cellceutix™

8 July2016

Cellceutix Corporation

100 Cummings Center

Beverly, MA

July 2016

Ticker: CTIX

Safe Harbor Forward-Looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 that involve risks, uncertainties and assumptions that could cause Cellceutix's actual results and experience to differ materially from anticipated results and expectations expressed in these forward looking statements. Cellceutix has in some cases identified forward-looking statements by using words such as "anticipates," "believes," "hopes," "estimates," "looks," "expects," "plans," "intends," "goal," "potential," "may," "suggest," and similar expressions. Such forward- looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Among other factors that could cause actual results to differ materially from those expressed in forward-looking statements are Cellceutix's need for, and the availability of, substantial capital in the future to fund its operations and research and development; including the amount and timing of the sale of shares of common stock to Aspire Capital; the fact that Cellceutix's compounds may not successfully complete pre-clinical or clinical testing, or be granted regulatory approval to be sold and marketed in the United States or elsewhere. A more complete description of these risk factors is included in Cellceutix's filings with the Securities and Exchange Commission. You should not place undue reliance on any forward-looking statements. Cellceutix undertakes no obligation to release publicly the results of any revisions to any such forward-looking statements that may be made to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events, except as required by applicable law or regulation.

Management Team

Name	Title	
Leo Ehrlich, CPA	Chief Executive Officer, Chief Financial Officer	Co-Founder, Cellceutix; Investor
Krishna Menon, PhD, DVM	Chief Scientific Officer	Co-Founder, Cellceutix
Arthur P. Bertolino, MD, PhD, MBA	President, Chief Medical Officer	

Board of Directors: Leo Ehrlich, CPA; Krishna Menon, PhD, DVM; Barry Schechter, MD; Zorik Spektor, MD; Mark Tobin, MBA

Dermatology Overview

Lead Compounds/Target Indications

Prurisol™ *Safe, effective orally-delivered anti-psoriasis compound entering Phase 2b trial under 505(b)(2) development pathway*

- Psoriasis

Brilacidin *Member of a new class of antibiotics with unique immunomodulatory properties advancing to multiple late-stage FDA trials*

- Hidradenitis Suppurativa
- Acne
- Atopic Dermatitis

(Oncology application: Oral Mucositis)

Cellceutix Pipeline – Dermatology

Product	Indication	Pre-clinical	Phase 1	Phase 2	Phase 3
Dermatology					
Prurisol	Psoriasis [1]				
Brilacidin	Hidradenitis suppurativa [2,3,4]				
	Acne, Atopic dermatitis [2,3,4]				

[1] Being developed under FDA 505(b)(2) pathway
[2] Leveraging safety data from Phase 2 ABSSSI trials to later-stage trials in other indications
[3] Dermal toxicology studies may be required and will be discussed with FDA
[4] Topical formulation is under development

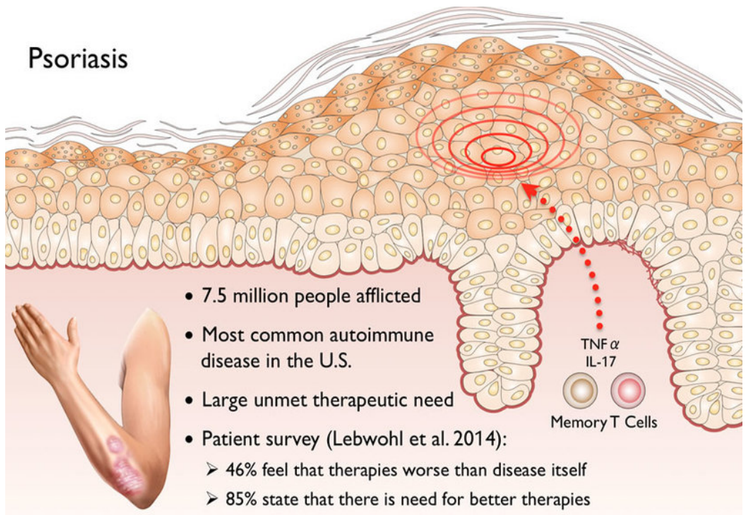
Leveraging data from previous studies to proceed into later phases

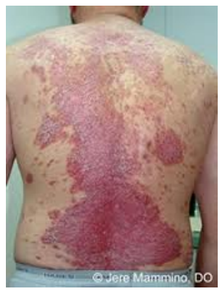
Dermatology Program

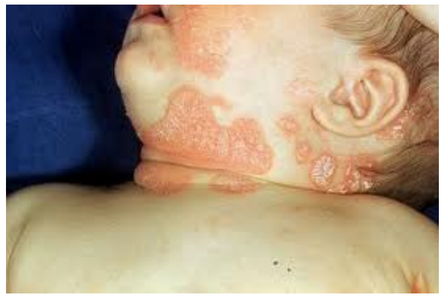
Psoriasis

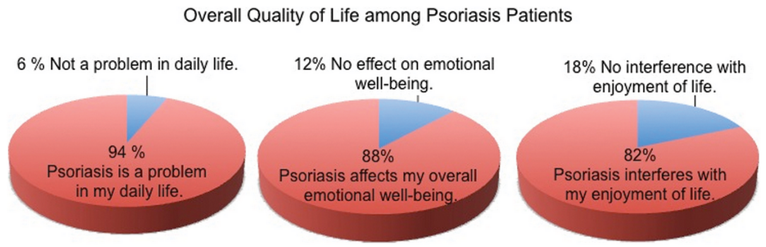
Debilitating Chronic Disease that Affects Millions

84% of those with moderate to severe psoriasis report suffering discrimination and humiliation.









Sources:
https://www.novartis.com/news/media-releases/largest-global-psoriasis-survey-shows-84-people-face-discrimination-and
http://www.cytherapharm.com/
http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0052935

Psoriasis
Costly to Treat, for Patients and for Society

The total cost burden of psoriasis estimated to be between $35 billion and $63 billion.

Figure 1. Adjusted Monthly Cost per PASI 75 at 1 Year[6]

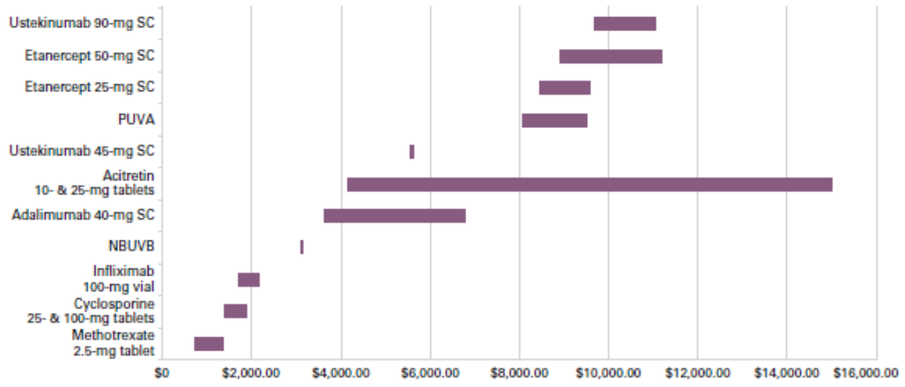


Figure 2. All-Cause Healthcare Costs in Patients With Moderate to Severe Psoriasis[3]

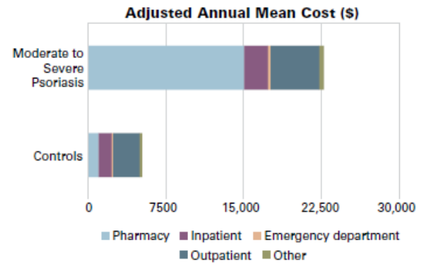
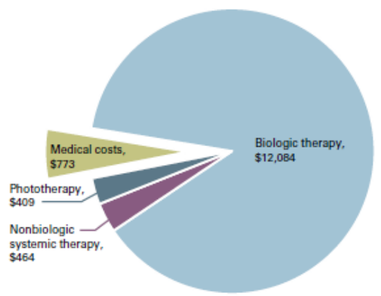
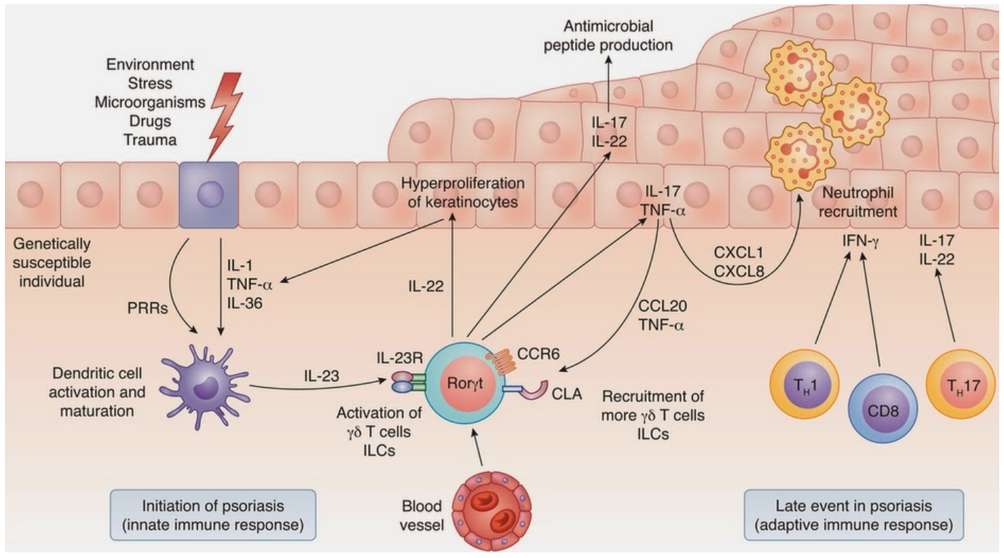


Figure 3. Psoriasis-Related Costs in Moderate to Severe Psoriasis: Treatment Versus Medical Costs[3]



Sources:
C. Evans, "Managed Care Aspects of Psoriasis and Psoriatic Arthritis," *Am J Manag Care.* 2016;22:S238-S243.
A. Menter, "Psoriasis and Psoriatic Arthritis," *Am J Manag Care.* 2016;22:S225-S237. 8 July2016

Psoriasis
Complex Pathogenesis with No Known Cure



Key Characteristics:

- A chronic, autoimmune disease that exhibits symptoms in the form of irritated, flaky skin.
- Increased proliferation and hyperplasia of the epidermal cells.
- Enhanced proliferation of keratinocytes in the psoriatic plaques.
- Growth cycle of skin cells is accelerated by faulty immune signals.
- Inflammatory skin disease in which neutrophils are associated with psoriatic lesions.
- Psoriasis-associated non-protein coding RNA induced by stress (PRINS) in psoriatic lesions and plasma IL-20 are increased.
- In psoriatic lesions, cyclic adenosine monophosphate (cAMP) levels are decreased, which may result in diminished regulation of cell division due to less activation of protein kinase.

