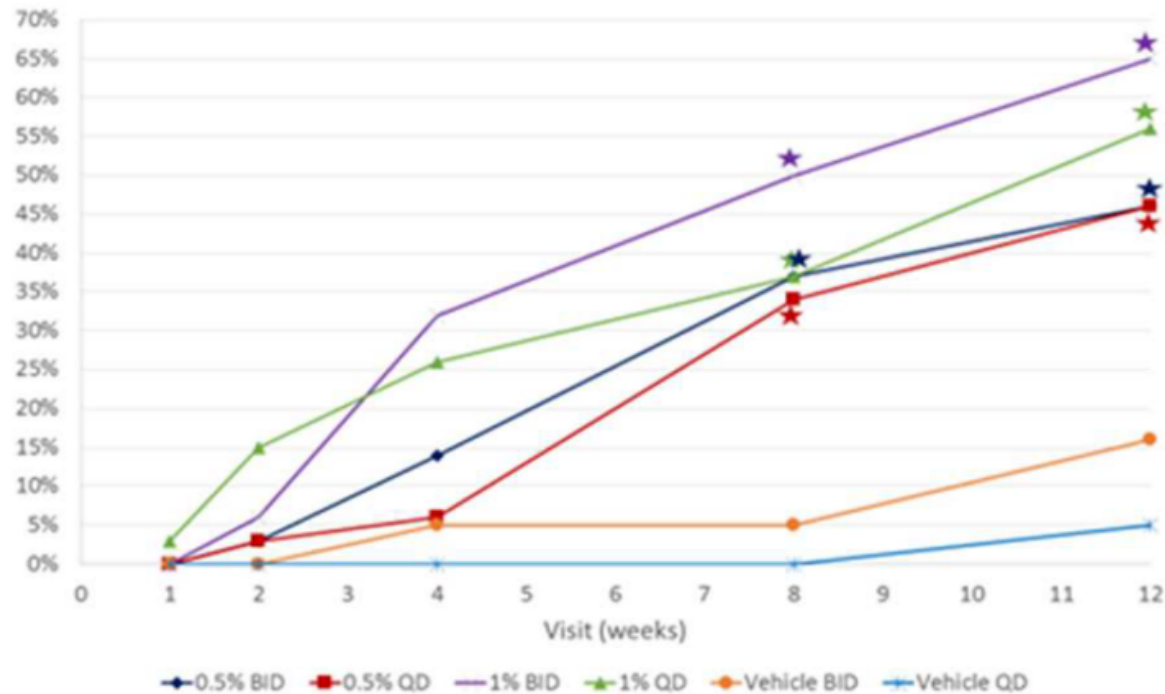
Market Opportunity & Development Status

- Topical therapies represent a significant market (~75% of scripts)
- Relatively little innovation in topical therapies as compared to biologics
 - Primarily TCS; topical JAKinibs have been unsuccessful in psoriasis to-date
- Promising data in Phase IIb trials in PsO and moderate-to-severe atopic dermatitis
- Ongoing pivotal program in PsO (PSOARING) with data expected in 2020:
 - Two 12-week Phase III trials (NCT03956355; NCT03983980)
 - Phase III long-term open-label safety study (NCT04053387)

Tapinarof: Promising Phase IIb Efficacy in Psoriasis

A previously completed Phase IIb trial in plaque psoriasis demonstrate impressive efficacy for a topical product, and support ongoing Phase III PSOARING development program

Proportion of patients experiencing a $\geq 75\%$ improvement from baseline PASI scores



PASI 75 of 56% at week 12 (1% QD) is comparable to Phase IIb efficacy of currently approved or late-stage oral therapies (Otezla, 41%; baricitinib, 54%; BMS-'165 TYK2, 69%)

Ongoing pivotal program in psoriasis (PSOARING[^]) with data expected in 2020

*p<0.05; BID, twice daily; EASI, eczema area and severity index; IGA, investigator global assessment; QD, once daily; PASI, psoriasis area and severity index; PGA, physician global assessment; [^]NCT03956355, NCT03983980, NCT04053387
Sources: Peppers K. *et al.*, 2019. *J. Am. Acad. Dermatol.*; Robbins K. *et al.*, 2019. *J. Am. Acad. Dermatol.*

Innovation in Atopic Dermatitis

Atopic Dermatitis Overview

Atopic Dermatitis (AD), the most common, severe, and long-lasting form of eczema, is a chronic inflammatory skin disease characterized by dry skin and pruritus

