

Advancing ABC-001 for Treatment of Atopic Dermatitis

Apr. 14, 2023 - ABC Biopharma
Presented by MAKE.it

SITUATION & TASK

ABC aims to launch Phase II for ABC-001, must:

Prioritize AD or PsO?

ACTIONS EXECUTED

Opportunity Analysis

by landscaping market, profitability

RECOMMENDATION

ABC should proceed with Phase II trials in

Atopic Dermatitis

in moderate-severe pediatric, adult cases

NEXT STEPS & KEY CONSIDERATIONS

- Phase II launch for AD
- Determine key candidates for partnerships or royalties to ensure IP security

Monoclonal Antibodies

Also called: mAb



Protein designed to target an antigen to promote an immune response.



Increasing use for various indications incl. cancer, rheumatoid arthritis, COVID-19

Atopic Dermatitis

Also called: AD or Eczema



Chronic disease characterized by flare ups of dry, itchy, inflamed skin



Observation of skin, scalp, and nails. Patch testing may be required



Age of Onset: 90% by 5 y/o, but can occur throughout life



Topical corticosteroids, oral antihistamines, or phototherapy

Plaque Psoriasis

Also called: Psoriasis or PsO



Chronic immune-mediated disease characterized by a rash with itchy, scaly patches



Observation of skin, scalp, knees, and trunk. Biopsy may be required

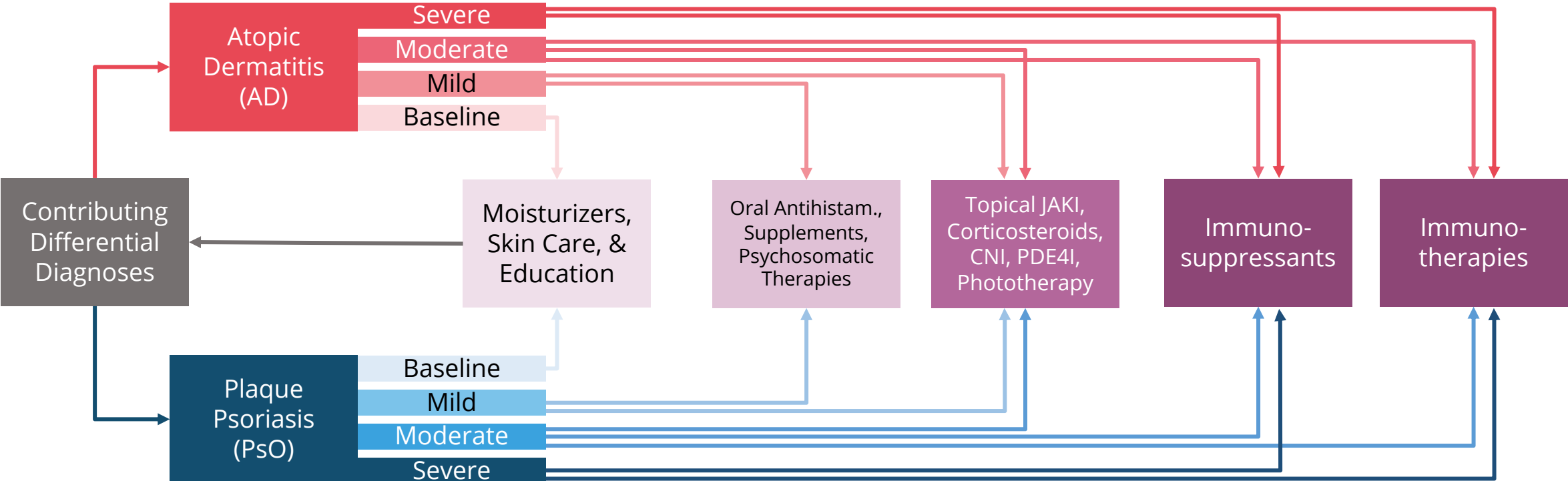


Age of Onset: Bimodal 15-35 y/o OR 50-60 y/o



Topical corticosteroids, oral antihistamines, or phototherapy

Immunotherapies including mAb used as last-line intervention for AD and PsO

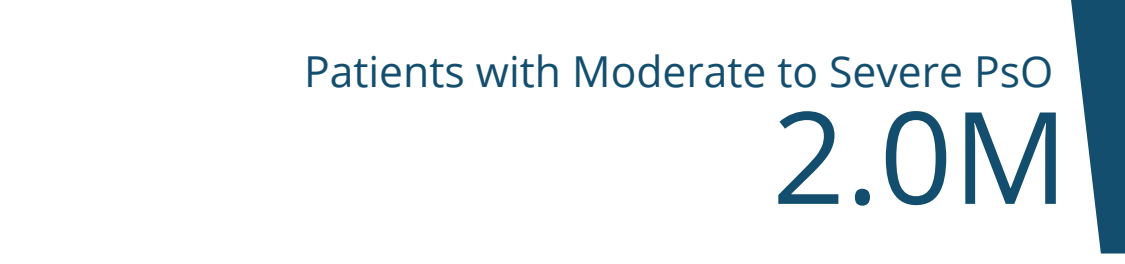
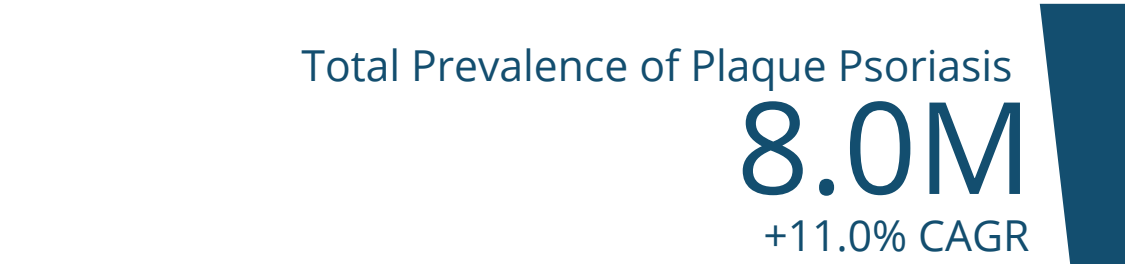


Note: PsO patients w/ psoriatic arthritis may undergo NSAIDs and/or DMARDs first

Larger addressable patient population in AD

Atopic Dermatitis

Plaque Psoriasis



Standards of care for PsO and AD involve similar products, but generic availability varies

		Atopic Dermatitis			Plaque Psoriasis		
ABC-001		Dupixent®	Vanos®	Eucrisa®	Humira®	Clobex®	Otezla®
Competition		Direct	Indirect	Indirect	Direct	Indirect	Indirect
Route of Administration	Injection	Injection	Cream	Cream	Injection	Cream	Oral
Line of Treatment	III	III	I+	II+	III	I+	II+
Estimated Cost/Year	\$32,000	\$32,000	\$278	\$8,659	\$79,980*	\$283	\$43,200

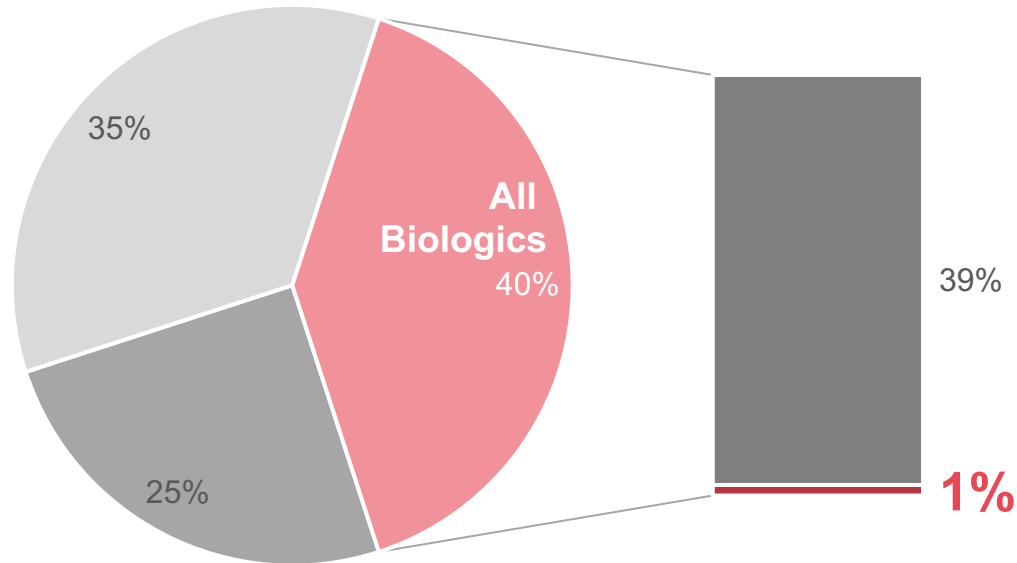
* = Humira biosimilars will enter market in 2023

