

# cellceutix™

## Corporate Overview

23rd Annual Newsmakers in the Biotech Industry Conference  
New York City, 9Sep2016



100 Cummings Center, Beverly, MA

Ticker: CTIX

(u)

# Safe Harbor; Forward-Looking Statements

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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.

# Corporate Overview

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Established in 2007, Cellceutix is a clinical-stage biopharmaceutical company dedicated to discovering and developing innovative compounds with dermatology, oncology, anti-inflammatory and antibiotic applications.

Cellceutix has three lead compounds, each with first-in-class potential, advancing in mid-to-late stage clinical trials under various special FDA designations.

## Prurisol

*Orally-delivered anti-psoriasis compound entering a Phase 2b trial utilizing advantages of the 505(b)(2) development pathway*

## Kevetrin

*p53-activating drug with three Orphan Drug designations starting a Phase 2a trial for ovarian cancer*

## Brilacidin

*Member of a new class of antibiotics with unique immunomodulatory properties advancing in clinical trials under Fast Track designations*

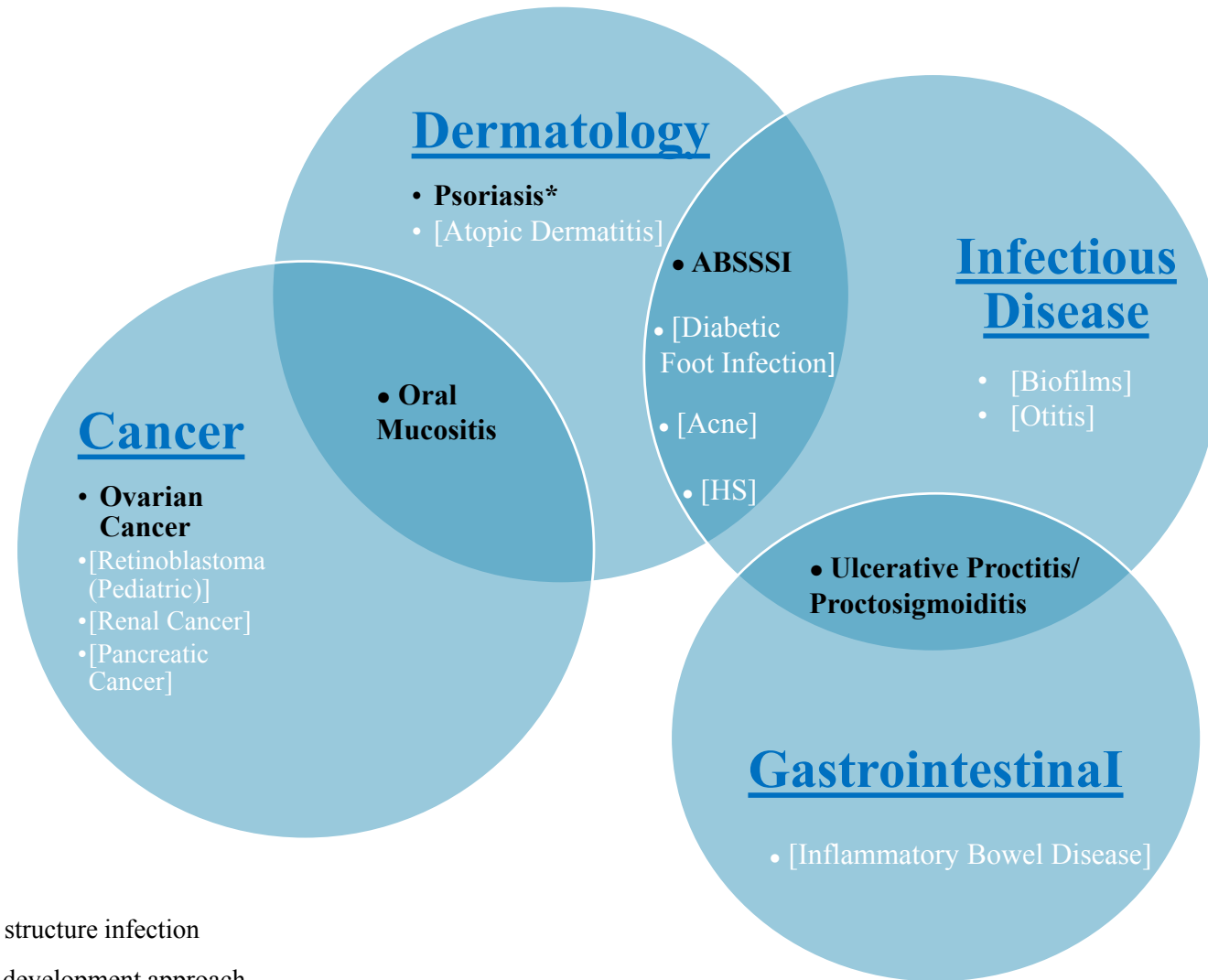
# Management Team

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Name	Title	
Leo Ehrlich, CPA	Chief Executive Officer, Chief Financial Officer	Co-Founder; Investor
Krishna Menon, PhD, DVM	Chief Scientific Officer	Co-Founder
Arthur P. Bertolino, MD, PhD, MBA	President, Chief Medical Officer	
Jane Harness, MS, MP	VP, Clinical Sciences and Portfolio Management	

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

# Pipeline—Therapeutic Areas



HS- Hidradenitis suppurativa

ABSSSI- Acute bacterial skin and skin structure infection

\*Utilizes advantages of FDA 505(b)(2) development approach for Prurisol, shortens development time, reduces costs

[ ] potential future indications

# Pipeline—Stages of Development

Exceptionally strong pipeline, novel mechanisms of action

Drug Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3	
<b>Kevetrin</b>	Ovarian Cancer	→				
<b>Brilacidin</b>	Oral Mucositis	→				
	ABSSSI*	→				
	UP/UPS**	→				
	Hidradenitis Suppurativa	→				
	Acne	→				
<b>Prurisol</b>	Psoriasis	→				

Planned to enter clinic

\*ABSSSI - Acute Bacterial Skin and Skin Structure Infections

\*\*UP/UPS - Ulcerative Proctitis/Proctosigmoiditis

# Pipeline—Special FDA Designations

Leveraging designations to expedite development, improve likelihood of drug approval



Drug Candidate	Designation Type	Date Granted
<b>Kevetrin</b>	Orphan Drug Designation for Ovarian Cancer	July 2015
	Orphan Drug Designation for Retinoblastoma	November 2015
	Rare Pediatric Disease Designation for Retinoblastoma	November 2015
	Orphan Drug Designation for Pancreatic Cancer	January 2016
<b>Brilacidin</b>	QIDP* Fast-Track Designation for ABSSSI**	December 2014
	Fast-Track Designation for Oral Mucositis	November 2015

