cellceutix

Corporate Overview

Arthur P. Bertolino, MD, PhD, MBA
President & Chief Medical Officer

Presented at: Biotech Showcase
San Francisco, CA, USA
January 9, 2017

Safe Harbor; Forward-Looking Statements

This presentation 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. These forward-looking statements include, but are not limited to, statements concerning future drug development plans and projected timelines for the initiation and completion of preclinical and clinical trials; the potential for the results of ongoing preclinical or clinical trials and the efficacy of Cellceutix's drug candidates; the potential market opportunities and value of drug candidates; other statements regarding future product development and regulatory strategies, including with respect to specific indications; any statements regarding Cellceutix's future financial performance, results of operations or sufficiency of capital resources to fund its operating requirements; any statements relating to Cellceutix's planned uplisting or use of proceeds; and any other statements that are not statements of historical fact. Forward-looking statements involve risks and uncertainties, which may cause Cellceutix's actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. 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; Cellceutix's ability to continue to fund and successfully progress internal research and development efforts and to create effective, commercially-viable drugs; and 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. Forward-looking statements speak only as of the date on which they are made. 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 presentation or to reflect the occurrence of unanticipated events, except as required by applicable law or regulation.

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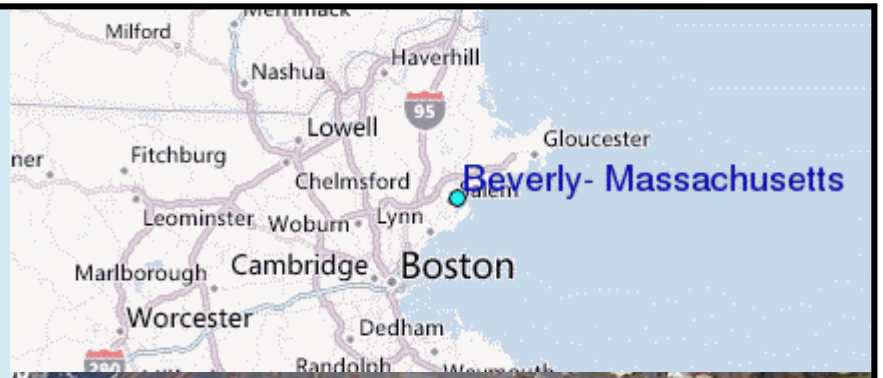


Corporate Focus and Management Team

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**.

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

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

Drug Candidates

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

Prurisol	*Orally-delivered **psoriasis** drug candidate in a Phase 2b trial utilizing advantages of the 505(b)(2) development approach*
Kevetrin	*p53-activating drug candidate with three Orphan Drug designations starting a Phase 2a trial for **ovarian cancer***
Brilacidin	*Drug candidate in a **new antibiotic class** with unique immunomodulatory properties advancing in clinical trials under Fast Track designations*

Pipeline—Stages of Development & Special FDA Designations

Exceptionally strong pipeline, novel mechanisms of action

Drug Candidate	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Prurisol	Psoriasis	→	→	→	
Kevetrin	Ovarian Cancer	→	→		
Brilacidin	UP/UPS*	→	→	→	
	Oral Mucositis	→	→	→	
	ABSSSI**	→	→	→	

Leveraging designations to expedite development, improve likelihood of drug approval, and gain added market exclusivity

Drug Candidate	Designation Type	Date Granted
Kevetrin	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
Brilacidin	QIDP*** Fast-Track Designation for ABSSSI**	December 2014
	Fast-Track Designation for Oral Mucositis	November 2015