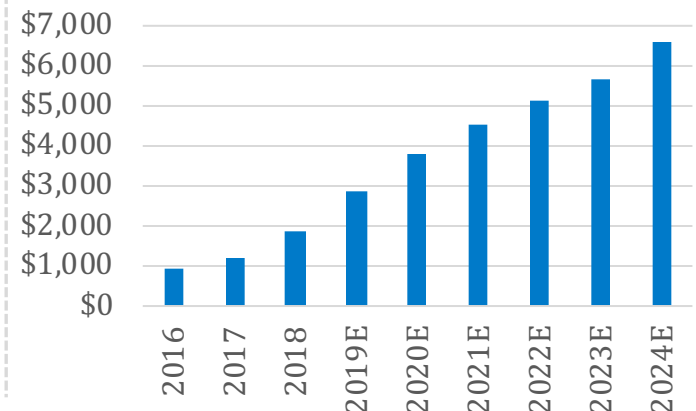
Disease Background

- Most often occurs early in life; often disappears as children age, but can return as flares
- Estimated US prevalence of ~13% in children and 7%-10% in adults¹
 - ~9.6 million children (<18) and ~16.5 million adults in the US have AD**
- Believed to be caused when the immune system over-reacts to an environmental trigger
 - Genetic predisposition, skin barrier dysfunction, and aberrant immune response (especially Th2/Th22)
- Significant disease burden, both through the direct symptoms of AD (e.g., itch) as well as an elevated risk of several comorbid conditions
- Nearly 5.9 million workdays annually lost due to eczema²
- Annual economic burden (direct and indirect) conservatively estimated at \$5.3 billion in 2015³

Market Opportunity

- The AD market is less developed than the PsO market
- Significant growth expected over next 5-10 years as several new drugs expected to come to market
- 2017 approval of Dupixent, the first biologic for AD sparked inflection towards growth

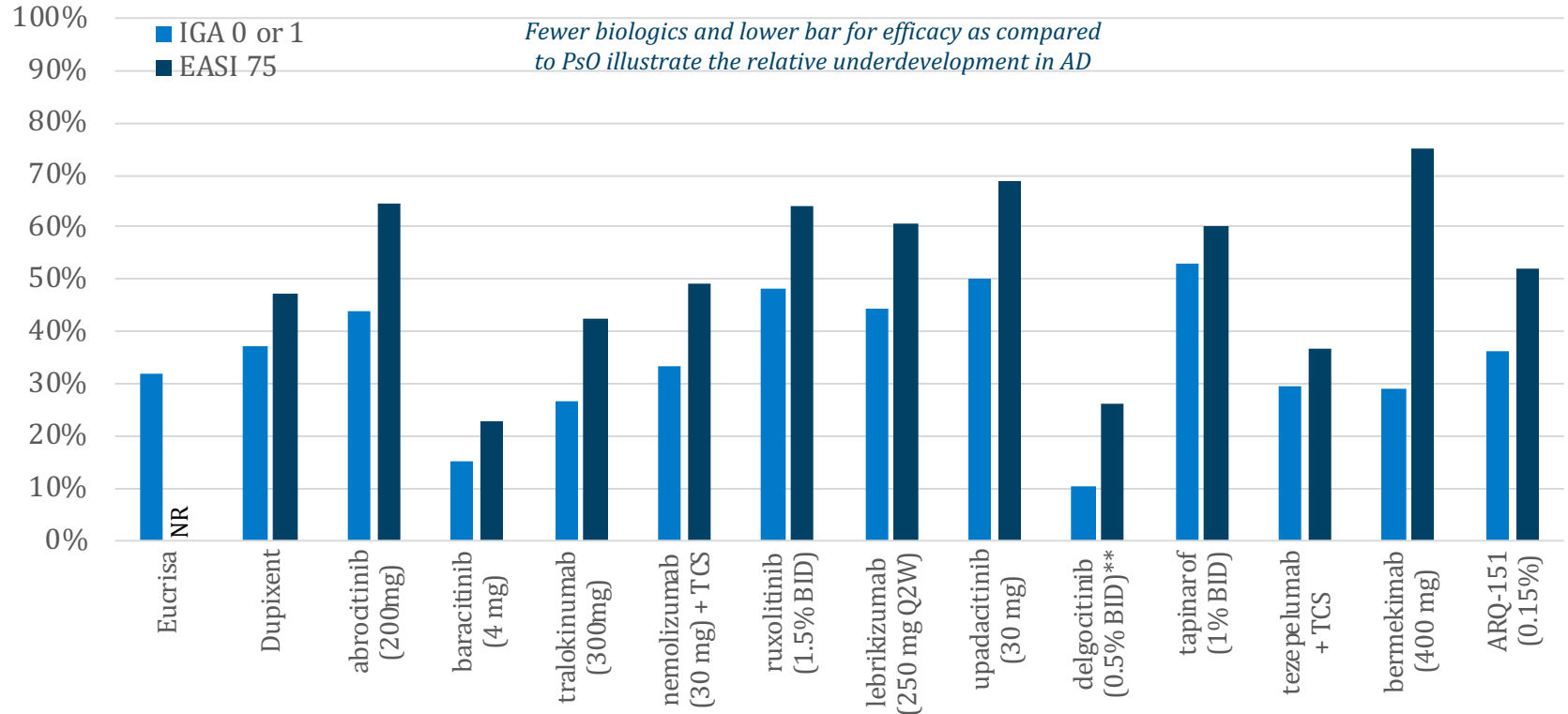
WW AD Sales (USD millions)*



Significant Room for Improvement Remains

Though development activity has increased in recent years, the number of drugs in development, and the efficacy seen in late-stage trials suggests a less developed market than psoriasis