Sources:
http://www.clinsci.org/content/120/1/1
http://www.nature.com/nri/journal/v9/n10/full/nri2622.html
http://pharmacytoday.org/article/S1042-0991(15)00025-0/pdf

Psoriasis

Condition Presents with Serious Co-Morbidities

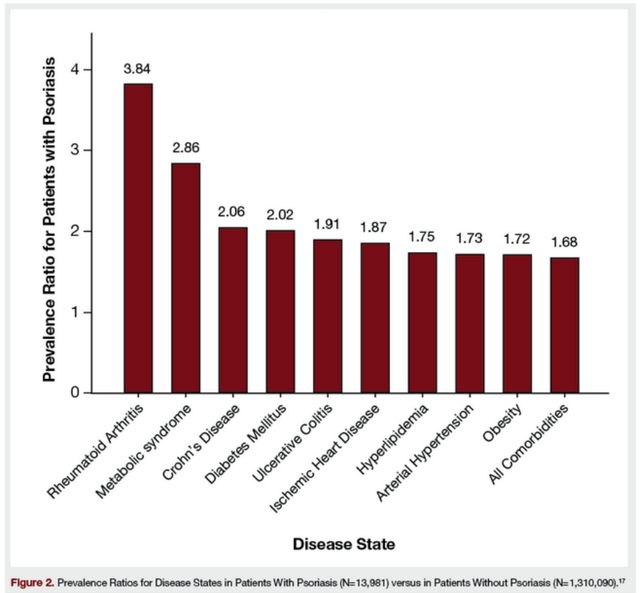
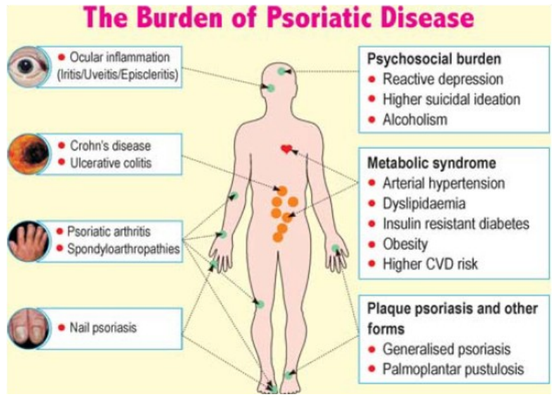


Figure 2. Prevalence Ratios for Disease States in Patients With Psoriasis (N=13,981) versus in Patients Without Psoriasis (N=1,310,090).[17]

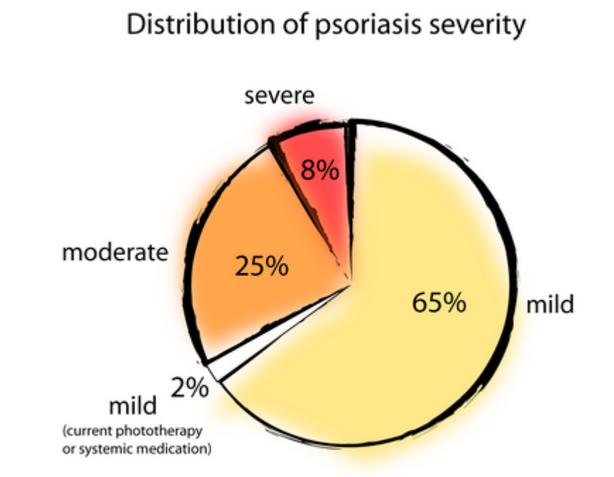


At a greater risk of developing infections

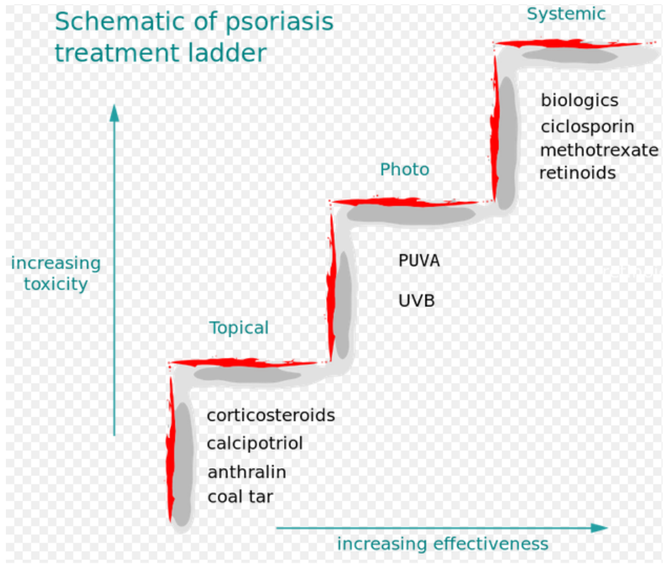
Sources:
http://www.journalofclinicalpathways.com/formulary-decisions-and-evolution-psoriasis-treatment
http://www.ijdvl.com/viewimage.asp?img=ijdvl_2013_79_7_10_115506_f2.jpg

Psoriasis

As Severity Increases, so too Does Treatment Toxicity…



Source: National Psoriasis Foundation (random sample of 278 adults with psoriasis



Source:
https://en.wikipedia.org/wiki/Psoriasis#/media/File:Psoriasis_treatment_ladder.svg

Psoriasis

… *Even as Systemics, Especially Biologics, Prove Efficacious*

Agent	Psoriasis			Psoriatic arthritis					
	Study	*N*	PASI 75/pbo (%)	Study	*N*	ACR20/pbo (%)	D/E +/–	Axial +/–	X-ray +/–
Secukinumab	Juncture	676	87/3.3	Future 2	397	54/7	–	ND	ND[a]
Ixekizumab	Uncover 2	1224	90/48	RHAP	417	60/31	+/–	ND	+
Brodalumab	Amagine 2	1831	86/8	Phase II	168	39/18	–	–	–
Tildrakizumab	Phase IIb	355	74/4	ND	ND	ND	ND	ND	ND
Guselkumab	Phase II	293	81/5	ND	ND	ND	ND	ND	ND
Apremilast	Esteem 1	844	33/5	PALACE 1	504	31/19	–	–	–

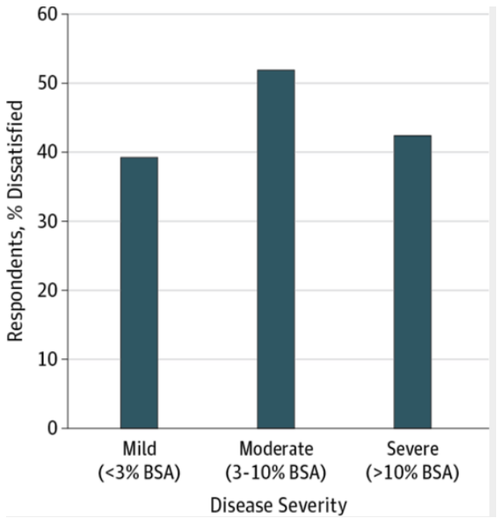
Source: "New Therapies for Psoriasis and Psoriatic Arthritis"
Christopher T. Ritchlin; James G. Krueger
Curr Opin Rheumatol. 2016;28(3):204-2 (May 2016)
http://www.medscape.com/viewarticle/861898

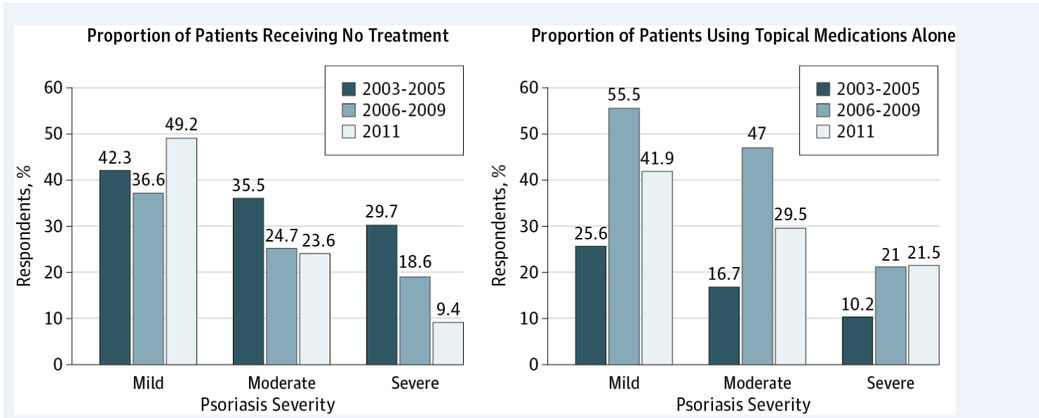
Also see: "Safety and Efficacy of Methotrexate in Psoriasis: A Meta-Analysis of Published Trials" (May 2016) http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0153740; "Efficacy and safety of systemic treatments for moderate-to-severe psoriasis: meta-analysis of randomized controlled trials" (February 2014) http://onlinelibrary.wiley.com/doi/10.1111/bjd.12663/full

Psoriasis

Dissatisfied, Patients Switch Treatment or Go Off It Altogether

55% of those with moderate to severe psoriasis do not believe "clear" or "almost clear" skin is a realistic goal.