*UP/UPS - Ulcerative Proctitis/Proctosigmoiditis

**ABSSSI - Acute Bacterial Skin and Skin Structure Infections

***QIDP – Qualified Infectious Disease Product

Cellceutix Anticipated Clinical Milestones

By Drug Candidate, Type of Event and Timeframe

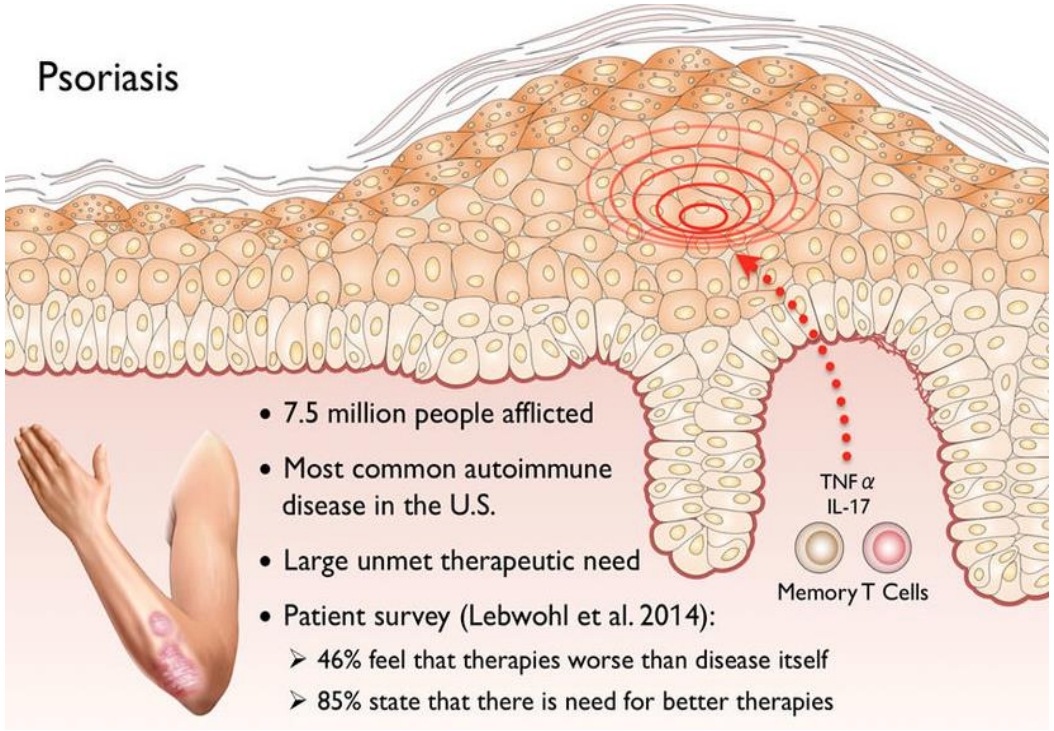
Drug Candidate			Event	Description	Period	Year	Delivered
Brilacidin	Kevetrin	Prurisol					
		X	Trial Progress	**Psoriasis-** Initiation Ph2b trial	4Q	2016	✓
X			Clinical Update	**Ulcerative Proctitis-** Interim Analysis Ph2a trial	4Q	2016	✓
	X		Trial Progress	**Ovarian Cancer-** Initiation Ph2a trial	1Q	2017	
		X	Clinical Update	**Psoriasis-** Interim Analysis Ph2b	1H	2017	
X			Clinical Update	**Oral Mucositis-** Interim Analysis Ph2	1H	2017	
X			Clinical Update	**Ulcerative Proctitis-** Complete Ph2a trial	1H	2017	
		X	Clinical Update	**Psoriasis-** Complete Ph2b trial	2H	2017	
X			Clinical Update	**Oral Mucositis-** Complete Ph2 trial	2H	2017	
	X		Clinical Update	**Ovarian Cancer-** PoC p53 modulation (Ph2a)	2H	2017	
X			Trial Progress	**ABSSSI-** Start Ph3 trial	*	2017	

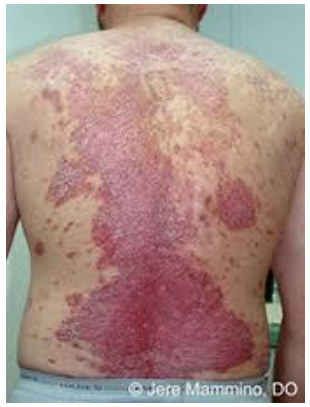
*Timetable dependent on reaching SPA agreement with FDA