Less Competitive Development Landscape than Psoriasis

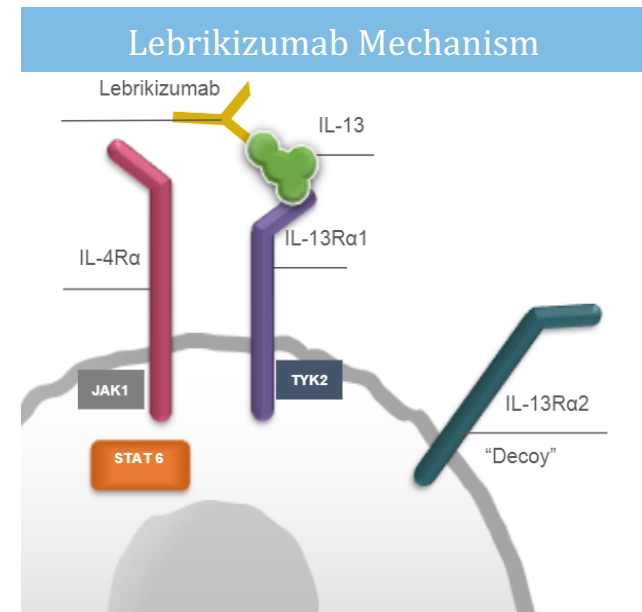


Est. US Approval	2016	2017	2020*	2020*	2020	2020	2022	2023	2023*	2023?	2023?	2024	2024?	2024+?
Target	PDE4	IL-4Rα	JAK1	JAK1/2	IL-13	IL-31RA	JAK1/2	IL-13	JAK1	Pan-JAK	AhR agonist	Anti-TSL	IL-1 ^α	PDE4
Admin.	Topical	Injection	Oral	Oral	Injection	Injection	Topical	Injection	Oral	Topical	Topical	Injection	Injection	Topical
Endpoint	Week 4	Week 16	Week 12	Week 16	Week 12	Week 16	Week 8	Week 16	Week 16	Week 4	Week 12	Week 16	Week 8	Week 4

Lebrikizumab: Targeting IL-13 for Atopic Dermatitis (AD)

Dermira's lebrikizumab selectively targets IL-13 to prevent receptor dimerization while leaving endogenous regulation of IL-13 intact

- IL-13 believed to mediate inflammation and amplify sensory neuron responses
- Selectively prevents formation of the IL-13R α 1/IL-4R α heterodimer receptor signaling complex while leaving endogenous regulation of IL-13 intact
- Allows for the safety observed with other IL-4/IL-13 monoclonal antibodies (e.g., dupilumab) with potentially better efficacy
- Currently being evaluated in Phase III program after positive results from Phase IIb study
 - Effects on itch were observed as early as Day 2 in patients receiving a loading dose
 - Received breakthrough therapy designation
- Two pivotal Phase III monotherapy studies ongoing
 - Top-line results from 16-week induction period of both Phase III studies expected first half of 2021

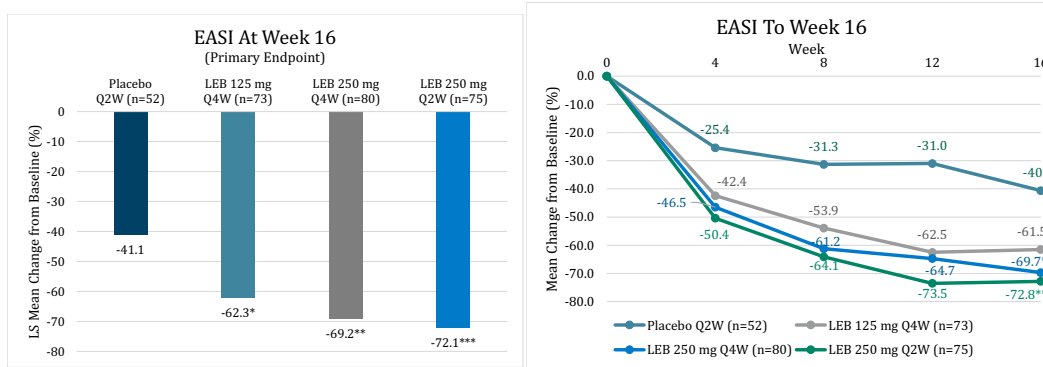


AD is projected to become one of the largest markets in dermatology by 2027

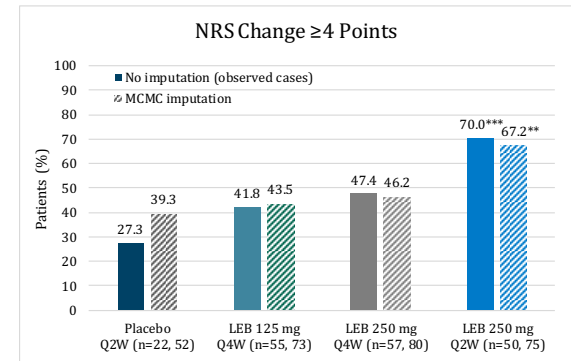
Lebrikizumab Demonstrates Promising Efficacy

In the Phase IIb study, lebrikizumab demonstrated dose-dependent responses across all endpoints