\*QIDP – Qualified Infectious Disease Product

\*\*ABSSSI – Acute Bacterial Skin and Skin Structure Infection

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# Dermatology Program

Prurisol

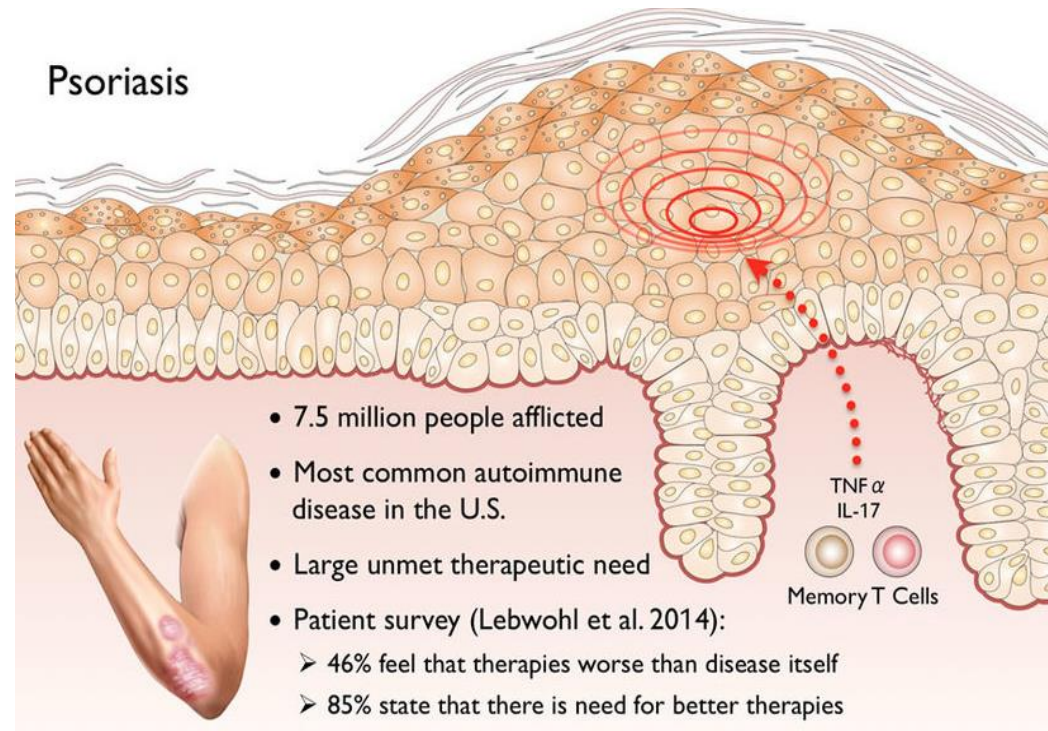
**Psoriasis**



# Prurisol

## *Psoriasis: Debilitating Chronic Disease That Affects Millions*

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



Overall Quality of Life among Psoriasis Patients



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>

# Prurisol

## MOA and Attributes

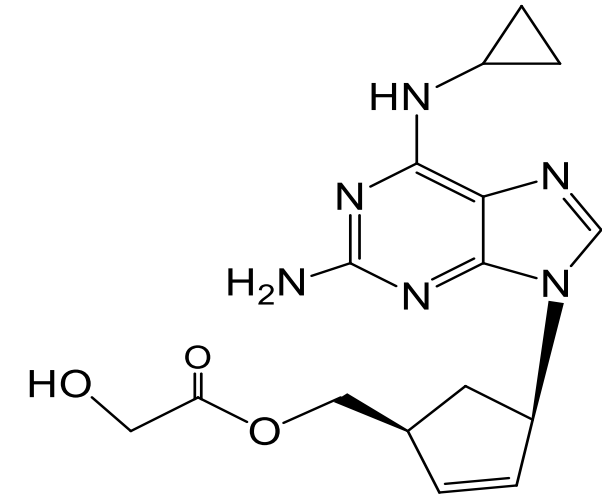
### Mechanism of Action (MOA)

- Acts through immune modulation and PRINS\* reduction
  - Reduces IL-20
  - Reduces skin cell proliferation rate

### Attributes

- Strong Intellectual Property(IP) and patent protections
- Small-molecule (<500 MW) (an ester of abacavir)
- Bioavailable
- Excellent in-vivo and in-vitro activity
- Efficacy in xenograft model
- Oral dosing
- Development plan utilizing advantages of **505(b)(2)** pathway  
[reference drug: Abacavir]

\*PRINS – Psoriasis-associated non-protein coding RNA induced by stress



**Prurisol**

[Abacavir ( $\alpha$ -hydroxyl) acetate; abacavir glycolate]

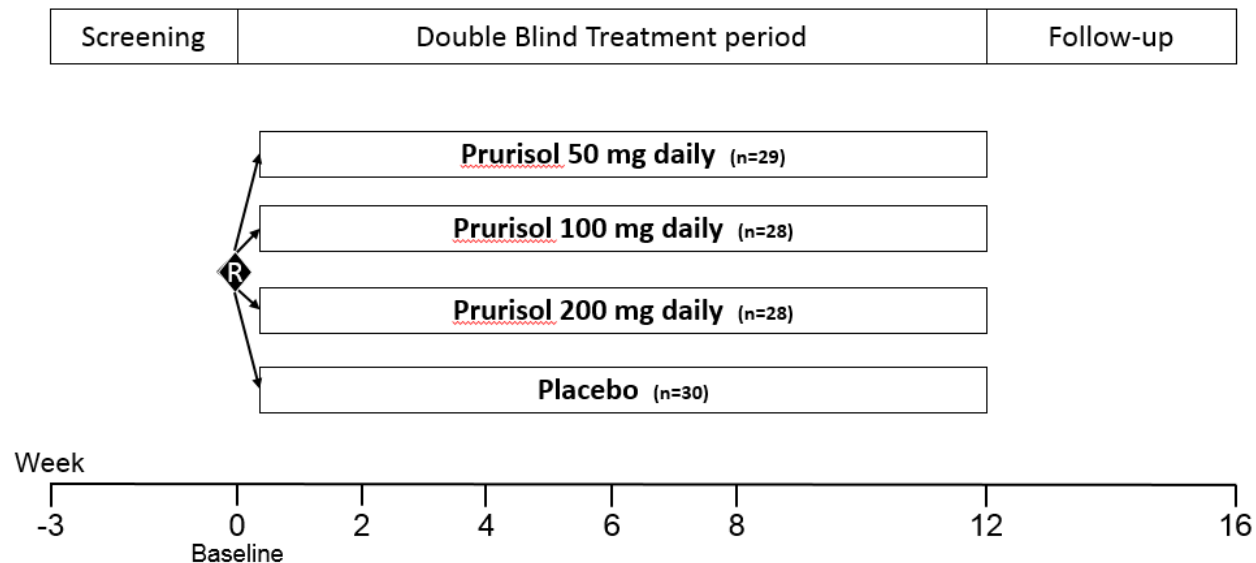
Molecular formula:  $C_{16}H_{20}N_6O_3$   
Molecular weight: 344.37