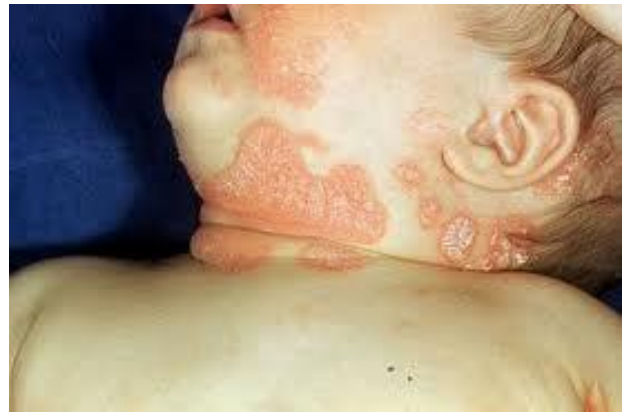
Prurisol

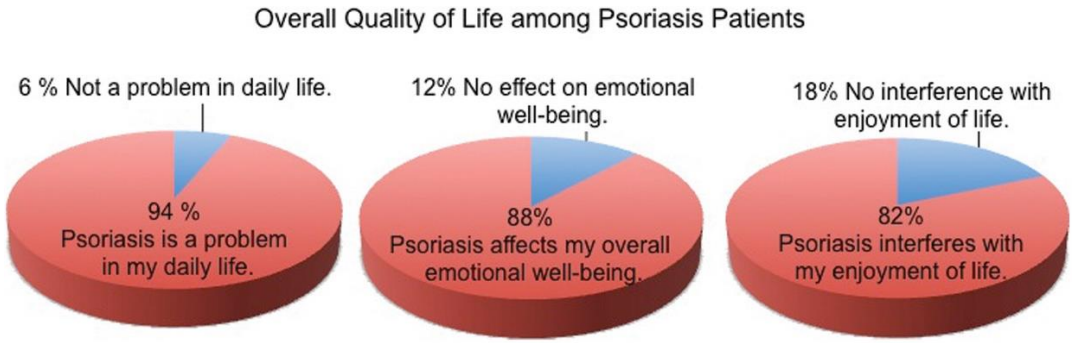
Psoriasis: Debilitating Chronic Disease That Affects Millions

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

Prurisol for Psoriasis

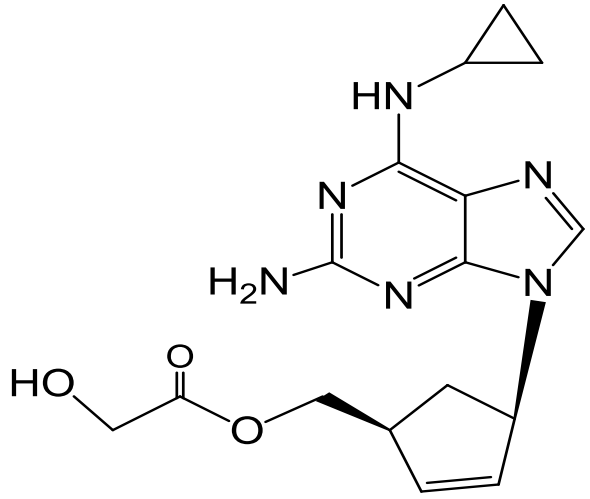
MOA and Attributes

Mechanism of Action (MOA)

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

Attributes

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



Prurisol

[Abacavir (α-hydroxy) acetate; abacavir glycolate]

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

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

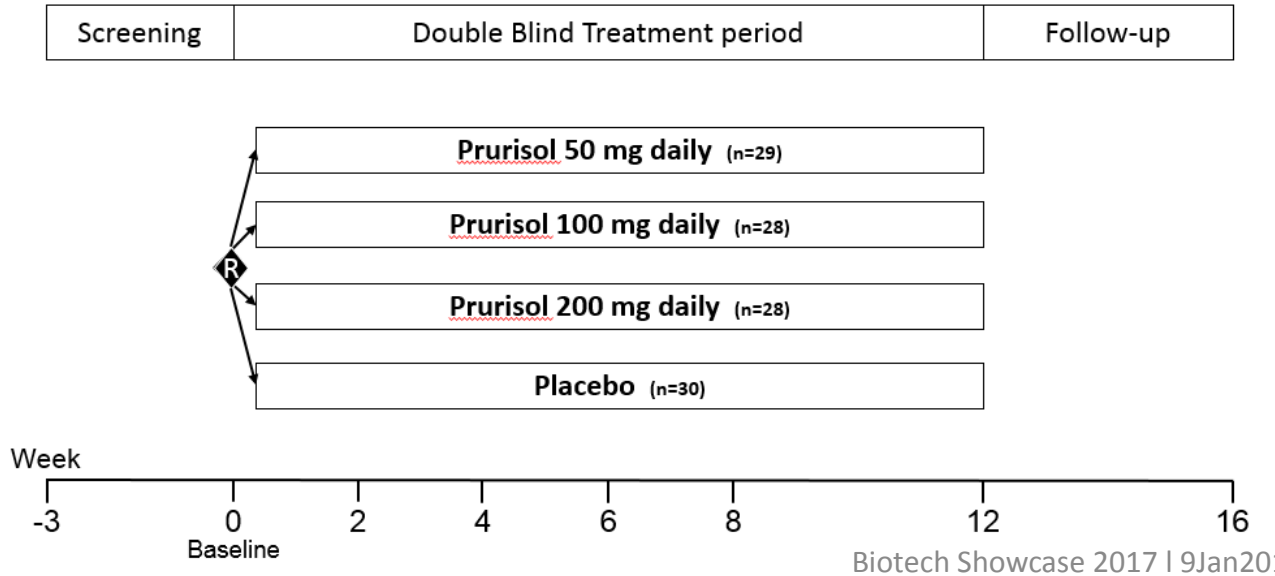
Prurisol for Psoriasis

*CTIX-0002 – Study Design for Phase 2a Clinical Trial in **Mild-to-Moderate Plaque Psoriasis***