ABC-001 is anticipated to be **competitively priced** with other third line therapies for both indications



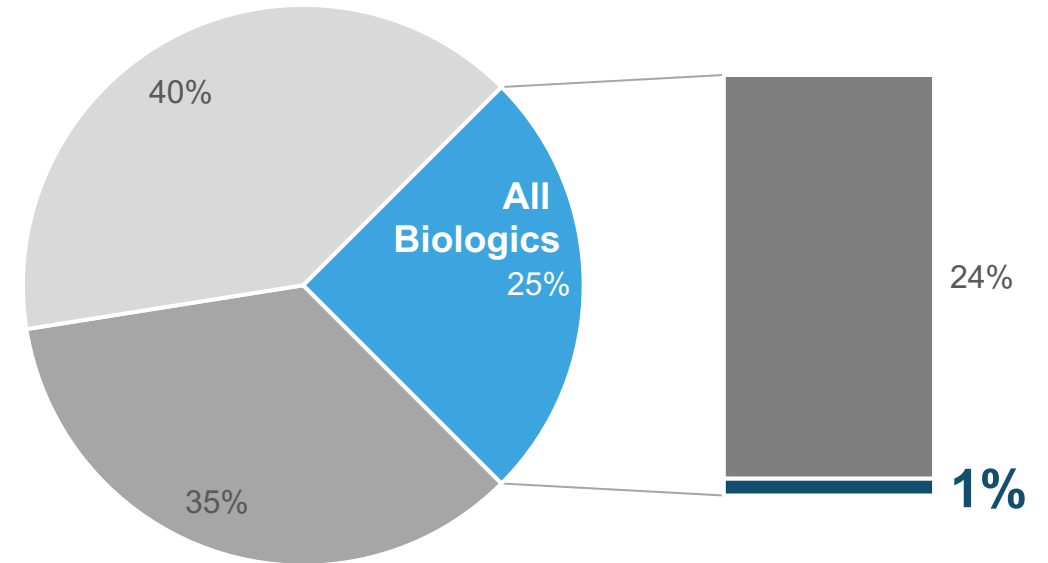
Prospective market share of ABC-001 for all age groups are similar across both indications

US Atopic Dermatitis Treatment Market Size (2030 est. \$7.1B)



- Topicals
- Other Systemic
- Other Biologics
- ABC-001 (Estimated, 2034)