Sources:
https://www.novartis.com/news/media-releases/largest-global-psoriasis-survey-shows-84-people-face-discrimination-and
http://archderm.jamanetwork.com/article.aspx?articleid=1729130

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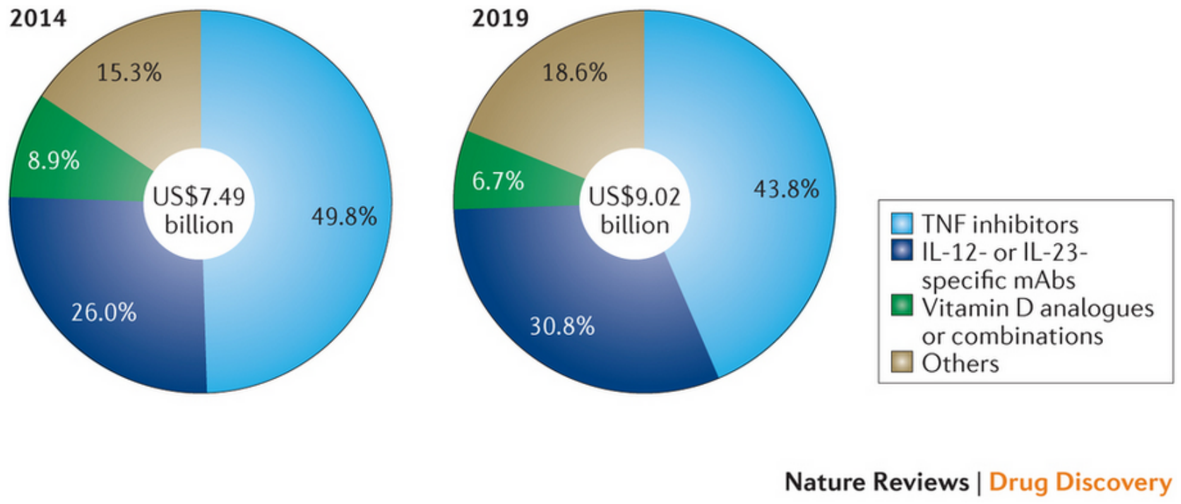
Psoriasis

Multi-Billion Dollar Market Expected to Become Even Larger



Source: http://www.nature.com/nrd/journal/v14/n11/full/nrd4763.html

Prurisol™

*Safe, Effective, Orally-Delivered Anti-Psoriasis Compound**

Prurisol (abacavir acetate), an ester of abacavir, is being developed under a **505(b)(2)** development pathway for the treatment of psoriasis with the advantage of an established safety profile based on Ziagen® (abacavir sulfate)

Key Attributes:

- Oral dosing (better patient compliance)
- Safe and well-tolerated
- Efficacy in humans may be superior to approved oral treatment
- Small-molecule (<500 MW)
- Bioavailable
- Robust *in vivo* activity
- Efficacy in xenograft model
- Five-step manufacturing process
- Strong IP / Patent Protections

Mechanism of Action:

- Mechanism acts through immune modulation and PRINS reduction
  - Reduces
    - IL-20
    - Skin cell proliferation rate

* based on Phase 2 data

Prurisol™

Intellectual Property and Patent Overview

Granted Patents

United States (Patent No 8895569) (Composition of Matter claim)
"Carbocylic Nucleosides and Their Pharmaceutical Use and Compositions"
Abstract: Abstract of the Disclosure Disclosed are compounds of the formula I and the pharmaceutically acceptable salts of such compounds. Also disclosed are processes for the preparation of such compounds, intermediates used in the preparation of such compounds, and the uses of such compounds in treating inflammatory skin diseases.
Australia (Patent No 2012363635)
Singapore (Patent No 11201404291T)
Taiwan (Patent No 1481611)

European Patent Office – application allowed on June 15, 2016 (grant will follow after formal steps completed).

Patents Expire 2032
(505(b)(2) pathway adds 3 to 5 years of market exclusivity in the U.S.)

Pending Patents

Argentina, Bangladesh, Brazil, Canada, China, Eurasian Patent Office, Hong Kong, India, Israel, Japan, Malaysia, Mexico, Pakistan, South Korea, Thailand.

A patent also is pending on the manufacturing process for Prurisol.

Prurisol™

Clinical Literature Supporting Mechanism of Action

PRINS / CD8 / IL-20

•“PRINS, a primate-specific long non-coding RNA, plays a role in the keratinocyte stress response and psoriasis pathogenesis” Pflügers Archiv - *European Journal of Physiology* (June 2016, Volume 468, Issue 6, pp 935–943).

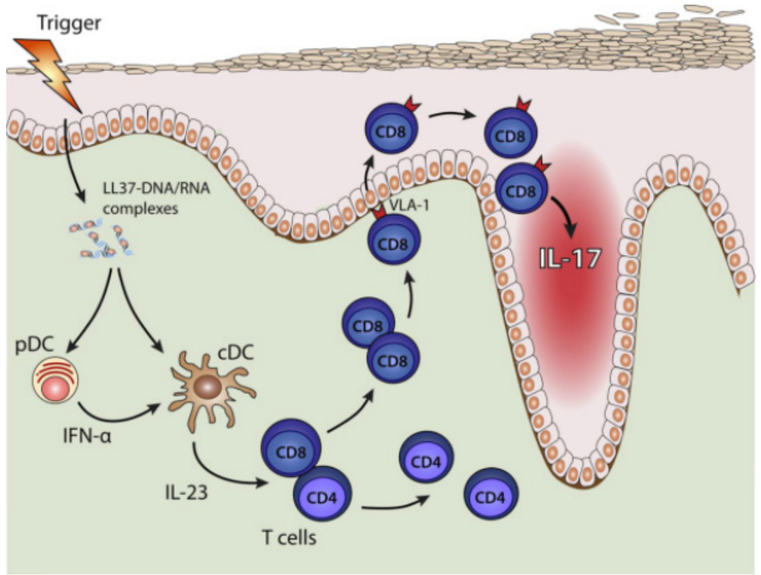
•“Targeting CD8+ T cells prevents psoriasis development.” ScienceDirect - *Journal of Allergy and Clinical Immunology* (January 9 2016; Letter to the Editor).

•“CD8(+) T cells in the lesional skin of atopic dermatitis and psoriasis patients are an important source of IFN-γ, IL-13, IL-17, and IL-22.” Hijnen D, et al. *J Invest Dermatol*. 2013.

•“Interleukin-20 as a target in psoriasis treatment.” *Ann N Y Acad Sci*. 2007 Sep;1110:368-81.

•“Interleukin-20 plays a critical role in maintenance and development of psoriasis in the human xenograft transplantation model.” *Br J Dermatol*. 2009 Feb;160(2):284-96.

•“Interleukin 20 regulates dendritic cell migration and expression of co-stimulatory molecules.” *Molecular and Cellular Therapies*



Source: http://www.sciencedirect.com/science/article/pii/S0091674915017352

Prurisol™

Pre-Clinical In Vivo Studies (KM-133) (Design)

A: SCID Mice

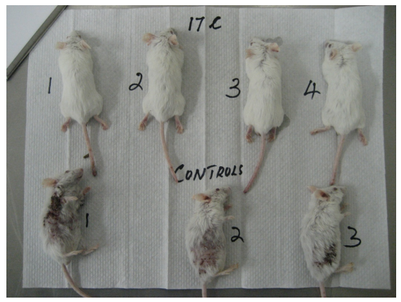
- TBI followed by transplant of human psoriatic skin xenograft
  - Controls
  - Prurisol (KM-133) 10 mg/kg once/day for 3 weeks
  - Prurisol (KM-133) 10 mg/kg twice/day for 3 weeks
  - MTX 7.5 mg/kg IP daily for 5 days
- Dose regimen: Oral administration
- Endpoints:
  - Clinical observations
  - Histology
  - PRINS in tissue
  - IL-20 in plasma
- Animals were followed for 140 days

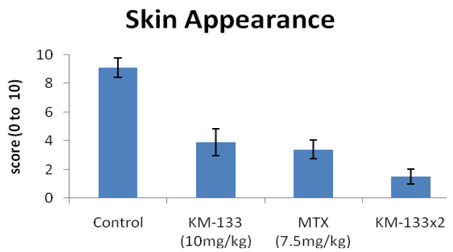
B: CD-1 Immunocompetent Mice

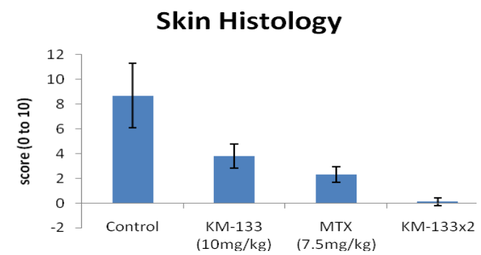
- Controls
  - Prurisol (KM-133) PO 10 mg/kg once/day for 3 weeks
  - Prurisol (KM-133) PO10 mg/kg twice/day for 3 weeks
  - Efalizumab 3 mg/kg SC once weekly for 3 weeks
- Endpoints:
  - CD4+ T cells in plasma
  - CD8+ T cells in plasma