Primary Efficacy Endpoint: percentage of subjects with ≥ 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

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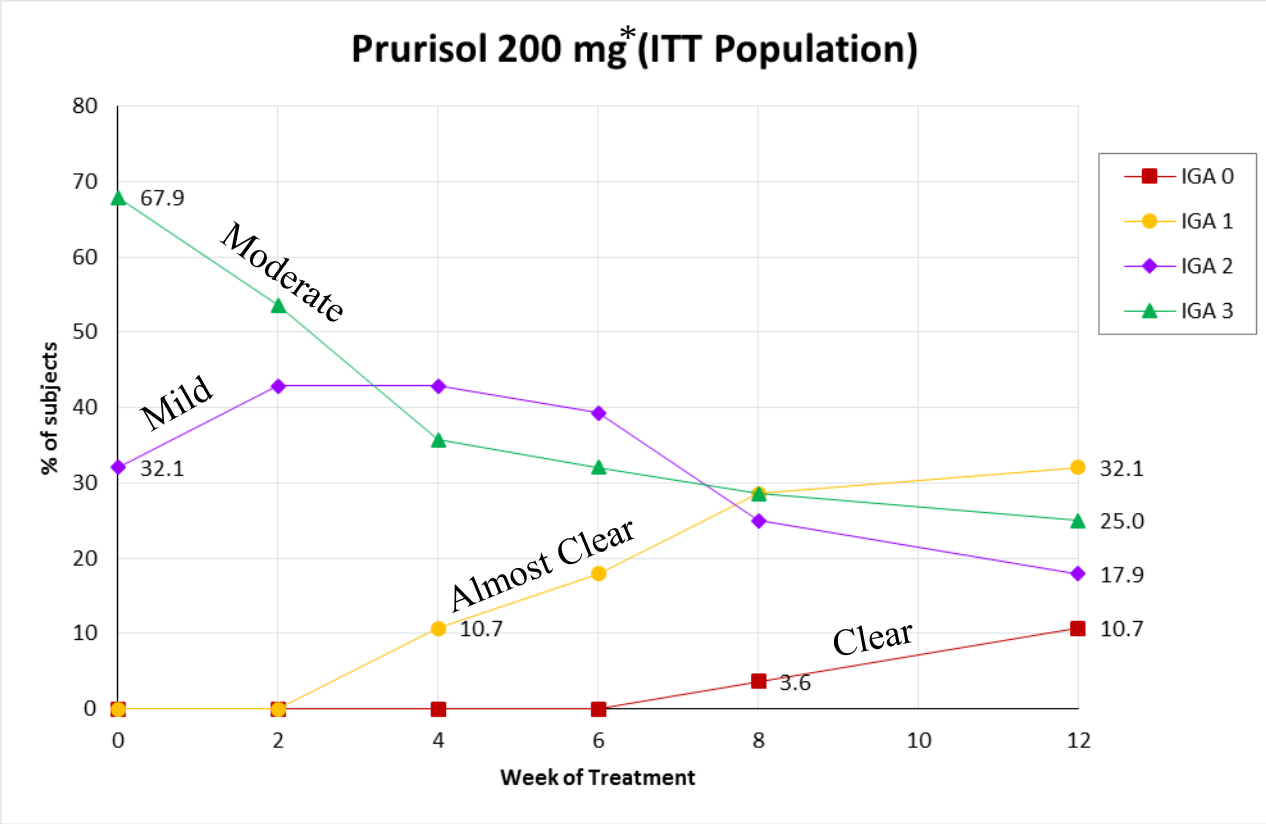
Prurisol for Psoriasis

CTIX-0002 – IGA Scores Over Time (200 mg group) & Topline Results

- IGA changes noted as soon as Week 2
- Progressive decrease of IGA scores to lower values over 12 weeks
- Time-based transition of original moderate & mild population to less psoriasis activity with emergence of almost clear and clear groups
  - At Week 12: 42.8% subjects (ITT) [and 55.0% subjects (PP)] achieved "clear" (0) or "almost clear" (1) in IGA