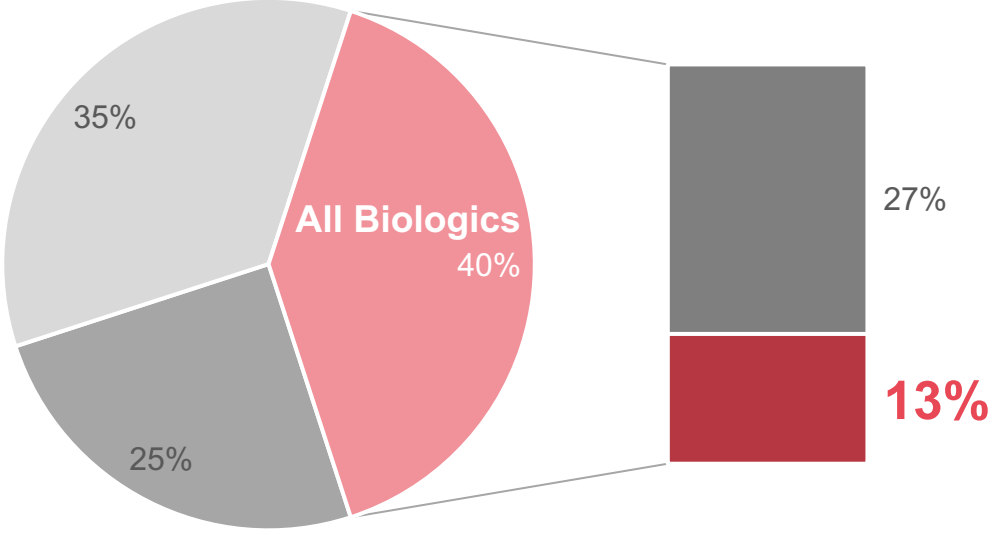
US Psoriasis Treatment Market Size (2030 est. \$11.9B)



- Topicals
- Other Systemic
- Other Biologics
- ABC-001 (Estimated, 2034)

Prospective market share for ABC-001 in AD is significantly larger in pediatric patients

US Pediatric Atopic Dermatitis Treatment Market Size (2030 est. \$7.1B)



■ Topicals ■ Other Systemic ■ Other Biologics ■ ABC-001 (Estimated, 2034)

Children with atopic dermatitis present an attractive opportunity for ABC-001, with only two other competitors anticipated in the biologics space at ABC-001's market entry.