Prurisol™

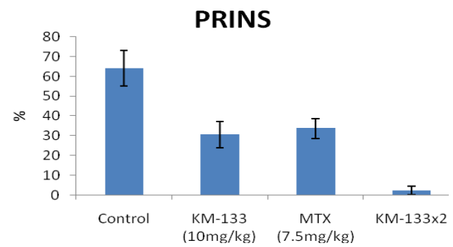
Pre-Clinical In Vivo Studies (KM-133) (Results)

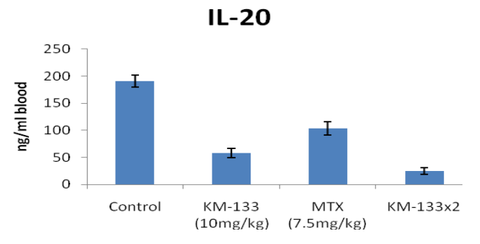






- **Oral treatment with Prurisol improved psoriatic lesions – confirmed by histology**
- **Mechanisms: Reduced PRINS expression and plasma levels of IL-20**

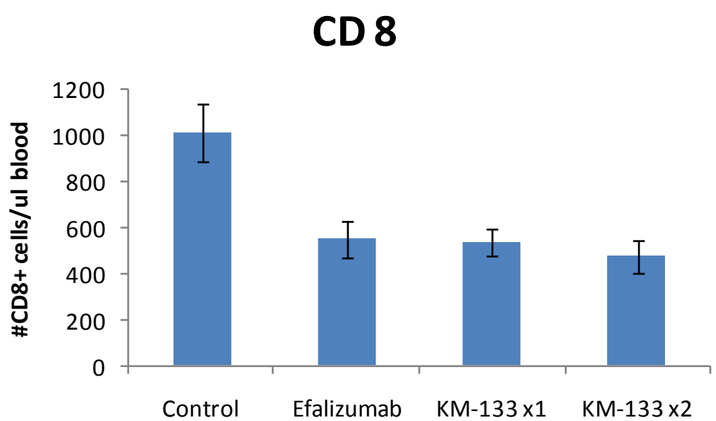


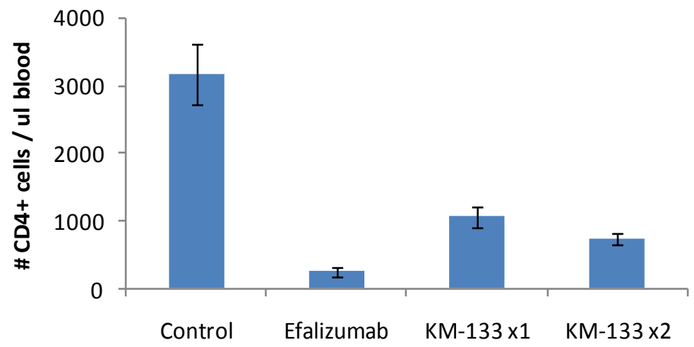


PRINS (Psoriasis-associated non-protein coding RNA induced by stress) assayed by RT-PCR expressed as PRINS RNA expression relative to normal tissue; Plasma IL-20 was not assayed in Efalizumab-treated animals.

Prurisol™

Pre-Clinical In Vivo Studies (KM-133) (Biomarkers)



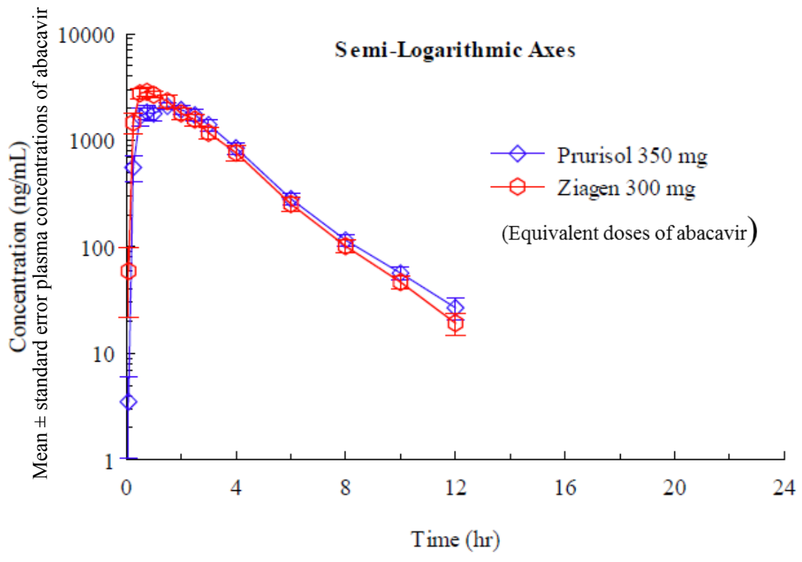


- Both Prurisol and Efalizumab affected immune function indicated by the reduction in CD8+ and CD4+ T cell populations, however, Efalizumab induced a greater reduction in CD4+ T cell populations than did Prurisol.
- In the clinic, when patients are treated with Efalizumab, physicians will suspend treatment if the CD4+ T cell counts fall below 250 /µl, then will resume once the CD4+ T cell count improves.
- Prurisol reduced CD4+ T cell levels but not below levels where treatment would need to be suspended.

Prurisol™

CTIX-0001 – Single-Dose, Crossover Pharmacokinetic and Bioequivalence Study Evaluating Oral Abacavir Acetate (Prurisol™) and Oral Abacavir Sulfate (Ziagen®) in Healthy Volunteers

AUC values were comparable for both Prurisol and Ziagen, within 80% to 125% equivalence window, indicating equivalent systemic exposure.
No serious adverse events, or other significant adverse events occurred over the course of the study.



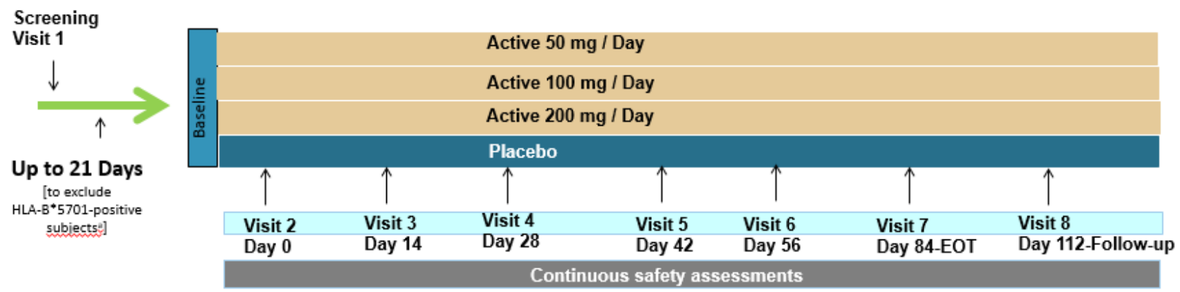
Parameter*	Prurisol 350 mg	Ziagen 300 mg
Cmax (ng/mL)	2,816 ± 703 (16)	3,617 ± 885 (16)
Tmax (hr)	0.88 (16) [0.50 – 2.50]	0.75 (16) [0.25 – 2.50]
AUC(0-t) (hr×ng/mL)	7,781 ± 2,072 (16)	8,420 ± 2,573 (16)
AUC(inf) (hr×ng/mL)	7,901 ± 2,079 (16)	8,523 ± 2,582 (16)
λz (1/hr)	0.3854 ± 0.1103 (16)	0.4033 ± 0.1183 (16)
t½ (hr)	2.00 ± 0.84 (16)	2.02 ± 1.30 (16)
CL/F (L/hr)	46.0 ± 12.8 (16)	38.5 ± 12.2 (16)
Vz/F (L)	136 ± 78.1 (16)	109 ± 67.5 (16)

*Arithmetic mean ± standard deviation except for Tmax for which the median range is reported. (N) Number of subjects.

For study details, see https://clinicaltrials.gov/ct2/show/NCT02101216

Prurisol™

CTIX-0002 – Phase 2 Study Design for Active Mild-to-Moderate Plaque Psoriasis



Dose Groups:
50 mg: **AM**: 1 Placebo & 1 Active **PM**: 2 Placebo
100 mg: **AM**: 1 Placebo & 1 Active **PM**: 1 Placebo &1 Active
200 mg: **AM**: 2 Active **PM**: 2 Active
Placebo: **AM**: 2 Placebo **PM**: 2 Placebo

- **Trial conducted at 9 sites in U.S.**
- **Prurisol (*abacavir acetate*) 50 mg tablets and matching placebo**
- **Dosing: BID for 84 days**
- **115 subjects, 4 arms, ~29 subjects per arm**

Primary efficacy endpoint: percentage of subjects with ≥ 2 point improvement in IGA rating at 84 days.
Investigator Global Assessment (IGA) rating: clear (0), almost clear (1), mild (2), moderate (3), severe (4)

Ziagen has risk of hypersensitivity reaction in those who carry the HLA-B*5701 allele. Allele frequency 1% to 6% depending on ethnicity.