Source: Table 14.2.1.2.1 (ITT Population) *Where % subject total <100%, basis is attrition without data imputation

- **Prurisol met the primary endpoint (a ≥ 2-point IGA reduction) in 35% of all patients who received a dose of 200 mg per day(Per Protocol)**
- Prurisol was well-tolerated—just one Serious Adverse Event (SAE) occurred and it was in the 50 mg dose group
- PK results showed a dose-dependent increase in drug exposure and maximum plasma concentration

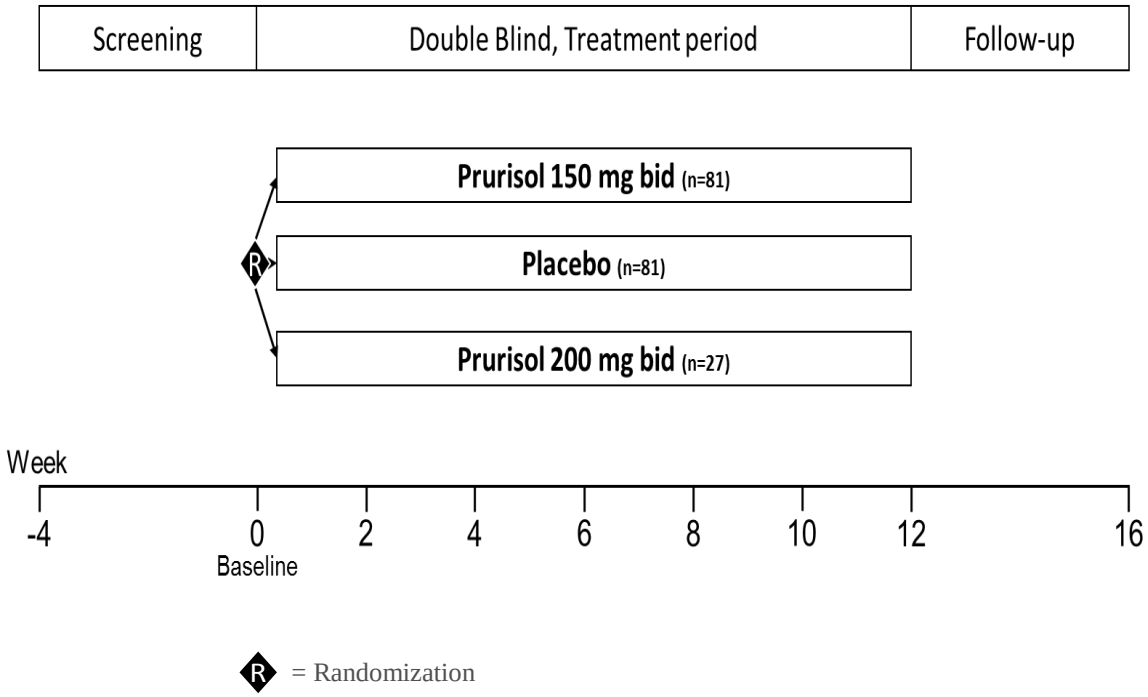
Among patients with the severest form of psoriasis in study, those having a baseline IGA score of 3 ("moderate"), the **primary endpoint was met in 46% of patients** who received 200 mg per day. These data were derived from analyses of all patients.

Prurisol for Psoriasis

Ongoing Phase 2b** Clinical Trial in **Moderate-to-Severe Plaque Psoriasis

- **Randomized, double-blind, parallel-group, placebo-controlled**
- **Treatment Groups**
  - Prurisol 300 mg: Pbo: Prurisol 400 mg
  - 3:3:1
- **Number of Subjects**
  - ~189
- **Treatment Duration**
  - 12 weeks (interim readout 2Q17)
- **Number of Sites (U.S.)**
  - ~25