# Prurisol

## CTIX-0002 – Study Design for Plaque Psoriasis Phase 2 Trial of Mild-to-Moderate Psoriasis

**Primary efficacy endpoint:** percentage of subjects with  $\geq 2$  point improvement in IGA rating at 84 days (12 weeks)  
Investigator Global Assessment (IGA) rating: clear (0), almost clear (1), mild (2), moderate (3), severe (4), very severe (5)

- Randomized, double blind, parallel group, placebo-controlled
- 4 treatment groups, 1:1:1:1 randomization, 12 weeks treatment
  - Prurisol
    - 50 mg daily (50 mg AM)
    - 100 mg daily (50 mg AM & 50 mg PM)
    - 200 mg daily (100 mg AM & 100 mg PM)
  - Placebo AM & PM



- Trial conducted at 9 sites in U.S.
- 115 subjects, 4 arms, ~29 per arm
- Efficacy, Safety & PK

For study details, see

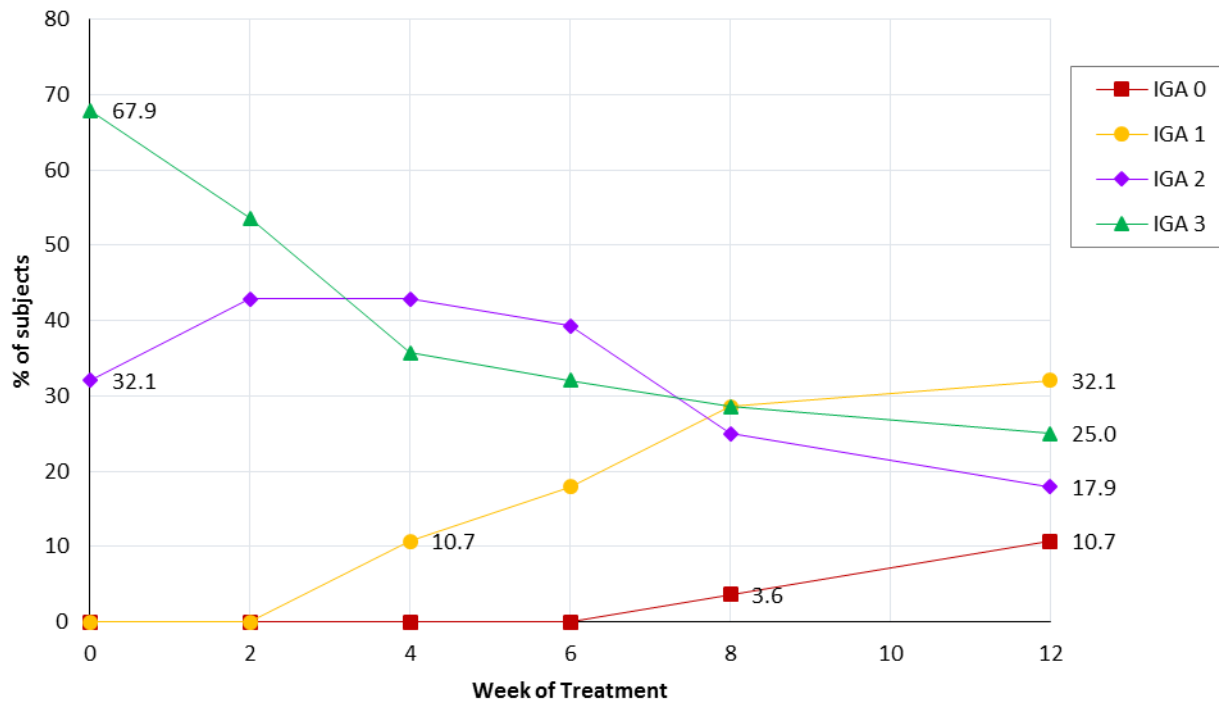
<https://clinicaltrials.gov/ct2/show/NCT02494479>

# Prurisol

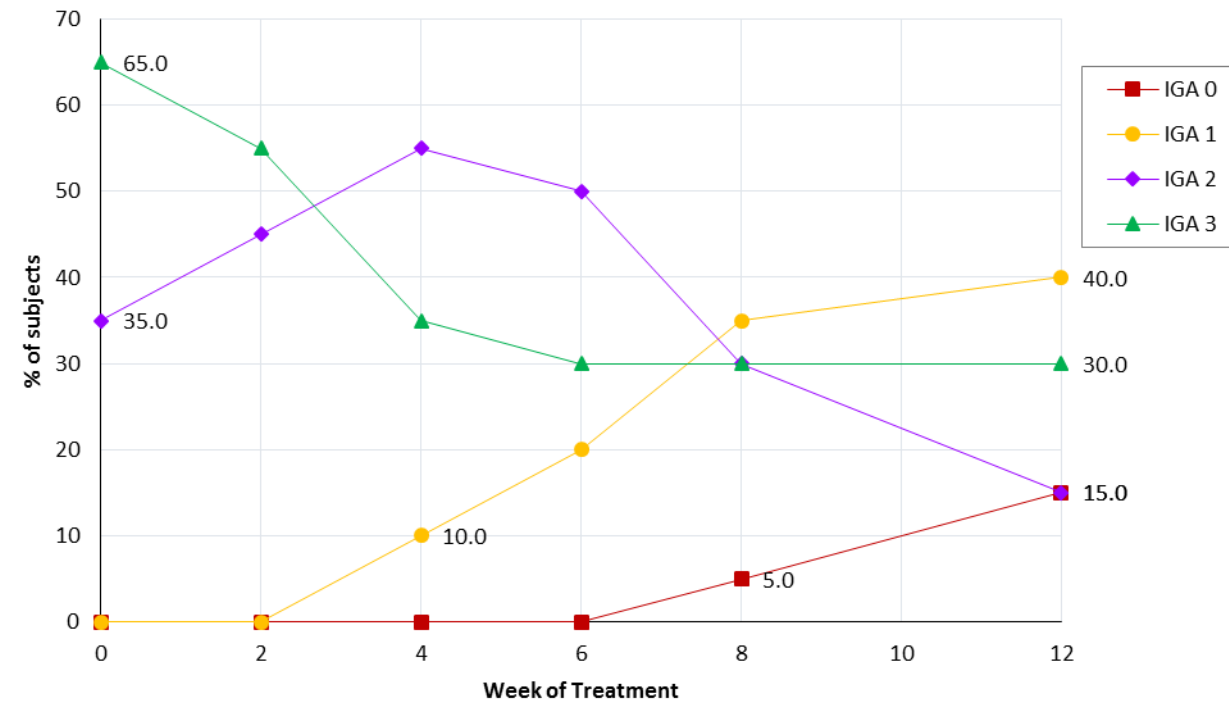
## CTIX-0002 (Phase 2 ): IGA Scores- Distribution Over Time (200 mg group) [Mild-to-Moderate Psoriasis]