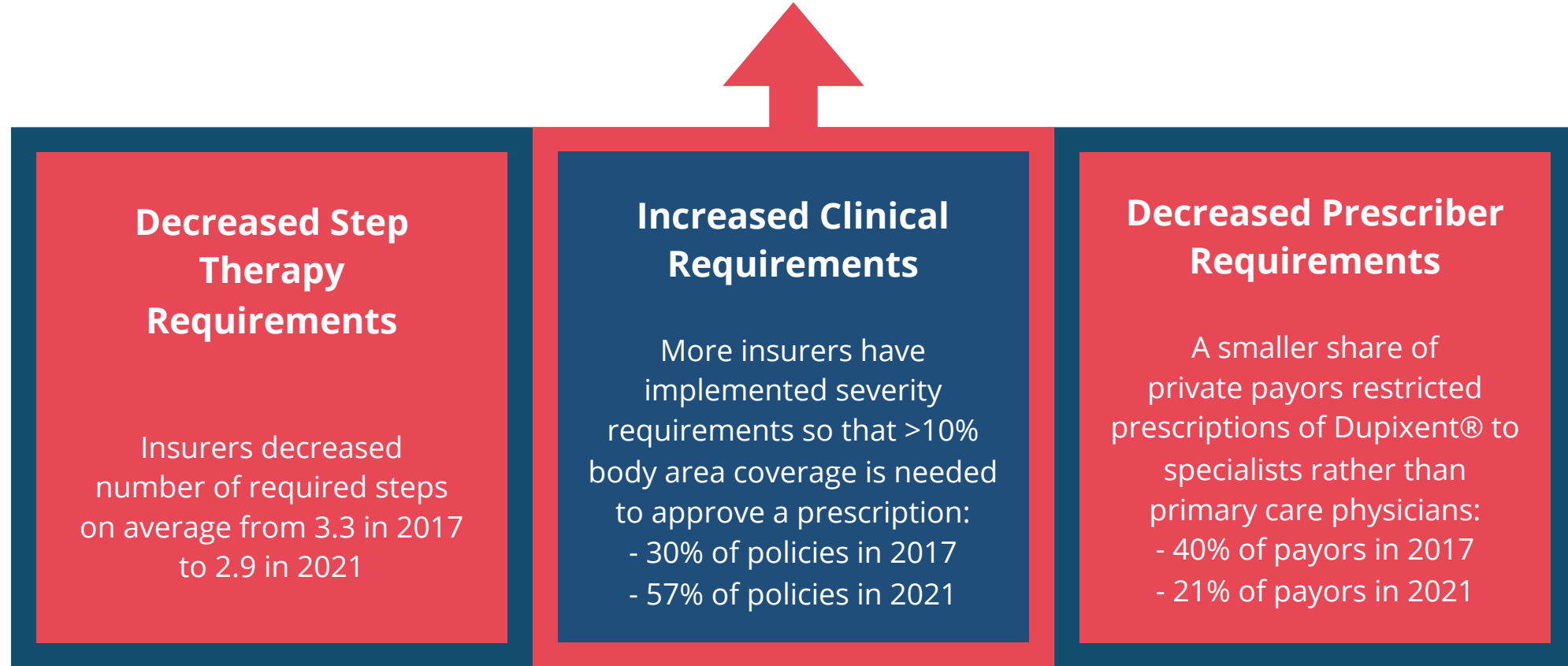


AD faces higher PoS, less competition past Phase 3

	Phase 2	Phase 3	Exclusivity	Generics
Rocatinlimab	2018-20 (AD) PsO Abandoned	TBA (AD) -	TBA (AD) -	Off Patent 2041 if Granted
Dupixent®	2013-14	2014-16 (Adult) 2017-21 (< 6y/o)	2017 (Adult) 2022 (< 5y/o)	Off Patent 2027
Eucrisa®	2017-19	2019-22	2023	
Humira®	2003	2004-07	2008	Off Patent 2016 Alt.s Entered '23
Otezla®	2007-09	2013-16	2017	
AD mAb (PoS)	25	5 (20%)	2 (40%)	None Yet
PsO mAb (PoS)	19	9 (47%)	2 (22%)	1 (50%)

PoS = Probability of Success

Payor coverage is expected to mirror the landscape encountered by Dupixent®



AD presents larger commercial opportunity

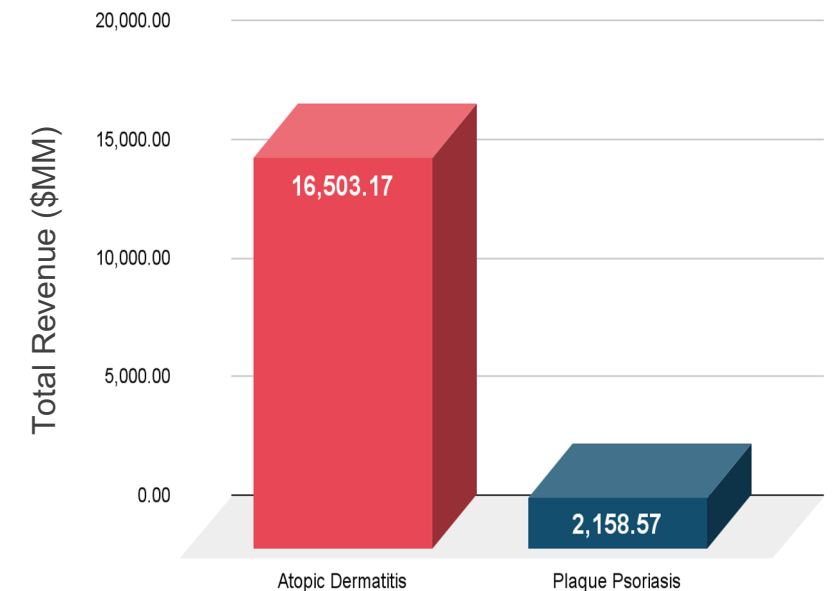
Model Assumptions

- 91.7% of adults, 4.1% of children in US insured
- 11.6% of household income used for healthcare
- 80% of healthcare budget used to treat AD/PsO
- 30% of overall cost is paid out of pocket
- 0.4%/yr US population growth
- Phase II/III trials completed in 2028 (5yrs), based on actual timeline for Dupixent
- 22% initial penetration rate
- Assumed patent start in 2018 based on 5 year Phase I trial

Annual Revenue, 2028-2038



Total Profit through 2038



Our Recommendations

01	Pursue Phase II trials for AD in adults <i>and children</i>	Safety and Efficacy must remain at least comparable to existing therapies
02	List price of ABC-001 should be <\$58k/yr.	Selling at a lower cost than Dupixent will help gain market share in pediatric markets
03	Probability of success for ABC-001 highly depends on IP security	Partnerships or royalties with competitors are critical to minimize risks against infringement