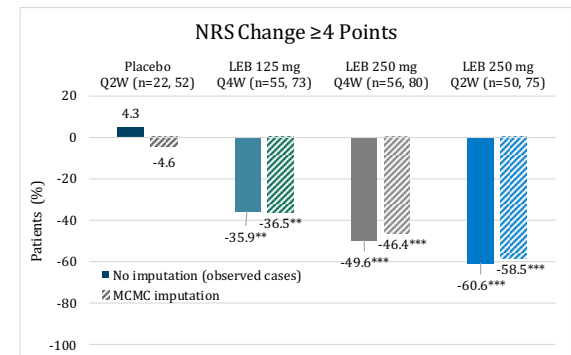
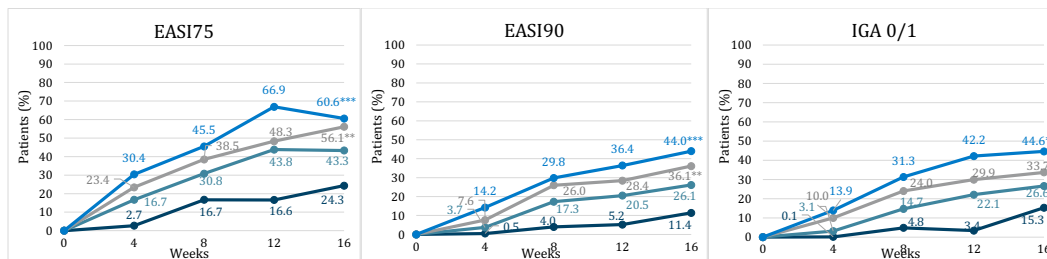
Early and sustained improvements in EASI



Robust improvements in pruritus scores



Dose-dependent improvements across secondary endpoints



*p<0.05, **p<0.0, ***p<0.001 versus placebo from pairwise Cochran-Mantel-Haenszel tests

LEB, lebrikizumab; LS, least squares; MCMC, Markov chain Monte Carlo; NRS, numeric rating scale

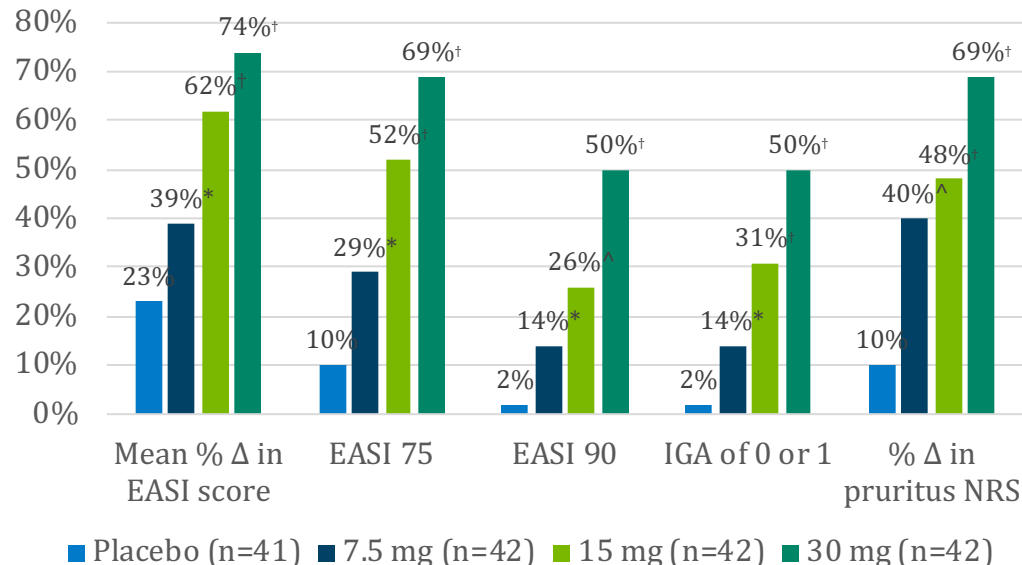
Source: Dermira company presentations

Rinvoq (upadacitinib): JAK1 Inhibition for AD

AbbVie's Upadacitinib is a JAK1 inhibitor approved for the treatment of rheumatoid arthritis, and in late-stage development for numerous inflammatory conditions including atopic dermatitis

- Approved for rheumatoid arthritis (RA); in late stage development for atopic dermatitis (AD), Crohn's disease, psoriatic arthritis, ulcerative colitis, and giant cell arteritis
 - Already shown superiority over Humira in PsO¹
- Successfully completed Phase II study in AD:
 - All dose groups (30/15/7.5 mg once-daily) met the primary endpoint with dose dependent relationship
 - No new safety signals identified, through long-term safety will be key for a dermatology indication given the class-wide black box warning

Strong Efficacy Signal in Phase II



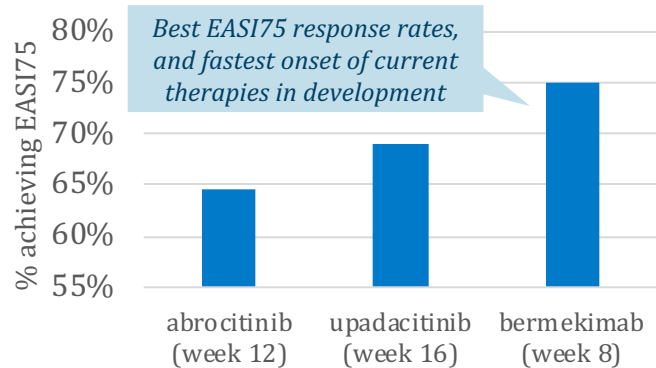
- Comprehensive Phase III program underway:
 - Measure Up 1 (NCT03569293); n=810, PC: March 2020
 - NCT03607422; n=810, PC: Feb 2020
 - NCT03568318 (combo with TCS); n=810, PC: March 2020
 - NCT03738397 (vs. dupilumab); n=650, PC: Sept. 2020