The study screened 153 subjects, with 115 enrolling. 38 failed screening; 16 had HLA-B5701 allele as the reason for screen failure. This rate (153/16 or 10.5%) is comparable to rates reported in the literature of 12.5%. For more info on HLA-B5701, see http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4422545/; http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm123927.htm http://www.gbcbiotech.com/farmacogenomica/guias/abacavir/CPIC%20Guidelines%20for%20HLAB%20genotype%20and%20Abacavi%20dosingr_Supplemental_Material.pdf

For study details, see https://clinicaltrials.gov/ct2/show/NCT02494479

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Prurisol™

CTIX-0002 – Phase 2 Topline Clinical Trial Results

- A Phase 2 trial of Prurisol in patients with **mild-to-moderate** chronic plaque psoriasis was completed in May 2016.
  - **Prurisol met the primary endpoint (a 2-point IGA reduction) in 35% of all patients who received a dose of 200mg per day.** Had one site, where investigator non-compliance was suspected to have occurred been removed from overall data analyses, **43%** of patients in the 200mg dosing arm would have met the primary endpoint.
  - Among patients with the severest form of psoriasis, those having a baseline IGA score of 3 ("moderate"), the primary endpoint was met in **46%** of patients who received 200mg per day. This data was derived from analyses of all patients.
  - Patients who received any dose of Prurisol, regardless of the treatment arm, had a 1-point IGA improvement.
  - Patients reported improved general skin condition, e.g., skin felt moist and smoother.
  - Prurisol was well-tolerated—**just one Serious Adverse Event (SAE)** occurred and it was in the 50mg dose group.
  - PK results showed **a dose-dependent** increase in exposure and maximum plasma concentration of the drug. The elimination half-life was similar in each of the three dosing levels (50mg, 100mg, 200mg), with an average of 1.3 hours. The clearance of the drug was also similar across dosing levels, with an average of 80.1 liters per hour.
- **In the second half of 2016, Cellceutix plans to initiate a Phase 2b trial of Prurisol, testing higher dosing regimens (300mg and 400mg arms), for the treatment of moderate-to-severe psoriasis. The company also is exploring Prurisol's use in treating eczema.**

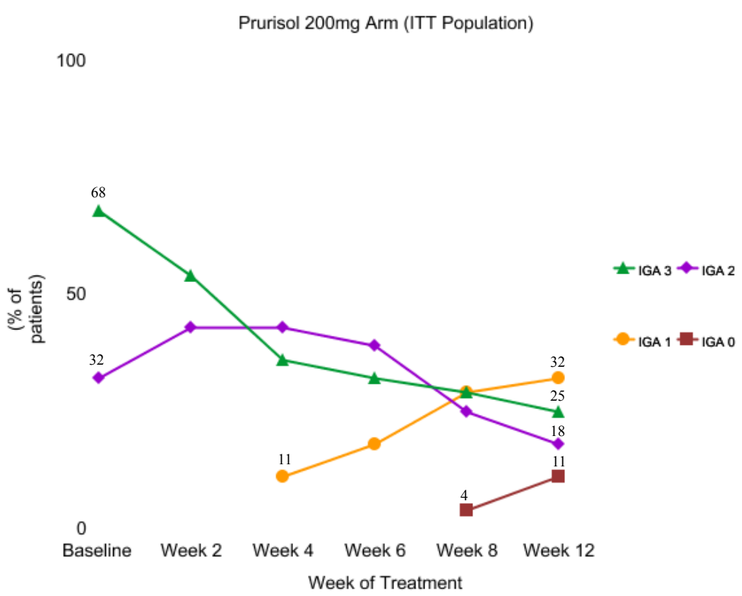
Press Releases
http://cellceutix.com/cellceutix-phase-2-trial-of-prurisol-for-mild-to-moderate-psoriasis-meets-primary-endpoint/
http://cellceutix.com/cellceutix-provides-additional-insight-into-successful-phase-2-trial-for-treating-psoriasis/
http://cellceutix.com/cellceutix-releases-pharmacokinetics-data-from-phase-2-trial-of-prurisol-for-treating-psoriasis-data-complements-efficacy-data-reported-last-week/ 8 July2016

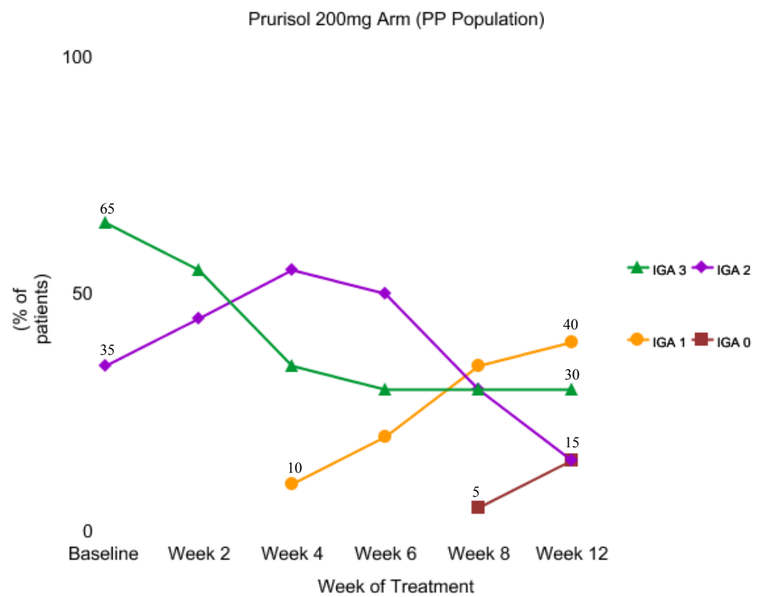
Note: The following slide, Number 26, deserves special attention to note the efficacy of Prurisol shown in the trial.

Benefits were apparent by two weeks and showed further improvement by the end of the study at 12 weeks.

Prurisol™

12-Week Results Show an Early, Strong and Dose-Dependent Response in 200mg Arm (Optimal Dosing Not Yet Determined)





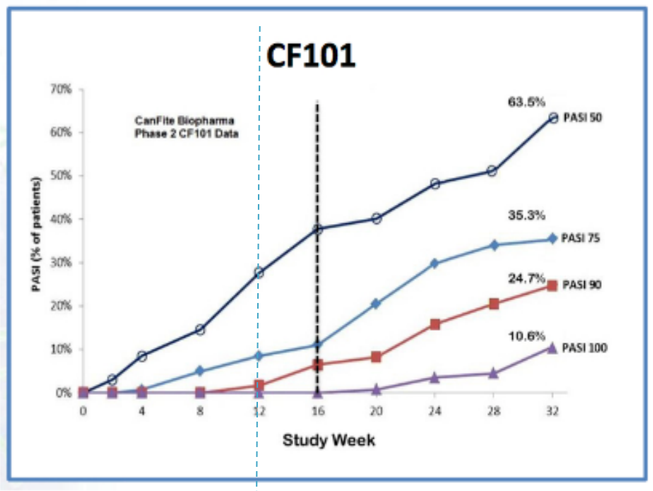
Study was not powered to achieve statistical significance, instead designed to establish proof-of-concept. Generally, an IGA score of 0/1 demonstrates a strong association with PASI 90 score; increasingly, a higher bar is being set as to establishing efficacy outcomes in psoriasis trials (see P. Spicer, Citeline, "The Next Wave of Psoriasis Drug Programs" May 2015)

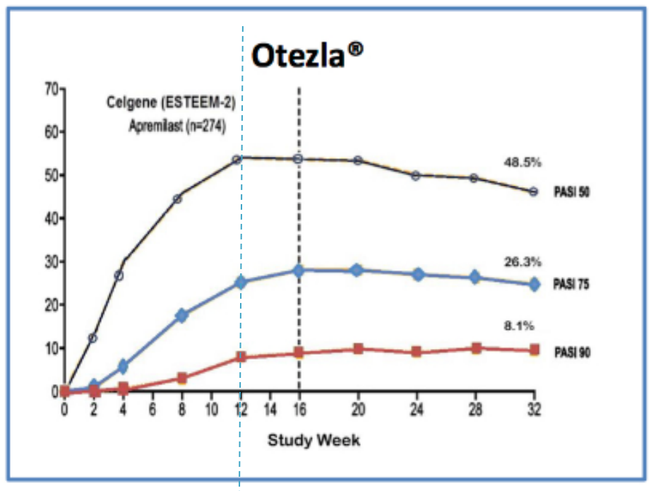
8 July2016

Prurisol™

12-Week Results of 2 other oral treatments.

Otezla® a blockbuster selling drug is fast on the uptake but then plateaus, with minimal efficacy above PASI 90 ("almost clear" psoriasis).
CanFite CF101,in clinical trials, is much slower to take effect (months longer).





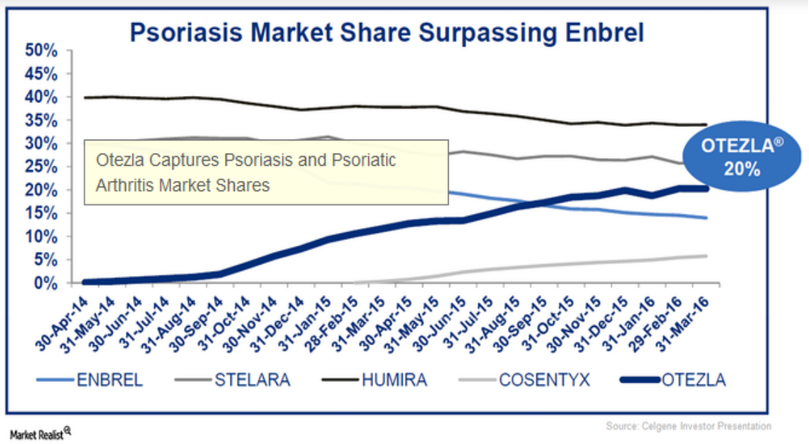
By Week 12, 46% of patients receiving 200mg of Prurisol with "moderate" psoriasis achieved IGA 0/1 (equivalent to PASI 90, which increasingly is the new standard).