MADIGAN BEDARD
PHD CANDIDATE, PHARMACOLOGY



ALEX BILLINGSLEY
PHD CANDIDATE, BIOMEDICAL ENGINEERING



KEITA YOKOYAMA AND
PHD CANDIDATE, BIOMEDICAL ENGINEERING



EMILY DEVERICKS ARE
PHD CANDIDATE, NUTRITIONAL BIOCHEMISTRY

M A K E ▶ I T

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APPENDIX

Revenue Models: AD and PsO, All Ages

Atopic Dermatitis												
Revenue Build	2023A	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E
US patient population (MM)	3.20	3.26	3.33	3.40	3.47	3.54	3.61	3.68	3.75	3.83	3.91	3.99
% insured	53.38%	53.38%	53.38%	53.38%	53.38%	53.38%	53.38%	53.38%	53.38%	53.38%	53.38%	53.38%
% ability to pay	27.30%	27.30%	27.30%	27.30%	27.30%	27.30%	27.30%	27.30%	27.30%	27.30%	27.30%	27.30%
TAM	0.87	0.89	0.91	0.93	0.95	0.97	0.98	1.00	1.03	1.05	1.07	1.09
% Getting Systemic Treatment	22%	30%	31%	33%	34%	34%	35%	35%	0.35	0.35	0.35	0.35
ABC-001 Market Share		14%	16%	19%	21%	21%	19%	16%	14%	13%	12%	11%
People receiving ABC-001 (MM)		0.036	0.046	0.057	0.068	0.067	0.063	0.058	0.052	0.046	0.043	0.040
Cost per yearly treatment (\$)		\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00
Revenue (\$MM)		\$1,154.06	\$1,467.09	\$1,814.97	\$2,167.09	\$2,159.16	\$2,017.61	\$ 1,852.11	\$ 1,659.89	\$ 1,470.55	\$ 1,380.75	\$ 1,286.73

Plaque Psoriasis												
Revenue Build	2023A	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E
US patient population (MM)	0.25	0.421	0.468	0.519	0.576	0.64	0.71	0.788	0.875	0.971	1.078	1.196
% insured	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%
% ability to pay	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%
TAM	0.11	0.185	0.205	0.227	0.252	0.28	0.311	0.345	0.383	0.425	0.472	0.524
% Getting Systemic Treatment	22%	30%	31%	33%	34%	34%	35%	35%	35%	35%	35%	35%
ABC-001 Market Share		0.98%	1.40%	2.00%	2.86%	4.08%	5.83%	8.33%	8.33%	8.33%	8.33%	8.33%
People receiving ABC-001		543	890	1,502	2,454	3,891	6,351	10,071	11,178	12,408	13,773	15,288
Cost per yearly treatment (\$)		\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00
Revenue (\$MM)		\$17.37	\$28.47	\$48.06	\$78.51	\$124.50	\$203.22	\$322.26	\$357.70	\$397.05	\$440.73	\$489.21

Revenue Model: AD, by Age Group

Atopic Dermatitis (Age < 18yrs)												
Revenue Build	2023A	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E
US patient population (MM)	1.40	1.43	1.46	1.49	1.52	1.55	1.58	1.61	1.64	1.68	1.71	1.74
% insured	4.10%	4.10%	4.10%	4.10%	4.10%	4.10%	4.10%	4.10%	4.10%	4.10%	4.10%	4.10%
% ability to pay	6.07%	6.07%	6.07%	6.07%	6.07%	6.07%	6.07%	6.07%	6.07%	6.07%	6.07%	6.07%
TAM	0.08	0.09	0.09	0.09	0.09	0.09	0.10	0.10	0.10	0.10	0.10	0.11
% Getting Systemic Treatment	22%	30%	31%	33%	34%	34%	35%	35%	0.35	0.35	0.35	0.35
ABC-001 Market Share		25%	28%	31%	34%	35%	33%	30%	28%	27%	26%	25%
People receiving ABC-001 (MM)		0.006	0.008	0.009	0.010	0.011	0.011	0.010	0.010	0.010	0.009	0.009
Cost per yearly treatment (\$)		\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00
Revenue (\$MM)		\$204.50	\$245.54	\$290.74	\$335.32	\$357.40	\$348.82	\$ 328.19	\$ 312.50	\$ 307.42	\$ 302.01	\$ 296.26