- IGA changes noted as soon as Week 2
- Progressive decrease of IGA scores to lower values over 12 weeks
- At Week 12, 42.8% subjects (ITT) and 55.0% subjects (PP) achieved “clear” (0) or “almost clear” (1) in IGA

### Prurisol 200 mg (ITT\* Population)



### Prurisol 200 mg (PP Population)



Source: Table 14.2.1.2.1 (ITT Population)

Source: Table 14.2.1.2.2 (PP Population)

# Prurisol

## CTIX-0002 – Phase 2 Topline Clinical Trial Results (*Mild-to-Moderate Psoriasis*)

- **Prurisol met the primary endpoint (a 2-point IGA reduction) in 35% of all patients who received a dose of 200mg per day.**
- 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 drug exposure and maximum plasma concentration

Among patients with the severest form of psoriasis in study, those having a baseline IGA score of 3 (“moderate”), the primary endpoint was met in **46%** of patients who received 200mg per day. These data were derived from analyses of all patients

### Current Perspectives

- Plans for 2H 2016 start of Prurisol Phase 2b trial, testing higher dosing regimens (300mg and 400mg arms), in treatment of **moderate-to-severe** psoriasis
- PASI 75 primary endpoint
- Utilize advantages of 505(b)(2) development approach

### Press Releases:

<http://cellceutix.com/cellceutix-phase-2-trial-of-prurisol-for-mild-to-moderate-psoriasis-meets-primary-endpoint/>

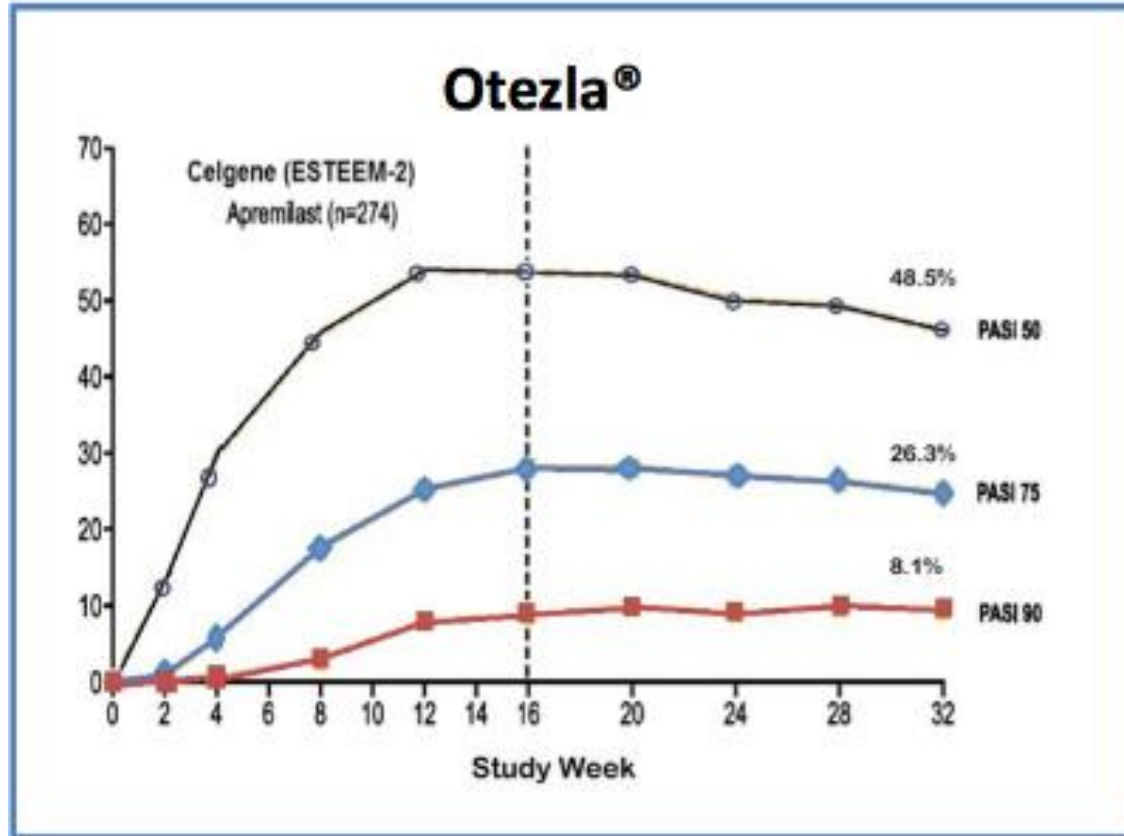
<http://cellceutix.com/cellceutix-provides-additional-insight-into-successful-phase-2-trial-for-treating-psoriasis/>

<http://cellceutix.com/cellceutix-releases-pharmacokinetics-data-from-phase-2-trial-of-prurisol-for-treating-psoriasis-data-complements-efficacy-data-reported-last-week/>

# Prurisol

## *Otezla® Emerging as a Blockbuster Drug*

*Otezla®, the main potential oral competitor, demonstrates only moderate efficacy by week 16*