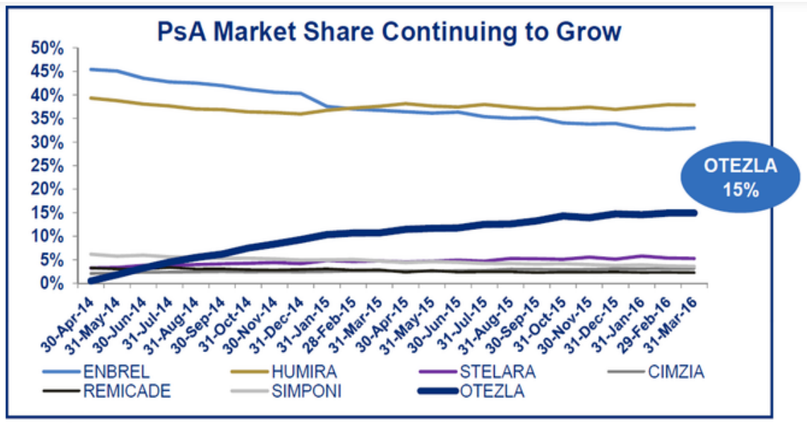
Sources:
http://www.baystreet.ca/articles/research_reports/lifesci/Can-Fite%20BioPharma041216.pdf

Prurisol™

… as Otezla® Continues to Emerge as a Blockbuster Drug

Celgene expects Otezla® to earn revenue of up to $1 billion in 2016 and in the range of $1.5 billion–$2 billion in 2017.





Source: http://marketrealist.com/2016/05/otezla-continues-capture-market-share-psoriasis-psoriatic-arthritis-segments-2016/

Prurisol™

The Goal: A Best-in-Class, Orally-Delivered Drug That Treats Many Types of Psoriasis, Regardless of Severity …

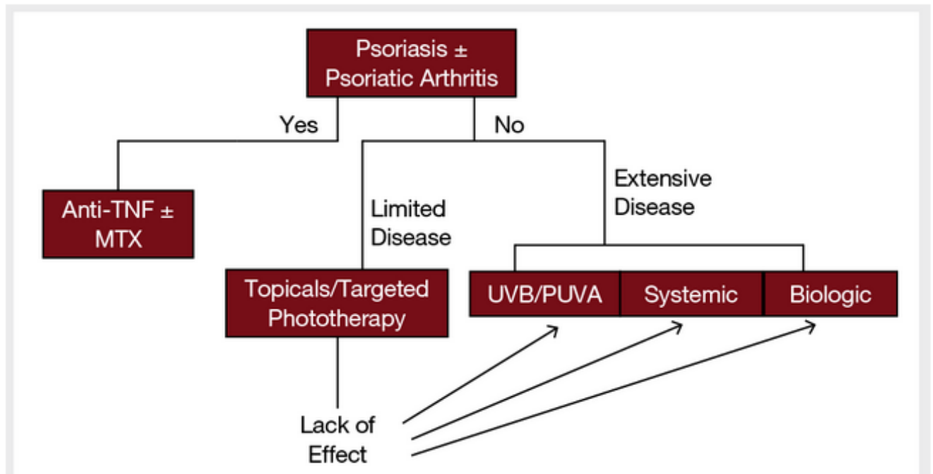


Figure 5. Algorithm for Treating Psoriasis.[28]

Prurisol™

Source: http://www.journalofclinicalpathways.com/formulary-decisions-and-evolution-psoriasis-treatment

8 July2016

Prurisol™

… and with an Efficacy Approaching That of Biologics but Without the Harmful Side Effects

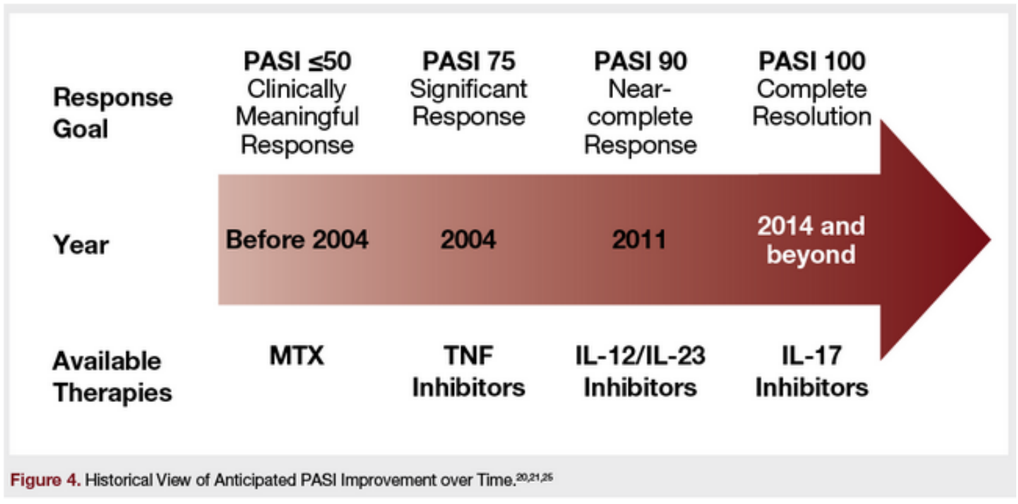


Figure 4. Historical View of Anticipated PASI Improvement over Time.[20,21,25]

Prurisol™

Source: http://www.journalofclinicalpathways.com/formulary-decisions-and-evolution-psoriasis-treatment

8 July2016

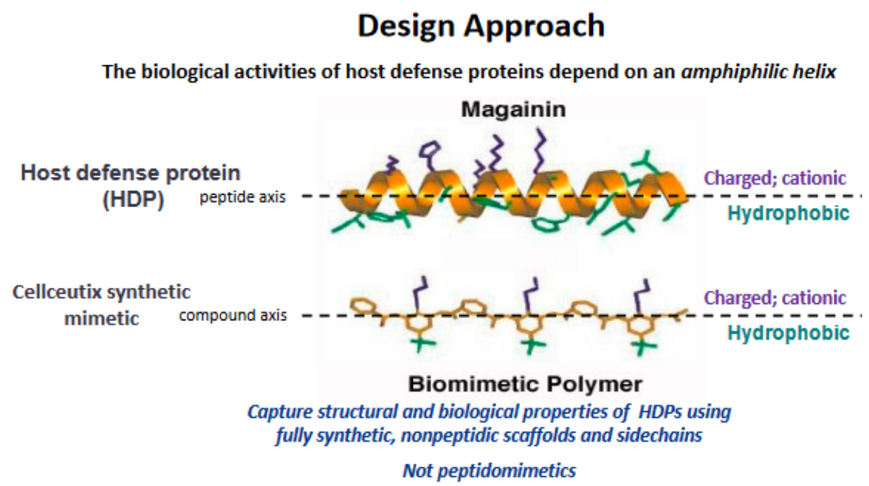
Host Defense Protein (HDP) Mimics

cellceutix

Host Defense Protein (HDP) Mimics
Background & Rationale

Small non-peptidic, fully synthetic mimic of HDPs developed as a systemic or topical agent

- **HDPs are Small Antimicrobial Peptides**
  - -Expressed widely in the animal kingdom
  - -Produced in skin, mucosal surfaces, neutrophils
  - -Target microbial membrane
- **First Line of Defense Against Foreign Invasion**
  - -Part of innate immunity
  - -Maintenance of epithelial barrier function
  - -Regulate microbiota
  - -Immunomodulatory – innate and adaptive immunity
  - -Anti-inflammatory properties
- **Address Global Problem of Antimicrobial Resistance**
  - Gram-positive (*e.g.*, MRSA) and Gram-negative (*e.g.*, CRE) development programs
  - Identified by CDC and FDA as high priority pathogens



Brilacidin

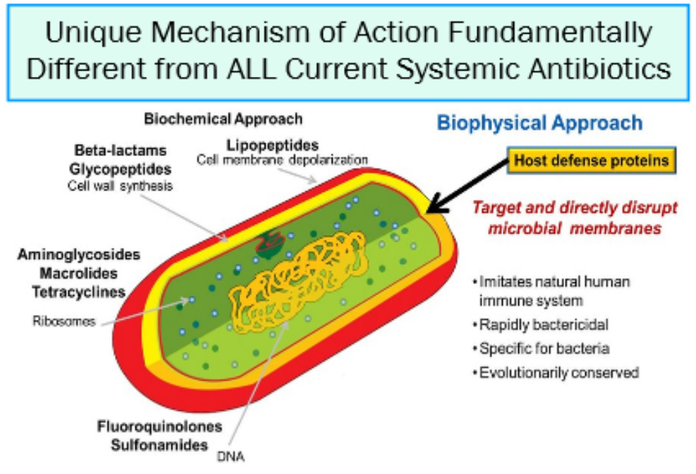
First-in-Class Anti-Inflammatory/Anti-Microbial Compound

Brilacidin is the first of a completely new class of antibiotics. Modeled after the body's innate host-defense response, Brilacidin kills bacteria quickly. Beyond antimicrobial properties, Brilacidin also functions in an immunomodulatory capacity, lessening inflammation and promoting healing.