Atopic Dermatitis (Age > 18yrs)												
Revenue Build	2023A	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E
US patient population (MM)	1.80	1.84	1.87	1.91	1.95	1.99	2.03	2.07	2.11	2.15	2.20	2.24
% insured	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%	91.70%
% ability to pay	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%	43.82%
TAM	0.79	0.80	0.82	0.84	0.85	0.87	0.89	0.91	0.93	0.94	0.96	0.98
% Getting Systemic Treatment	22%	30%	31%	33%	34%	34%	35%	35%	0.35	0.35	0.35	0.35
ABC-001 Market Share		13%	15%	18%	20%	19%	17%	15%	13%	11%	10%	9%
People receiving ABC-001 (MM)		0.030	0.038	0.048	0.057	0.056	0.052	0.048	0.042	0.036	0.034	0.031
Cost per yearly treatment (\$)	32000	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00	\$32,000.00
Revenue (\$MM)		\$949.56	\$1,221.55	\$1,524.22	\$1,831.77	\$1,801.76	\$1,668.79	\$ 1,523.92	\$ 1,347.35	\$ 1,163.05	\$ 1,078.64	\$ 990.34

Commercial Opportunity: AD and PsO

Atopic Dermatitis											
Commercial Opportunity	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E
Revenue (\$MM)	\$ 1,154.06	\$ 1,467.09	\$ 1,814.97	\$ 2,167.09	\$ 2,159.16	\$ 2,017.61	\$ 1,852.11	\$ 1,659.89	\$ 1,470.55	\$ 1,380.75	\$ 1,286.73
Operating Costs											
Cost of sales (\$MM)	\$ 114.40	\$ 145.43	\$ 179.91	\$ 214.81	\$ 214.03	\$ 200.00	\$ 183.59	\$ 164.53	\$ 145.76	\$ 136.85	\$ 127.53
R&D cost (\$MM)	\$ 100.00	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Profit	\$ 939.66	\$ 1,321.66	\$ 1,635.06	\$ 1,952.27	\$ 1,945.13	\$ 1,817.61	\$ 1,668.52	\$ 1,495.36	\$ 1,324.79	\$ 1,243.90	\$ 1,159.20

Plaque Psoriasis											
Commercial Opportunity	2028E	2029E	2030E	2031E	2032E	2033E	2034E	2035E	2036E	2037E	2038E
Revenue (\$MM)	\$17.37	\$28.47	\$48.06	\$78.51	\$124.50	\$203.22	\$322.26	\$357.70	\$397.05	\$440.73	\$489.21
Operating Costs											
Cost of sales (\$MM)	\$1.72	\$2.82	\$4.76	\$7.78	\$12.34	\$20.14	\$31.94	\$35.46	\$39.36	\$43.69	\$48.49
R&D cost (\$MM)	\$100.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Profit	(\$84.35)	\$25.65	\$43.29	\$70.73	\$112.16	\$183.08	\$290.31	\$322.25	\$357.69	\$397.04	\$440.72

Citations

Slide 3: Indication and mAb Basic Overview

<https://www.mayoclinic.org/diseases-conditions/atopic-dermatitis-eczema/diagnosis-treatment/drc-20353279>

<https://www.mayoclinic.org/diseases-conditions/psoriasis/symptoms-causes/syc-20355840>

<https://www.verywellhealth.com/monoclonal-antibody-6890067>

Slide 4: Immunotherapies as Last-Line Intervention for AD and PsO

<https://allergyasthmanetwork.org/what-is-eczema/eczema-statistics/>

<https://aafa.org/wp-content/uploads/2022/08/Atopic-Dermatitis-in-America-Study-Overview.pdf>