Bermekimab: Anti-IL-1 α for AD

XBiotech's Bermekimab, recently in-licensed by J&J, is an anti-IL-1 α antibody in development for a range of indications, including atopic dermatitis and hidradenitis suppurativa

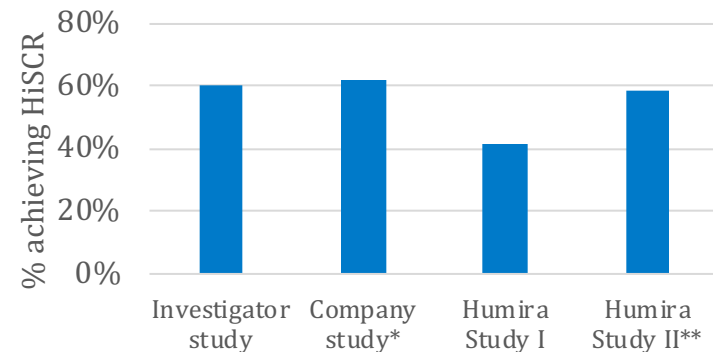
- Derived from natural human humoral response against IL-1 α
- IL-1 α is produced by activated leukocytes and has numerous biological effects
- Single-product asset being develop in a range of dermatology, immunology, and oncology indications
- Recently acquired by J&J for \$750 million upfront with up to \$600 million in milestones
- Promising data from open-label Phase II studies in AD and hidradenitis suppurativa (HS)

Atopic Dermatitis



Also demonstrated strong improvements in itch (~70% mean % reduction) and pain (>80% mean % reduction)

Hidradenitis Suppurativa



Also demonstrated strong improvements in pain (54%-64% reduction from baseline)

Innovation in Other Dermatology Indications

PF-06651600: Selective JAK3 Inhibitor for Alopecia

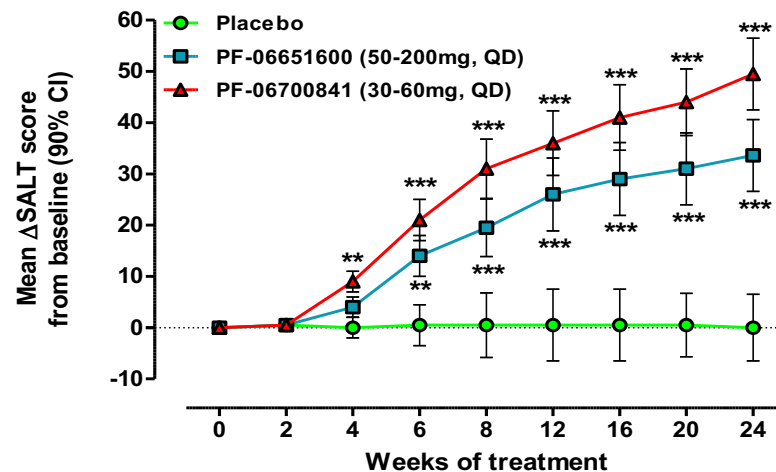
Pfizer's PF-'600, a JAK3 inhibitor, is currently being tested in Phase IIb/III trials after a successful Phase IIa study in Alopecia Areata (AA)

- Given autoimmune etiology, recent development has focused on JAKinibs as potential therapy
- PF-06651600 is the only JAK3-selective JAKinib in development for AA
- Binds to a unique cysteine residue (Cys-909) in the catalytic domain of JAK3 that is not shared by other JAK isoforms, but is shared by 5 kinases in the TEC family (BTK, BMX, ITK, RLK, TEC)¹
 - Preclinical data suggests that of the cytolytic function of CD8+ T cells and NK cells is driven by inhibition of TEC kinases¹

PF-06651600 Phase IIa trial

- 95 patients with moderate-to-severe AA ($\geq 50\%$ scalp hair loss), randomized 1:1 to 200 mg QD PF-06651600, or placebo
 - Onset of effect at 6 weeks with continued improvement out to 24 weeks
 - Received breakthrough therapy designation for AA
 - Currently in ongoing Phase IIb/III dose-ranging study (n=660; primary completion, September 2020)
 - Despite better efficacy, PF-06700841 (JAK1/TYK2), was not progressed due to safety issues (2 cases of rhabdomyolysis)
- Concert's CTP-543 (deuterated ruxolitinib) has also shown efficacy, however commercialization strategy is uncertain

Efficacy analysis for the Phase II trial of Pfizer's JAKinib portfolio for alopecias



p<0.01, *p<0.001 vs. placebo; CI = Confidence interval; JAK = Janus-associated kinase; SALT = Severity of alopecia tool; All values are placebo normalized