Mechanism of Action:

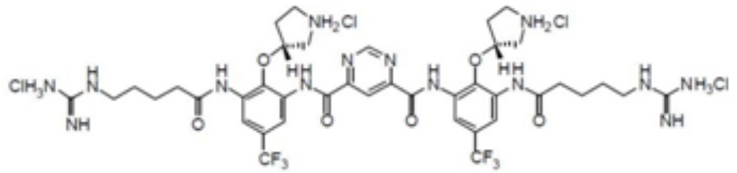
- Brilacidin is an immunomodulatory and anti-inflammatory agent
  - Inhibits the production of TNF-α, IL-1β, MCP-1, MMP-9, IL-6
  - HDP dysfunction implicated in inflammatory disorders of skin and mucosal surfaces
    - Inflammatory bowel disease (IBD), atopic dermatitis, acne, skin infections, cystic fibrosis…
- Brilacidin also functions as an anti-microbial, piercing the cell walls of bacteria (bactericidal)

Received FDA QIDP Fast Track designation for ABSSSI (additional 5 years of market exclusivity in the U.S.)
Strong IP/Patent Protections



Brilacidin

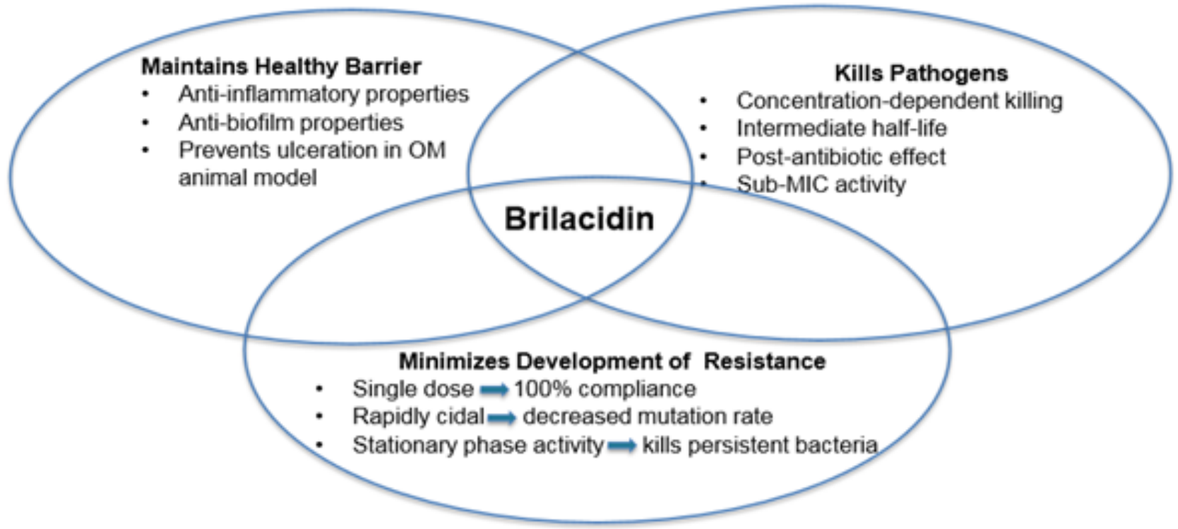
Safe and Well-Tolerated Based on Phase 2b Study for ABSSSI



- There was a reduction in the frequency, severity, and duration of adverse events, compared to the Phase 2a study.
  - Blood pressure events in 0.6 mg/kg single-dose regimen were low, similar to or better than Daptomycin (active control).
  - There were no treatment-related SAEs or hypertension-related SAEs.
  - Numbness/tingling was mild, transient, and decreased in frequency and severity.
- PK/PD model correctly predicted decrease in AEs with lower total dose, particularly, low single-dose regimens.

Brilacidin

Novel Immunomodulatory Agent to Treat Infectious Disease and Disorders of Innate Immunity

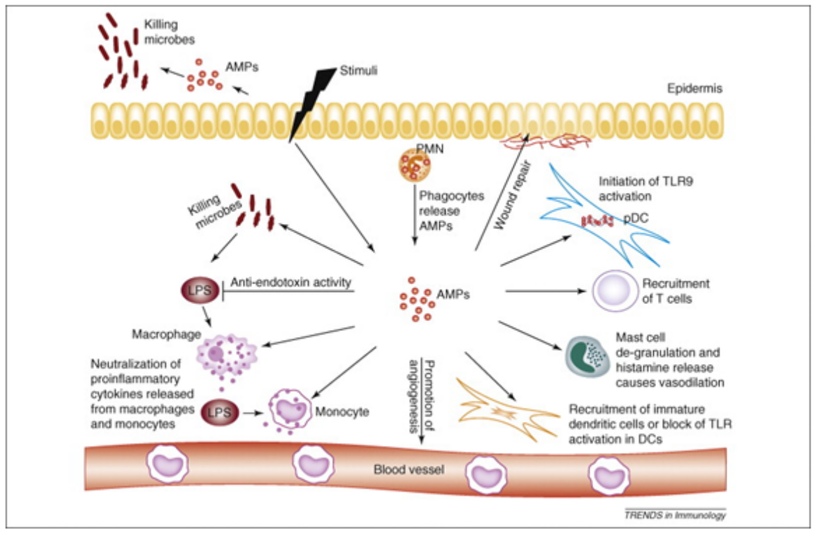


Brilacidin

Clinical Literature Supporting Therapeutic Potential

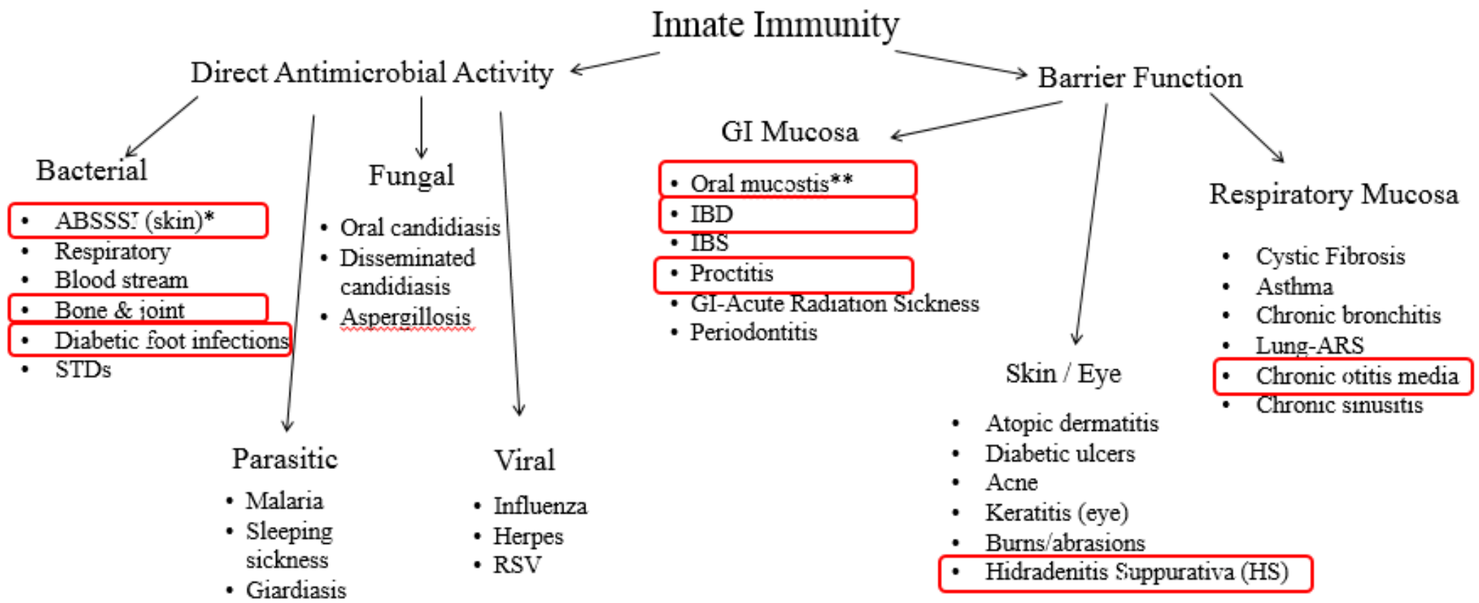
"The most relevant biological role of host defense peptides is immunomodulation." (source)

- "Therapeutic Potential of Antimicrobial Peptides." *New Weapons to Control Bacterial Growth* pp 433-451 Date: 25 March 2016.
- "Mammalian Antimicrobial Peptides: Promising Therapeutic Targets Against Infection and Chronic Inflammation." *Current Topics in Medicinal Chemistry,* 16(1): 99-129. (2016).
- "The Role of Antimicrobial Peptides in Chronic Inflammatory Skin Diseases." *Dermatol Alergol.* 2016 Feb; 33(1): 6–12.
- "Antimicrobial Peptides: Do They Have a Future as Therapeutics?" Part of the series Birkhäuser *Advances in Infectious Diseases* pp 147-154 Date: 25 December 2015.
- "The New Insight into the Role of Antimicrobial Proteins-Alarmins in the Immunopathogenesis of Psoriasis." *Journal of Immunology Research*. Vol 2014, Article ID 628289.
- "Antimicrobial Peptides Stage a Comeback." *Nature Biotechnology*. Vol 31, No 5 (May 2013).
- "Antimicrobial Peptides in the Pathogenesis of Psoriasis." *Journal of Dermatology.* 2012; 39: 225-230.
- "Antimicrobial Peptides: An Overview of a Promising Class of Therapeutics." *CEJB* 2(1) 2007 1-33.
- "The Role of Antimicrobial Peptides in Innate Immunity." *Integr. Comp. Biol.*, 43:300-304 (2003).
- "Antimicrobial Peptides of Multicellular Organisms." *Nature*. Vol 415