<https://nationaleczema.org/research/eczema-facts/>

Slide 5: Larger Addressable Patient Population in AD

AD:

[Inadequate Disease Control, Treatment Dissatisfaction, and Quality-of-Life Impairments Among US Patients Receiving Topical Therapy for Atopic Dermatitis \(nih.gov\)](#)

<https://aafa.org/asthma-allergy-research/our-research/atopic-dermatitis-in-america>

BCC Research: Global Markets for Allergy Diagnostics and Treatments

PsO:

<https://www.psoriasis.org/psoriasis-statistics>

<https://www.who.int/publications/i/item/9789241565189>

BCC Research: Immunotherapy Drugs Global Markets Report 2021, Autoimmune Disorder Therapies 2020

Citations, Continued

Slide 6: Competitive Analysis: Current Standard of Care

Drug pricing estimates: <https://www.goodrx.com/>
<https://www.aad.org/member/clinical-quality/guidelines/psoriasis>
<https://www-ncbi-nlm-nih-gov.libproxy.lib.unc.edu/pmc/articles/PMC8470589/>

Slides 7 and 8: Competitive Analysis: Prospective Market Share

AD:
Fenske, C., Boytsov, N., Guo, J. *et al.* Prescription Market Share and Treatment Patterns in Atopic Dermatitis: A Retrospective Observational Study Using US Insurance Claims. *Adv Ther* 39, 2052–2064 (2022). <https://doi.org/10.1007/s12325-022-02071-y>
Pantazi, E., Valenza, G., Hess, M. *et al.* The atopic dermatitis market. *Nat Rev Drug Discov* 17, 237–238 (2018).
<https://doi.org/10.1038/nrd.2017.192>
<https://www.arizton.com/market-reports/atopic-dermatitis-treatment-market>

PsO:
<https://www.globaldata.com/store/report/plaque-psoriasis-market-analysis/>
<https://www.grandviewresearch.com/industry-analysis/psoriasis-drugs-market>
<https://www.thebusinessresearchcompany.com/report/psoriasis-drugs-global-market-report>

Citations, Continued

Slide 9: Regulatory Process Comparison

Clinical Trials Data:

<https://clinicaltrials.gov/ct2/results?term=Drug%2C+Monoclonal+Antibody&type=Intr&cond=Atopic+Dermatitis&draw=2&rank=24#rowId23>

<https://clinicaltrials.gov/ct2/results?cond=Plaque+Psoriasis&term=Drug%2C+Monoclonal+Antibody&Search=Search&type=Intr>

Additional Information on Competition:

<https://www.npr.org/sections/health-shots/2023/01/31/1152513058/>

["AbbVie 'comfortable' after Humira biosim launch, as CEO forecasts 'stable' sales for star med into next year", Fierce Pharma, Feb 9, 2023](#)

["3 Challenges to Patents on Therapeutic Monoclonal Antibodies", Harvard Law School Bill of Health \(blog\), Mar. 3, 2021](#)

[Rocatinlimab patent](#)

[Humira patent](#)

Slide 10: Payor Coverage Landscape *in re* Dupixent®

[US Commercial Payer Coverage of Dupilumab Varies Widely - Center for the Evaluation of Value and Risk in Health \(tuftsmedicalcenter.org\)](#)

Citations, Continued

Slide 11: AD provides greater commercial opportunity by patent expiration

Farid SS, Baron M, Stamatis C, Nie W, Coffman J. Benchmarking biopharmaceutical process development and manufacturing cost contributions to R&D. *MAbs*. 2020 Jan-Dec;12(1):1754999. doi: 10.1080/19420862.2020.1754999. PMID: 32449439; PMCID: PMC7531566.

[U.S. Health Care Coverage and Spending \(fas.org\)](#)

<https://www.statista.com/statistics/631987/percent-of-income-spent-on-health-plan-by-us-employees/>

<https://medicaid.ncdhhs.gov/pdlapril-1-2023revised-03292023/download?attachment>

<https://www.macrotrends.net/countries/USA/united-states/population-growth-rate>