Source: PFE company reports; EADV 2018 presentation

Biologics to Continue to Transform Atopic Diseases

Dupixent

- IL-4R α monoclonal antibody
- Approved indications: atopic dermatitis, eosinophilic asthma, chronic rhinosinusitis with nasal polyposis (CRSwNP)
- In development for: eosinophilic esophagitis (EoE), chronic obstructive pulmonary disorder (COPD), grass, peanut allergy
- Estimated WW 2024 sales: \$6.2 billion

Ligelizumab

- Anti-IgE antibody (i.e., high-affinity Xolair)
- In development for: chronic spontaneous urticaria (CSU)
- Pivotal data expected 2021

Antolimab

- Anti-Siglec-8 antibody, directly targeting cell surface proteins on eosinophils and mast cells
- In development for: eosinophilic gastritis/gastroenteritis, chronic spontaneous urticaria, idiopathic systemic mastocytosis, and severe allergic conjunctivitis
- Pivotal data as early as 2021

Bermekimab

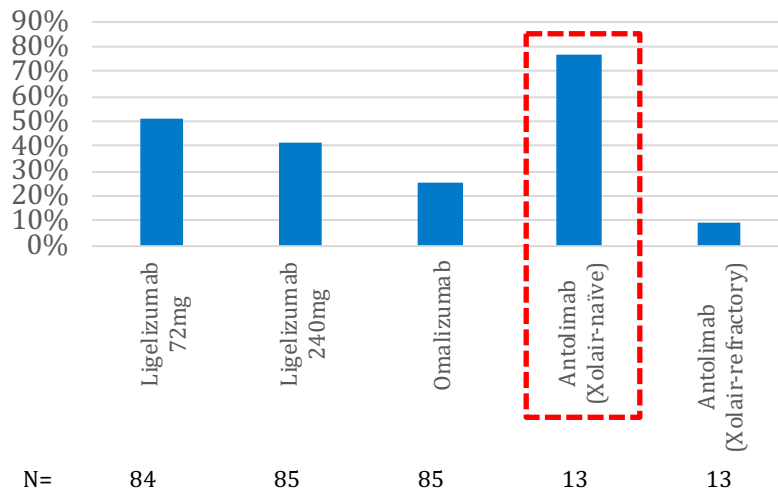
- Anti-IL-1 α monoclonal antibody
- Indications in development: pyoderma gangrenosum, hidradenitis suppurativa, plaque psoriasis, acne vulgaris, atopic dermatitis, systemic scleroderma, and various oncology indications
- Recently acquired by JNJ for \$750 million upfront with up to \$600 million in milestones

Antolimab for Atopic Disorders

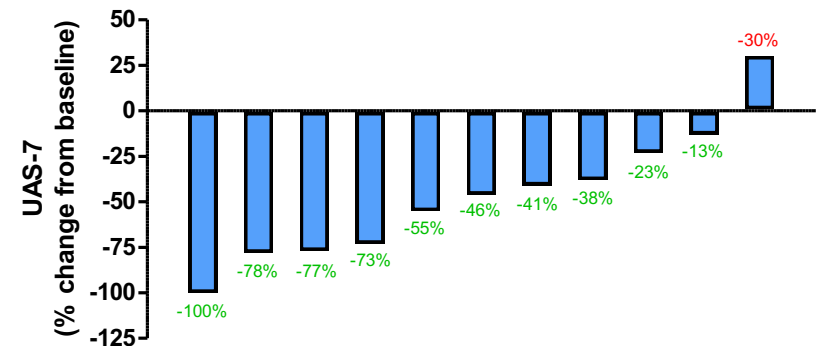
Allakos' antolimab (AK002) is an afucosylated anti-siglec-8 monoclonal antibody that depletes eosinophils and inhibits mast cells

- Engages siglec-8 to deplete eosinophils and inhibit mast cells
- Data from GI disorders suggests better and faster eosinophil depletion than Dupixent
- Has generated promising data from an open-label Phase II study in chronic spontaneous urticaria (CSU), and the company has openly discussed starting a study in AD
- While not pure dermatology, urticaria is clearly related to dermatology, and the drug may have potential in additional dermatology indications such as AD