Study Design Schematic



For study details, see
https://clinicaltrials.gov/ct2/show/NCT02949388

Prurisol for Psoriasis

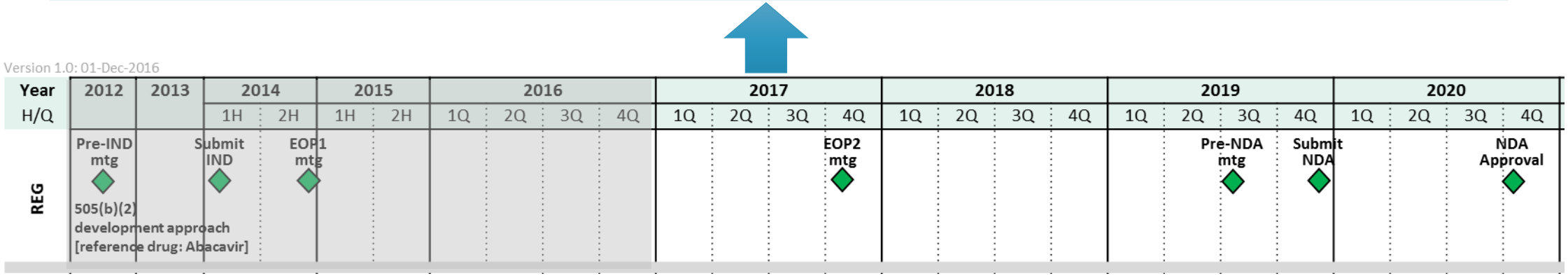
2017 – An Inflection Point

Near-Term Value Drivers

- **2Q 2017 – Phase 2b Interim Data**
- **3Q 2017 – Phase 2b Complete Top-line Data**
- **4Q 2017 – End-of-Phase 2 Meeting with FDA**

Broader Context

- ❖ **Big Pharma Recognizes Value of Safe, Effective Oral Psoriasis Drug**
- ❖ **Cellceutix Actively Discussing Partnerships for Late-Stage Studies**
- ❖ **Targeting NDA Submission to FDA in 4Q 2019**



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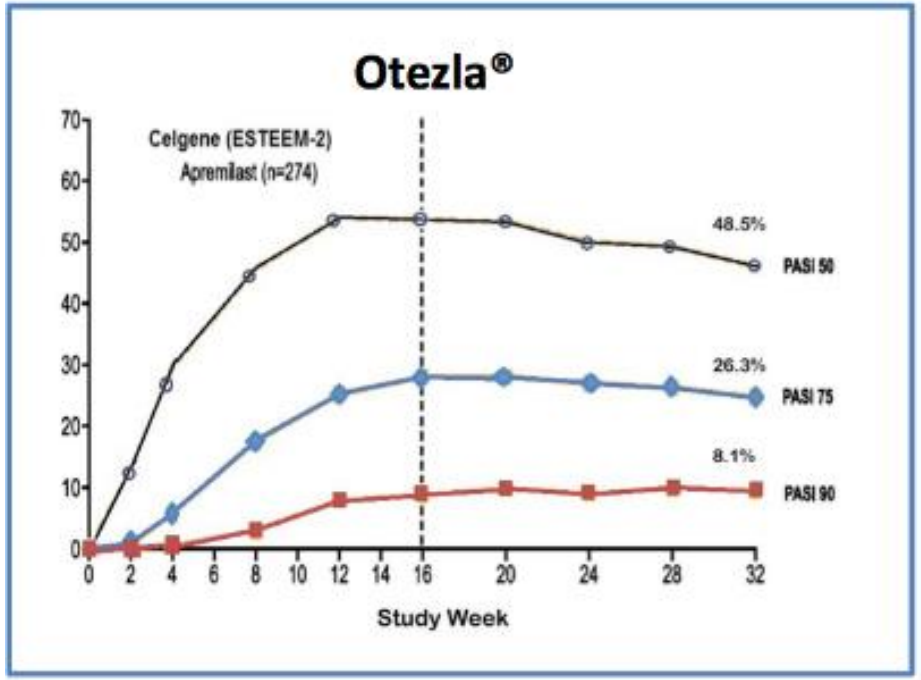
Prurisol for Psoriasis

Market Opportunity, Competitive Landscape

Otezla® Emerging as a Blockbuster Drug

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



Source: http://www.baystreet.ca/articles/research_reports/lifesci/Can-Fite%20BioPharma041216.pdf; Cellceutix research