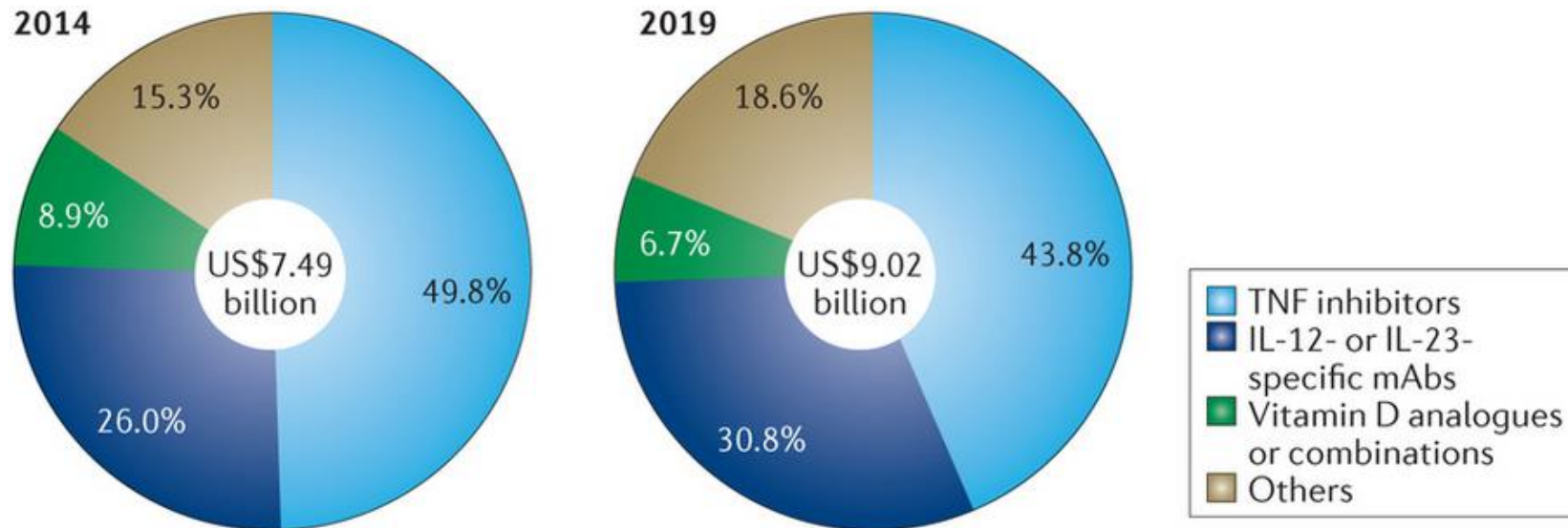
**Celgene expects Otezla® to earn revenue of up to \$1 billion in 2016 and \$1.5 billion to \$2 billion in 2017**

Sources:

[http://www.baystreet.ca/articles/research\\_reports/lifesci/Can-Fite%20BioPharma041216.pdf](http://www.baystreet.ca/articles/research_reports/lifesci/Can-Fite%20BioPharma041216.pdf)

# Prurisol

*Psoriasis: A Multi-Billion Dollar Market Expected to Become Even Larger*



Nature Reviews | Drug Discovery

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

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# Cancer Program

Kevetrin



# Kevetrin

## Program Summary

### Kevetrin

*A p53-activating drug with multiple FDA Orphan Drug designations starting a Phase 2a trial for platinum-resistant ovarian cancer*

- **Induces apoptosis and shows potent anti-tumor activity**
  - In several wild type p53, mutant p53 and null or deleted p53 human tumor xenograft models
- **Targets and regulates (modulates) multiple molecular targets and signaling pathways**
  - Enhancing anti-tumor activity, reducing toxicity and overcoming drug resistance
- **Apoptosis induced in non-genotoxic manner**
  - Most currently available chemotherapeutic drugs are genotoxic and damage DNA
- **Does not affect cell viability in normal cells at concentrations that kill the tumor cells**
  - The existence of such a therapeutic window raises hope for the treatment of a wide range of tumors with reduced safety concerns
- **Well-tolerated with minimal adverse effects in the completed Phase 1 clinical trial**

### Current Perspectives

- Ovarian Cancer (OC) indication supported by Phase 1 solid tumor trial
- p53 modulation to be directly measured in upcoming OC trial
- Oral formulation and delivery advances are underway and may provide for even better exposure and toleration

# Kevetrin

## Phase 1 Clinical Trial Results (Solid Tumors)



- **Phase 1 trial dose escalation completed 4Q2015 at 11<sup>th</sup> cohort (750 mg/m<sup>2</sup>)**
  - 28 day cycle: once/ week infusion for 3 weeks with 1 week of rest
  - In subjects with advanced **ovarian cancer**:
    - 73% had an increase in p21 biomarker (3% to 73% increase)
    - 29% had stable disease
  - 47% of gynecological cancers had stable disease
- **Pharmacokinetic parameters show approximate dose-dependent exposure; and as expected terminal half-life, clearance, volume of distribution**
  - Parameters suggest rapid and extensive distribution from systemic circulation into tissues
- **Only 1 dose limiting toxicity observed**
  - No significant hematological or other systemic effects
- **p21 as a biomarker for p53 activation showed:**
  - p21 increased by  $\geq 10\%$  in 48% of the 31 evaluable patients
  - p21 increased in 11 (73%) of patients with gynecological cancers

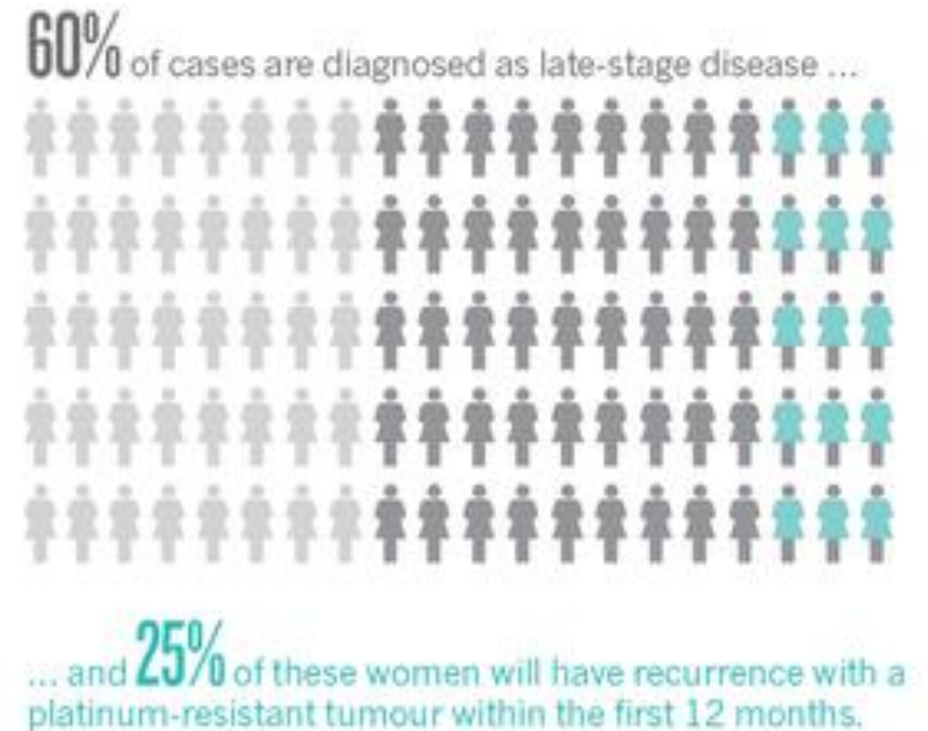
For study details, see:

<https://clinicaltrials.gov/ct2/show/NCT01664000>

# Kevetrin

## *Upcoming Phases 2a Clinical Trial in Late-Stage Ovarian Cancer*

- **Combination therapy**
  - Kevetrin (starting dose 250 mg/m<sup>2</sup>) 3 times/ week with dose escalation
  - Doxil® (doxorubicin hydrochloride liposome infusion) every 4 weeks
- **Endpoints**
  - Safety
  - Efficacy based on RECIST criteria using scans
  - PK
- **Proposed biomarkers**
  - p53 (in tumor and ascites cells)
  - Plasma and ascites
    - CCL2 (MCP-1)
    - miRNA-27a
    - miRNA-1274b
    - miRNA-25
  - Additional tumor biomarker- mir34a



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# Multidisciplinary Programs- Brilacidin

**Infectious Disease:** Acute Bacterial Skin and Skin Structure Infection (ABSSSI)

**Dermatology/Cancer:** Oral Mucositis (OM)

**Gastrointestinal:** Ulcerative Proctitis/Ulcerative Proctosigmoiditis (UP/UPS)

**Dermatology:** Hidradenitis Suppurativa (HS); Acne

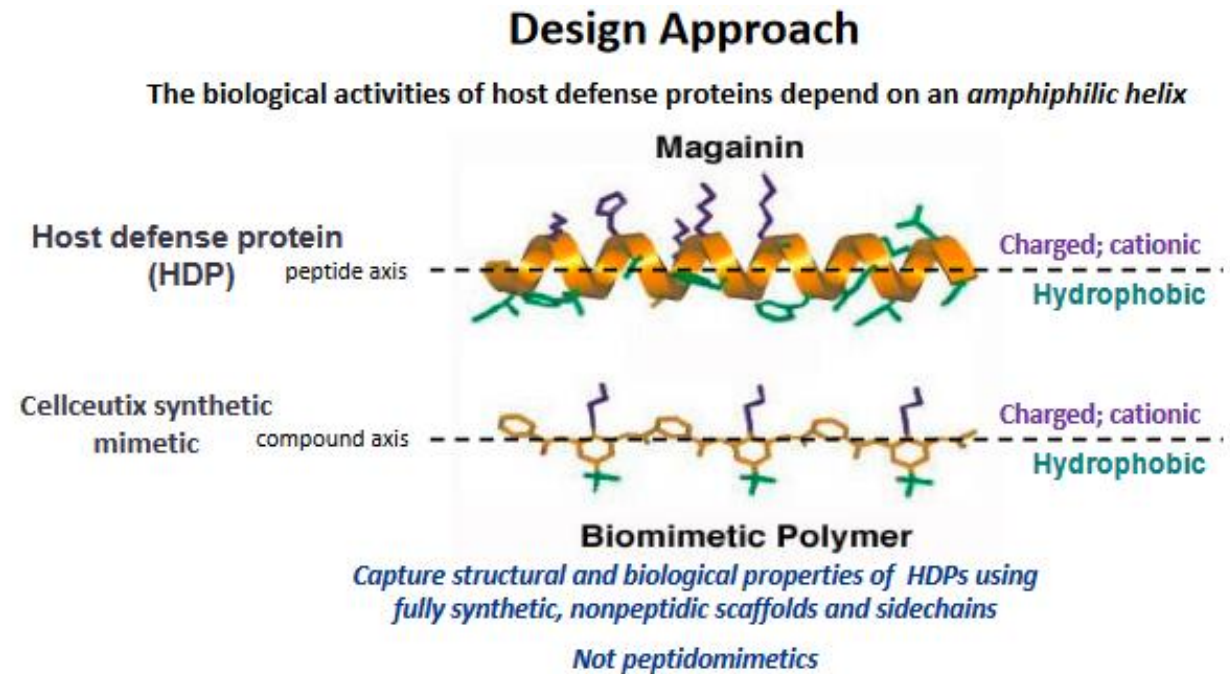
## A Host Defense Protein (HDP) Mimic

# Brilacidin

## *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

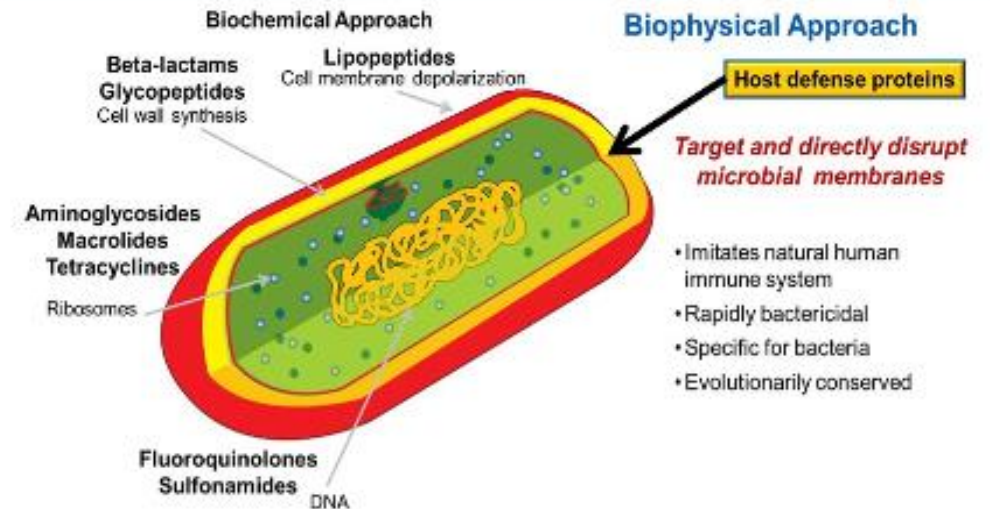
## *First-in-Class Anti-Inflammatory/Anti-Microbial Compound*

**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:

- An **immunomodulatory** and **anti-inflammatory** agent
  - Inhibits the production of **TNF- $\alpha$** , **IL-1 $\beta$** , **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)