Proportion of patients with HSS7 = 0 in CSU trials



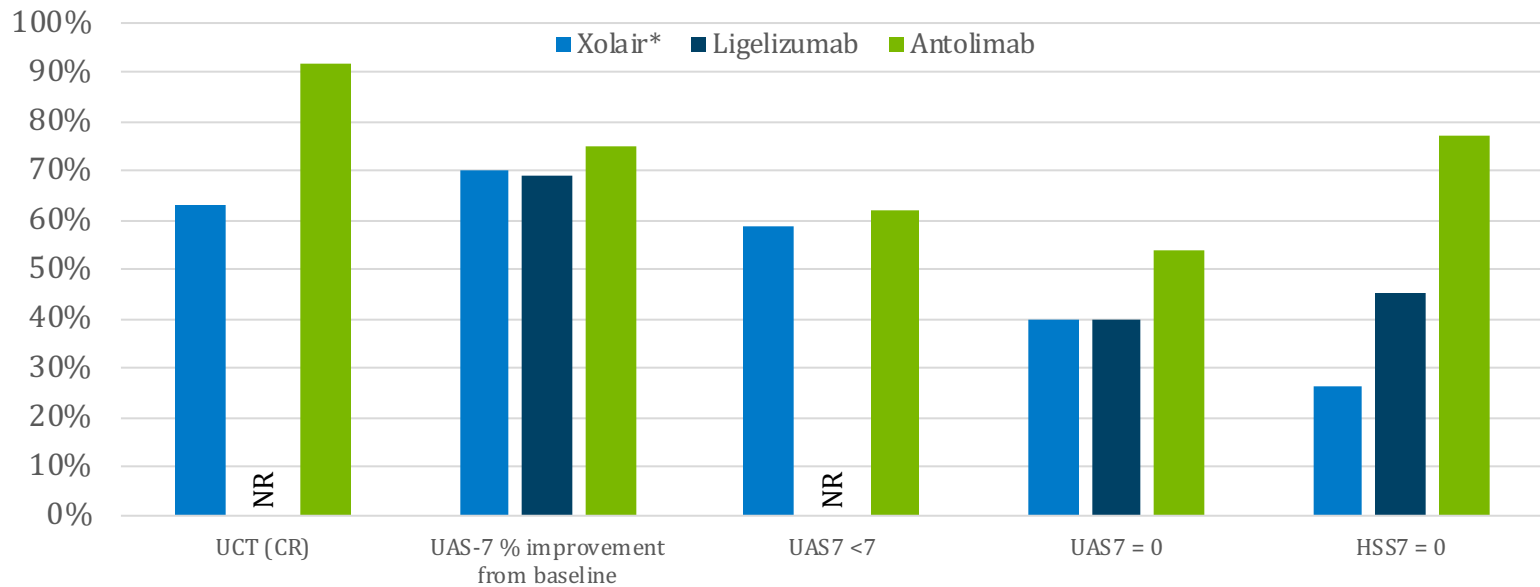
Individual patient UAS-7 score responses in Xolair-refractory patients treated with antolimab



Antolimab Looks Competitive in CSU

Based on data from the open-label Phase II study in CSU, antolimab compares favorably to the leading mast-cell targeted biologics used for the treatment of patients with antihistamine refractory CSU

Comparison to Xolair and Ligelizumab in CSU



*Showing best data for each endpoint across ASTERIA I/II Phase III trials, GLACIAL Phase III trial, and Phase IIb trial of Xolair vs. ligelizumab
Sources: Saini S. *et al.*, 2015. *J. Invest Dermatol*; Maurer M. *et al.*, 2013. *NEJM*; Kaplan A. *et al.*, 2019. *JACI*; Maurer M. *et al.*, 2018. *EAACI*;
William Blair & Company LLC

UCT, urticaria control test; UAS-7, urticaria activity score; HSS7, hives severity score (sum of average daily score from 7 preceding days)

Krystal Biotech: Gene Therapy Platform for Dermatology

Skin TARgeted Delivery (STAR-D) Platform uses modified herpes simplex virus 1 (HSV) vectors to treat skin diseases

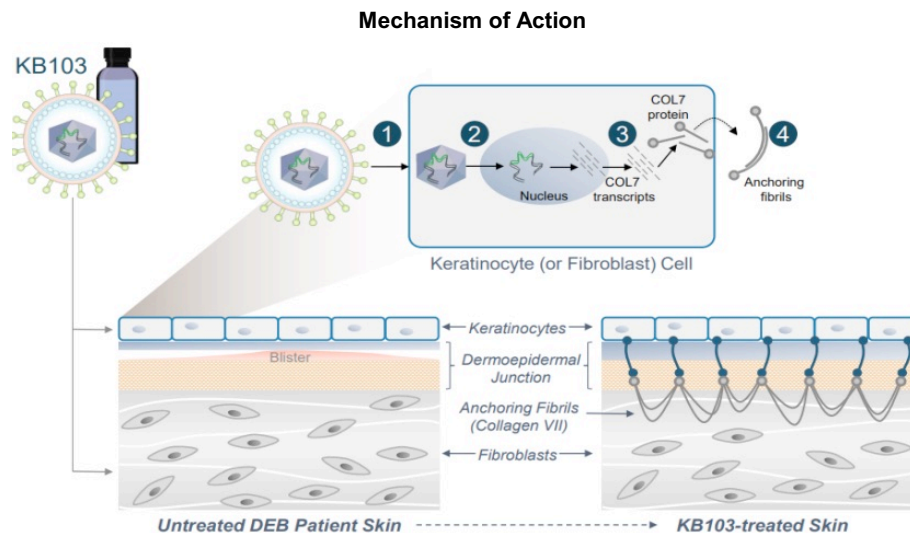
- Lead candidate is KB103 (bercolagene telserpavec; B-VEC) for recessive dystrophic epidermolysis bullosa (dystrophic EB, DEB)
 - DEB is a rare, genetic connective tissue disease that causes skin to tear and blister form minor contact
 - Caused by mutations in the COL7A1 gene that codes for the COL7 protein which anchors the dermis to epidermis
- No approved treatments for DEB; palliative treatments cost \$200k-\$400k annually^{2,3}
- WW prevalence up to 125,000¹