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

Recent Psoriasis Deals

$640 million

Allergan

vitae Pharmaceuticals

RORγt IL-17 modulation

$490 million

Dr. Reddy's

XenoPort

Monomethylfumarate prodrug

$790 million

PURDUE

exicure

SNA-based therapeutics

$595 million

Boehringer Ingelheim

abbvie

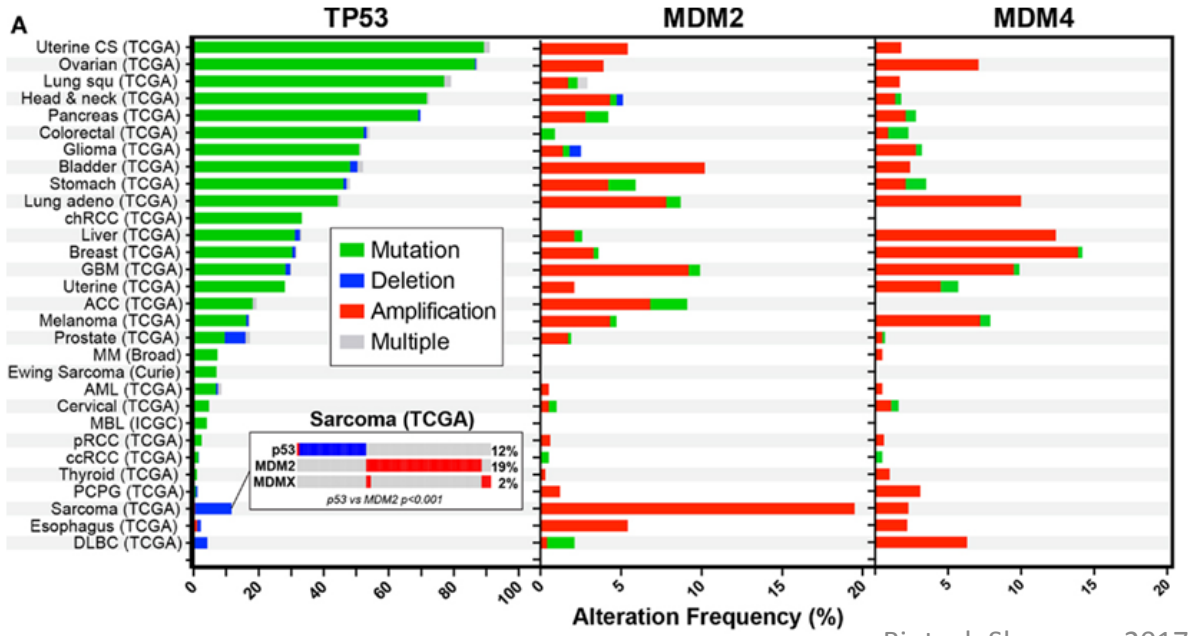
Anti-IL-23 mAb

Kevetrin for Ovarian Cancer

Program Summary

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

- **Induces apoptosis** and shows potent anti-tumor activity
- **Multiple molecular targets and signaling pathways** targeted and regulated (modulates)
- **Non-genotoxic induction of Apoptosis**
- **Does not affect normal cell viability** at concentrations that kill tumor cells
- **Well-tolerated with minimal adverse effects** in the completed Phase 1 clinical trial



Current Perspectives

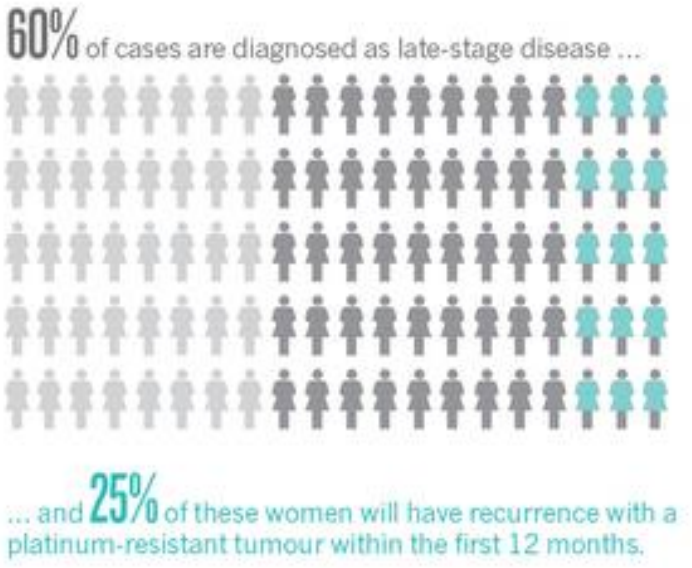
- **Ovarian Cancer (OC)** indication supported by Phase 1 advanced solid tumor trial.
- **p53 pathway modulation** to be measured in upcoming OC trial.
- **Oral formulation** and delivery advances are underway. This better aligns with Kevetrin's short half-life (approximately 2 hours, with the drug clearing the body within one day, though on average, between 8 and 10 hours) and may provide for even greater drug exposure and toleration.