### Unique Mechanism of Action Fundamentally Different from ALL Current Systemic Antibiotics



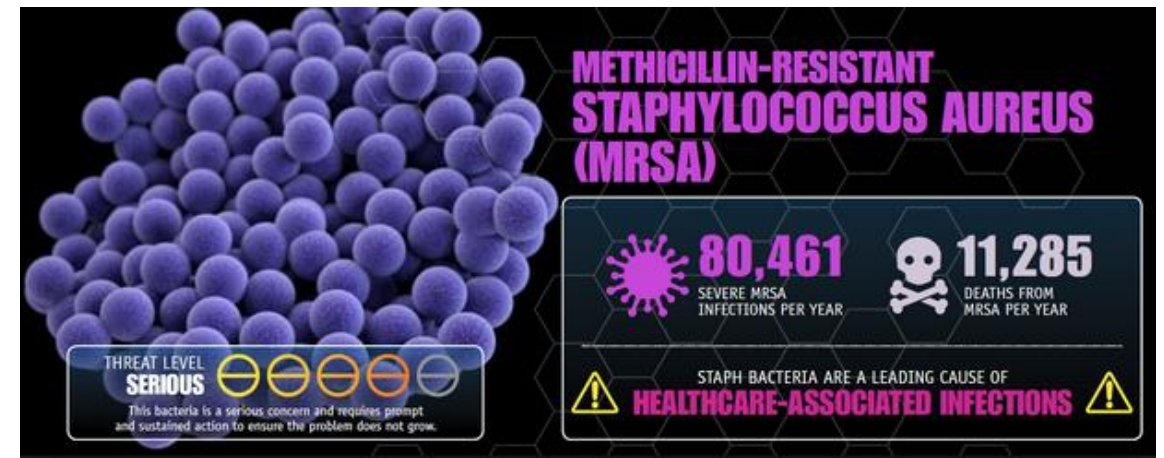
### Note:

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

# Brilacidin

## *ABSSSI\* as a Development Strategy: Gateway Concept*

- **Serious infections frequently caused by MRSA**
- **Well-defined developmental path with regulatory clarity**
- **Gateway to serious infections with unmet medical need**
  - Mitigate risk by evaluating drug in a more clearly defined disease setting
  - Build clinical safety database
  - Establish differentiating properties and leverage advantages



\*ABSSSI - Acute Bacterial Skin and Skin Structure Infection

# Brilacidin

## ABSSSI Phase 2b Primary Endpoint – United States

### Early Clinical Response at 48-72 hours

	<b>Brilacidin 0.6 mg/kg IV x 1 day (N=53)</b>	<b>Brilacidin 0.8 mg/kg IV x 1 day (N=53)</b>	<b>Brilacidin x 3 days (N=53)</b>	<b>Daptomycin (N=50)</b>
Number assessed	51	48	52	48
Clinical Response (%)	47 (92.2)	46 (95.8)	51 (98.1)	45 (93.8)
95% C.I.	(84.8, 99.5)	(90.2, 100)	(94.3, 100)	(86.9, 100)

ATS = All Treated/Safety Population  
Pre-specified analysis population in statistical analysis plan (SAP) for primary endpoint

Per FDA Guidance—ABSSSI (October 2013)



# Brilacidin

## *Gram-Positive Program Summary [HDP Mimics for MRSA in Skin Infections (ABSSSI\*)]*

- **Safe and effective in three Phase 2 studies**
- **Convenient single-dose regimen**
  - Pharmacoeconomic advantages
- **Efficacy comparable to 7-day regimen of robust comparator (daptomycin x 7 days)**
- **QIDP designation (Nov 2014) under the GAIN Act**
  - Eligible for Fast Track and Priority Review
- **Minimal potential for development of resistance**
  - Novel class, with no cross-resistance
  - Novel mechanism of action confers fitness disadvantage for bacterial resistance
  - Single dose removes non-compliance as driver for resistance
- **Immunomodulatory, with anti-biofilm properties**
  - May accelerate the healing process
- **Phase 3 planning in progress**
  - Response to Special Protocol Assessment (SPA) comments from FDA in process

### Current Perspectives

- Experience with ABSSSI provides foundation for strategy to also expand program into other indications taking advantage of anti-inflammatory & antibacterial properties

Proof of Concept being tested in:

Oral mucositis (OM)  
UP/UPS\*

\*UP/UPS -Ulcerative proctitis/  
proctosigmoiditis

For most recent study details, see:

<https://clinicaltrials.gov/ct2/show/NCT02052388>

# Brilacidin

## *Oral Mucositis (Clinical Overview)*

- **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

## *Oral Mucositis (Market Overview)*

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- **Significant Market**

- ~450,000 patients/year in U.S. alone<sup>1</sup>
- ~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<sup>2</sup>
- 62% of patients require hospitalization; 70% with grade 3 or 4 require gastric feeding tubes<sup>2</sup>
- Oral mucositis adds ~\$18,500 to the cost of treatment<sup>3</sup>
- 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- hematologic malignancies); some medical devices with no or little relevant efficacy data (*e.g.*, Gelclair)
- Limited treatment alternatives and development pipeline

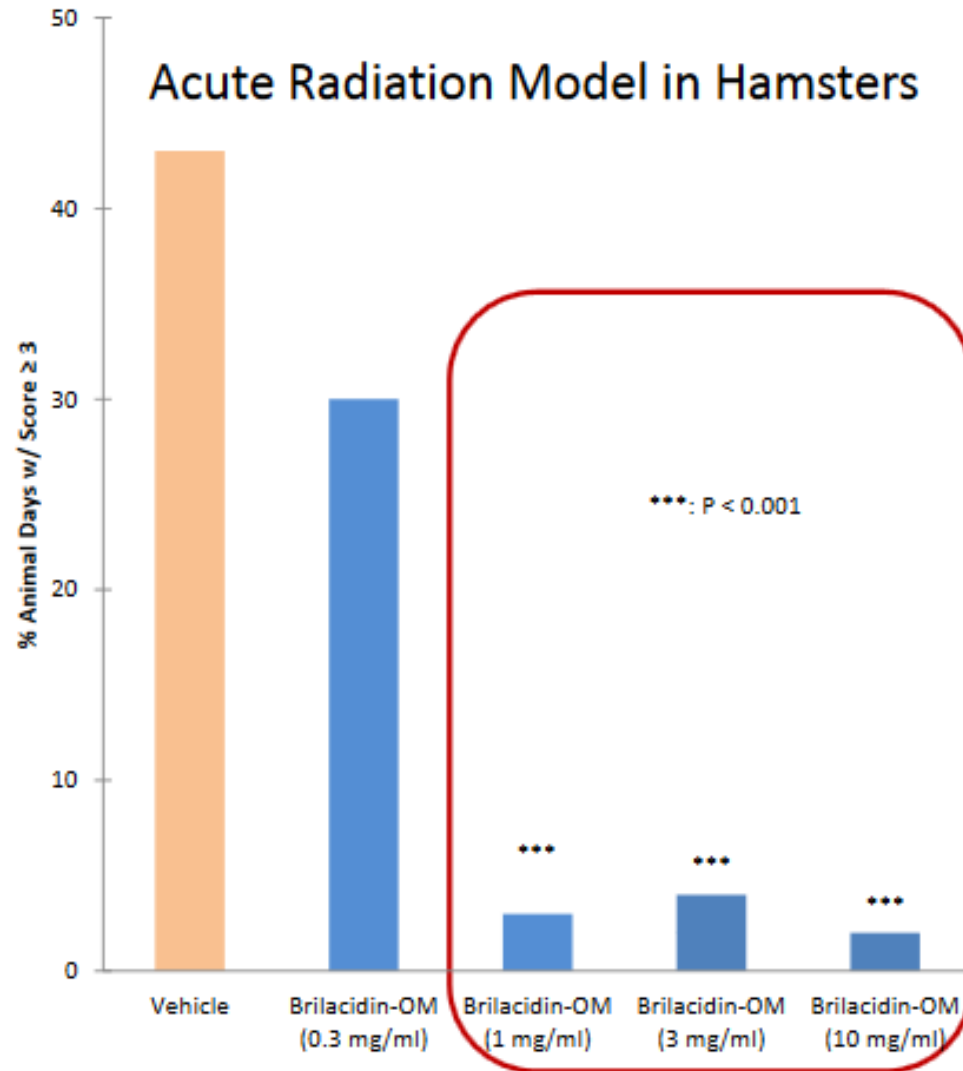
<sup>1</sup> S. Sonis and information based on GLOBOCAN Cancer Statistics