Source: http://www.cell.com/trends/immunology/abstract/S1471-4906%2809%2900005-2

HDP Mimics for Other Indications
Platform Opportunities & Gateway Concept



ABSSSI indication is gateway for antibiotic opportunities

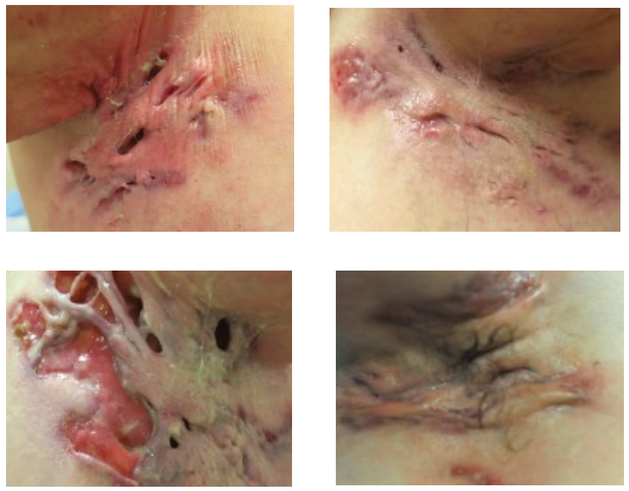
****Oral mucositis is gateway for anti-inflammatory opportunities***

Brilacidin

Dermatology Indication – Hidradenitis Suppurativa

- **Hidradenitis Suppurativa** (acne inversa):
  - A debilitating inflammatory skin disease characterized by recurrent abscesses and formation of sinus tracts, typically where skin rubs together, e.g., armpits, groin, between the buttocks and under the breasts.
  - The etiology of the disease, which causes significant physical and psychosocial distress to both men and women, remains largely not understood with no cure and only limited treatment options.
  - Reports of prevalence range widely from approximately one-half a percent up to approximately four percent of the general population.
- Brilacidin has a broad range of anti-inflammatory effects on various key effector cells that may be involved in Hidradenitis Suppurativa, as well as other diseases such as acne, ulcerative colitis and Crohn's, diseases affecting millions of people.

  A Phase 2 trial of Brilacidin-Hidradenitis Suppurativa is planned



Source:
http://www.globalacademycme.com/fileadmin/pdf/supplement_pdf/SANv33_Hidradenitis_Sppl.pdf

Brilacidin

Additional Dermatology Indications

Propionibacterium Species (acne) and Atopic Dermatitis

Activity of brilacidin and comparators against evaluated *Propionibacterium* spp.[1]
MIC (µg/mL)

	Brilacidin	Erythromycin	Clindamycin	Minocycline	Doxycycline	Metronidazole
MIC_{50}	0.5	0.03	0.03	0.06	0.12	>64
MIC_{90}	1	>128	1	0.25	0.5	>64
MIC range	0.25 to 2	0.015 to >128	≤0.015 to >16	0.03 to 2	0.03 to 4	>64

[1] *Propionibacterium* spp. includes: *P. jensenii, P. granulosum, P. avidum , P. acnes*

- Brilacidin demonstrated anti-inflammatory activity specific to Atopic Dermatitis.
- Inflammatory cytokines were considerably reduced in a controlled lab environment.
- Large market opportunity for new treatments for atopic dermatitis:
  - www.forbes.com/sites/genemarcial/2016/06/15/will-a-new-suitor-for-anacor-emerge/
  - http://dermatologytimes.modernmedicine.com/dermatology-times/news/merger-boost-eczema-offerings
  - http://www.datamonitorhealthcare.com/dupilumab-on-the-verge-of-becoming-first-targeted-therapy-in-atopic-dermatitis/
  - http://www.dddmag.com/article/2016/06/pfizer-anacor-merger-set-leverage-companies-atopic-dermatitis-space

Oral Mucositis (OM)

Brilacidin

Oncology Indication – Oral Mucositis (Background)

- Frequent complication of chemoradiation for head and neck tumors
  - May appear within 5-10 days of start of chemoradiation treatment
  - Can persist 1-6 weeks or longer depending on severity
- Painful and debilitating inflammation & ulceration; increases susceptibility to bacterial infections
  - Probability is increased with poor dental hygiene; any and all use of tobacco products; overall poor health; and previous chemoradiation treatment for head and neck cancers
- Patients unable to speak or eat
  - Often requires insertion of feeding tube
- Can be dose-limiting leading to reduction/cessation of radiation and chemotherapy for cancer
- Severe cases require hospitalization
  - Increased overall cost of cancer treatment
- No currently approved medications for prevention of OM in this population

Brilacidin

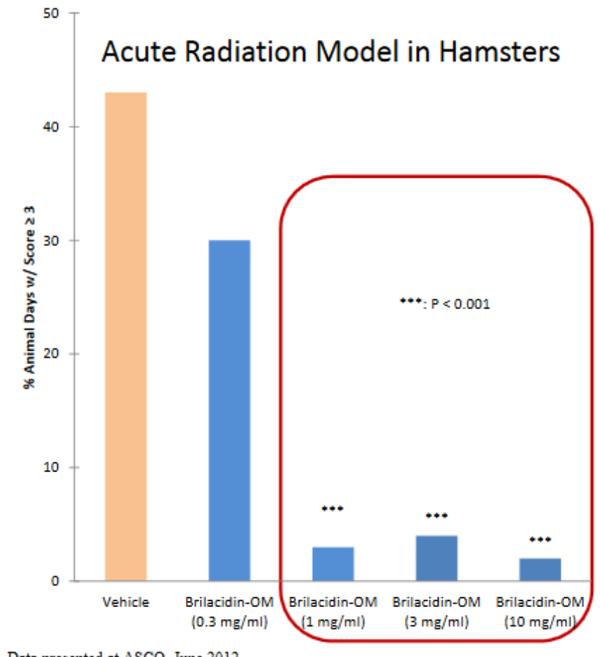
Oncology Indication – Oral Mucositis (Market Overview)

- **Significant Market**
  - ~450,000 patients/year in U.S. alone[1]
  - ~167,000 patients in US at risk for ulcerative oral mucositis
  - 80-100% of head and neck cancer patients develop ulcerative oral mucositis
- **Cost of Mucositis**
  - 4-fold increased risk for septicemia in oral mucositis[2]
  - 62% of patients require hospitalization; 70% with grade 3 or 4 require gastric feeding tubes[2]
  - Oral mucositis adds ~$18,500 to the cost of treatment[3]
  - 2010 Red Book price of Kepivance: $9,900 per treatment cycle (six infusions)
- **Limited competition**
  - Only one drug available (Kepivance for IV infusion; limited label); some medical devices with no or little relevant efficacy data (*e.g.*, Gelclair)
  - Limited treatment alternatives and development pipeline

[1] S. Sonis and information based on GLOBOCAN Cancer Statistics
[2] Sonis ST et al. Perspectives on cancer therapy-induced mucosal injury. Cancer. 2004;100:1995-2025
[3] Nonzee et al. Cancer 2008, 113:1446-52

Brilacidin

Oncology Indication – Oral Mucositis (Pre-Clinical)



Data presented at ASCO, June 2012

Study Design:

- Brilacidin-OM administered 3x/day as topical rinse @ doses of 0.3, 1, 3 or 10 mg/ml over 28 days

Results seen with Brilacidin-OM:

- **Reduced animal days w/ ulcerative oral mucositis by >90%**
  - **From 42.7% to 2-4%**
- High statistical significance

Brilacidin

Oncology Indication – Oral Mucositis (Phase 2 Trial in Progress)

Brilacidin Mitigates Radiation-Induced Damage

Study Design

- Phase 2, Multi-center, Randomized, Double-blind, Placebo-controlled (10 sites in US; 5 currently open to enrollment)
- 60 subjects – 30 each of drug or placebo (Water for Injection)
- "Swish and spit" brilacidin 3x/daily for 7 weeks – 16 ml oral rinse
- Interim analysis after 36 subjects (18 per treatment group) by a Data Monitoring Committee (DMC); will review safety and efficacy results

Primary Endpoints

Control and prevent oral mucositis in patients receiving chemoradiation therapy for Head and Neck Cancer

- To evaluate the efficacy of topically applied Brilacidin vs placebo in delaying the onset of severe OM (WHO Grade ≥ 3)
- To evaluate the safety and tolerability of topically applied Brilacidin administered three times daily for approximately 7 weeks

Secondary Endpoints

- Assessing the ability of Brilacidin to reduce the incidence and duration of ulcerative and severe OM (WHO Grade ≥ 2)
- Other secondary endpoints will include assessment of the following due to OM:
  - Mouth and throat soreness, analgesic consumption for pain
  - Use of gastrostomy tube for nutritional support
  - Number of unplanned office visits/ER visits for hospital admissions
  - Incidents of unplanned delays and/or breaks in chemoradiation therapy

For study details, see https://clinicaltrials.gov/ct2/show/NCT02324335

8 July2016

Brilacidin

Oncology Indication – Oral Mucositis (Planned Development)

Phase 2 POC (~60 pts)	Phase 3 (~240 pts)	NDA

Brilacidin-Oral Mucositis has received FDA Fast Track designation

Note: Kepivance/palifermin approved on single Phase 3 study (~300 patients total)

Cellceutix Corporation

100 Cummings Center

Beverly, MA

July 2016

Ticker: CTIX