1

KB103 enters the compromised skin and transduces keratinocytes and fibroblasts

2

KB103 enters the nucleus of transduced cells and the vector genome is deposited (episomally)



3

COL7A1 transcripts are generated, allowing production and secretion of COL7 protein

4

Secreted COL7 protein assembles into anchoring fibrils which hold the dermis and epidermis together

¹Debra International

²Rashidghamat E., Mellerio J.E., Management of chronic wounds in patients with dystrophic epidermolysis bullosa: challenges and solutions, Chronic Wound Care Management and Research Volume 2017:4, 45-54

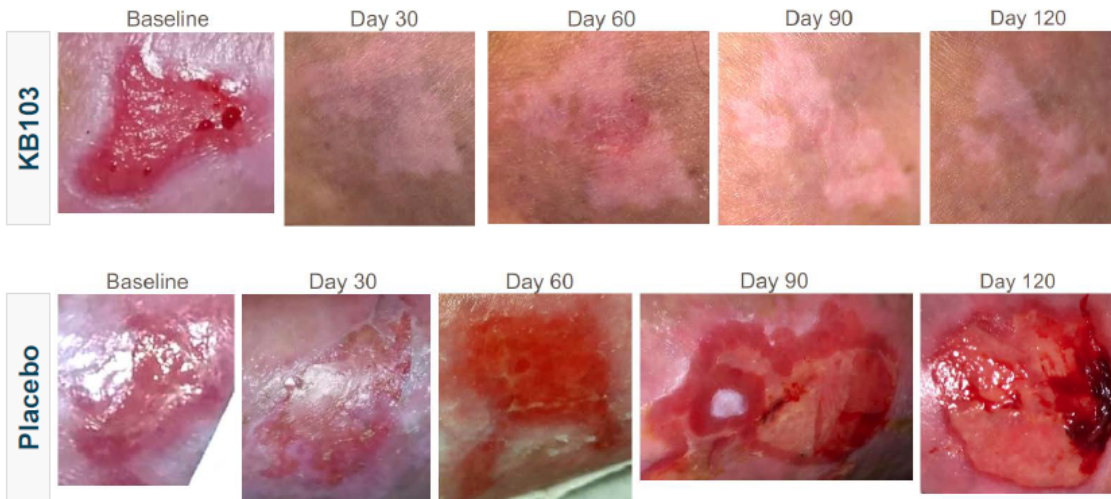
³GENEGRAFT Report Summary. (2015, February 16). Retrieved December 13, 2016, from http://cordis.europa.eu/result/rcn/156078_en.html

Source: Krystal Biotech company presentation

KB103: Clinical Data To-Date

Combined results from a combined 8 patients in the Phase I (GEM-1) and Phase II (GEM-II) studies demonstrate good efficacy, as well as good safety/tolerability

Illustrative Wound Healing Data from Patient 05 in Phase II study



9/10* wounds closed completely after initial administrations

17.4 average time (days) to 100% wound closure (of the 9 treated wounds)

113 average duration (days) of wound closure at last time point measured

- No treatment related adverse events
- No immune response or blistering observed around the sites of administration
- Blood and urine samples revealed:
 - No viral shedding
 - No AEs associated with routine labs
 - No antibodies to COL7 detected

RMAT designation
PRIME eligibility
Fast Track Designation Granted
Orphan Drug Designation in US and EU
Rare Pediatric Disease Designation in US
Eligibility for Priority Review Voucher

Pivotal study expected to begin in first half of 2020; BLA filing expected in the second half of 2020

Summary

Dermatology Remains a Great Area of Innovation

- Recent years have seen major clinical improvements in dermatology drug development, as evidenced by improvement in psoriasis with PASI 100 now being a realistic goal for treatment
- The large number of high-quality products in development, spanning different mechanisms of action and routes of administration (oral, biologic, topical) as well as gene therapy across the indications discussed illustrates ongoing innovation
- These therapies have the potential to touch the lives of millions of patients in the US alone (>8 million PsO; >18 million AD; >6 million AA) offering significant improvements in health and QoL
- Significant commercial opportunity
 - Top 10 PsO therapies generating 2018 global sales >\$14 billion in PsO alone
- New leaders emerging (AbbVie, Pfizer, Merck, Regeneron, Incyte, Eli Lilly), with several smaller innovators also entering the scene (Dermira, Krystal, Allakos, Nimbus, Concert, Dermavant, Revance, Novan, Principia)

Indication	Drug	2024E Sales*
PsO	BMS-986165	1,233
PsO	Skyrizi	2,616
PsO	tapinarof	NA
AD	lebrikizumab	248
AD	Rinvoq	NA
AD	Dupixent	4,138
AA	PF-06651600	112
AA	CTP-543	165
CSU	ligelizumab	94
CSU	antolimab	256^
Multiple	bermekimab	NA
DEB	KB103	275
TOTAL		9,137



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01/08/20

DJIA:	28583.70
S&P 500:	3237.18
NASDAQ:	9068.58

OTHER DISCLOSURES

Current Rating Distribution (as of 01/08/20)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	68%	Outperform (Buy)	22%
Market Perform (Hold)	30%	Market Perform (Hold)	8%
Underperform (Sell)	0%	Underperform (Sell)	0%

* Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

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