<sup>2</sup> Sonis ST et al. Perspectives on cancer therapy-induced mucosal injury. *Cancer*. 2004;100:1995-2025

<sup>3</sup> Nonzee et al. *Cancer* 2008, 113:1446-52

# Brilacidin

## 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

## *Oral Mucositis (Phase 2a Trial in Progress)*

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### **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*

- Efficacy of topically applied Brilacidin vs placebo in delaying the onset of severe OM (WHO Grade  $\geq 3$ )
- Safety and tolerability of topically applied Brilacidin administered three times daily for approximately 7 weeks

### **Secondary Endpoints**

- Reduction of incidence and duration of ulcerative and severe OM (WHO Grade  $\geq 2$ )
- Other secondary endpoints:
  - 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>

# Brilacidin

## *Ulcerative Proctitis and Ulcerative Proctosigmoiditis (Ongoing Phase 2a Clinical Trial)*

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### STUDY DESIGN

- Open-label, sequential dose escalation
- Brilacidin (N=6 per cohort)
  - Cohort A: 50 mg once daily for 42 days
  - Cohort B: 100 mg once daily for 42 days
  - Cohort C: 200 mg once daily for 42 days

“Understanding and controlling inflammation has become a central goal of modern medical investigation.”

[Dr. Jerome Groopman](#)

### OBJECTIVES

#### Primary:

- Assess the frequency of clinical and endoscopic remission
  - Brilacidin administered per rectum in subjects with active UP or UPS
  - 6 weeks of treatment

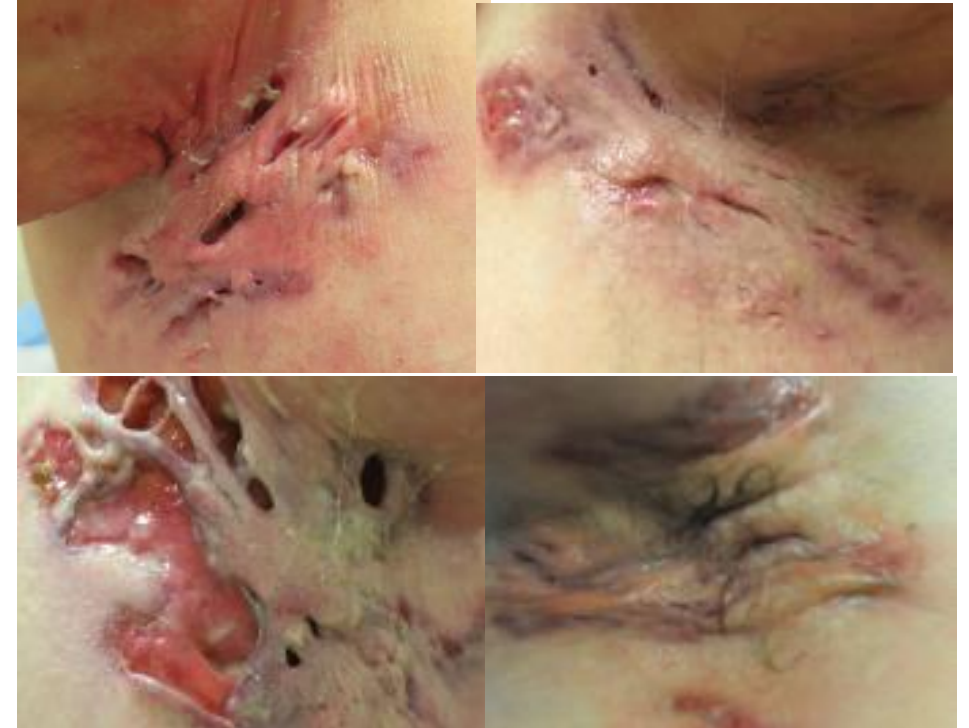
#### Secondary:

- Evaluate safety and tolerability of brilacidin when administered per rectum
- Assess systemic exposure and/or pharmacokinetics of Brilacidin administered per rectum
- Assess efficiency of brilacidin by biomarker evaluation of the biopsy samples for IL-6 and IL-1 $\beta$

# Brilacidin

## *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.
- Planned Phase 2 trial of Brilacidin-H. suppurativa.



Source:

[http://www.globalacademycme.com/fileadmin/pdf/supplement\\_pdf/SANv33\\_Hidradenitis\\_Sppl.pdf](http://www.globalacademycme.com/fileadmin/pdf/supplement_pdf/SANv33_Hidradenitis_Sppl.pdf)

# Brilacidin

*Acne (Propionibacterium Species)*

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Activity of brilacidin and comparators against evaluated *Propionibacterium* spp.<sup>1</sup>

MIC (µg/mL)

	Brilacidin	Erythromycin	Clindamycin	Minocycline	Doxycycline	Metronidazole
<b>MIC<sub>50</sub></b>	0.5	0.03	0.03	0.06	0.12	>64
<b>MIC<sub>90</sub></b>	1	>128	1	0.25	0.5	>64
<b>MIC range</b>	0.25 to 2	0.015 to >128	≤0.015 to >16	0.03 to 2	0.03 to 4	>64

<sup>1</sup>*Propionibacterium* spp. includes: *P. jensenii*, *P. granulosum*, *P. avidum*, *P. acnes*



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# Intellectual Property and Patents

Strong portfolio including:

Categories:

1. **Brilacidin**, and related compounds
2. Delparantag and related compounds
3. Anti-microbial – surfactants and related compounds
4. **Kevetrin** and related compounds
5. **Prurisol** and related compounds

**Cellceutix Corporation**  
**100 Cummings Center**  
**Beverly, MA**

**Ticker: CTIX**