Source: http://journal.frontiersin.org/article/10.3389/fonc.2016.00007/full

Kevetrin for Ovarian Cancer

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

- **Kevetrin Therapy**
  - Kevetrin (starting dose 250 mg/m^2) 3 times/week over 3 weeks (dose escalation in 2nd cohort)
- **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 – miRNA-34a
  - Pathways analyses via RNA sequencing



Goal: Establish p53 MOA directly in tumor cells

Multidisciplinary Programs - Brilacidin

Gastrointestinal	Inflammatory Bowel Disease: Ulcerative Proctitis/Ulcerative Proctosigmoiditis (UP/UPS)
Dermatology/Cancer	Oral Mucositis (OM)
Infectious Disease	Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Brilacidin

IBD—Ulcerative Proctitis and Ulcerative Proctosigmoiditis (Phase 2a Trial in Progress)

Study Design

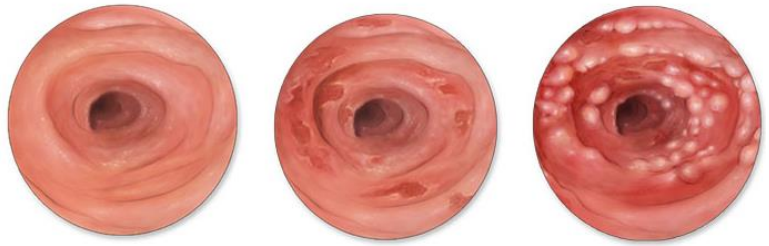
- Open-label, sequential dose escalation

- Brilacidin (N=6 per cohort) once daily for 42 days
  - Cohort A: 50 mg
  - Cohort B: 100 mg (currently dosing this cohort)
  - Cohort C: 200 mg

Objectives

Primary:

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



Healthy Colon *Ulcerative Colitis* *Crohn's Disease*

Interim Results in First Study Cohort

All **4 subjects evaluated** demonstrated a clinical response, measurable by the **Modified Mayo Disease Activity Index** (MMDAI)

- **Partial MMDAI** (Day 42)
  - **2 of 4** subjects achieved **full response** (100% reduction)
  - **2 of 4** subjects had **notable improvement** (50% reduction)

- **MMDAI** (Day 42; 3 of 4 subjects completed endoscopy)
  - **1 of 3** subjects achieved **full response** (100% reduction)
  - **2 of 3** subjects had **notable improvement** (50% reduction)

- **Patient Quality of Life**, as measured by the Short Inflammatory Bowel Disease Questionnaire (SIBDQ)
  - **Improved** after 6-week treatment with Brilacidin

- **Safety**
  - **Generally well-tolerated**
  - Subjects had stable normal vital signs

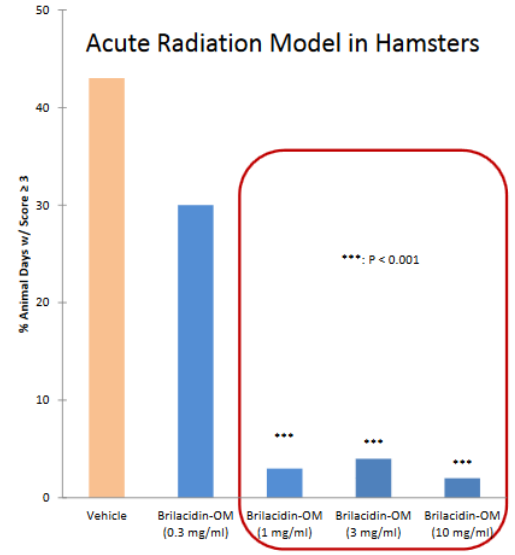
- **Drug Concentrations in Plasma**
  - All levels at all time points **below the lower limit of quantification** (ie, <100 ng/mL)
  - Consistent with **very limited systemic exposure** from administration per rectum by enema

For current standard of care, see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4876845/

Brilacidin

Oral Mucositis—Animal Model Results (Phase 2 Trial in Progress)

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

Clinical Predictability of the Hamster Oral Mucositis Models
Studies by Dr. Stephen Sonis, Harvard *

	Effect in animal model % reduction	Effect in Clinic % reduction
ActoGenix AG013 (HTF-1)	33%	30%
SciClone SCV-07	33%	30%
Velafermin (hFGF-20)	37%	51%
BRILACIDIN	**94%**	*Interim Phase 2 Results Anticipated Q2 2017*

**Cellceutix Clinical Advisor*

Phase 2 Trial

Study Design

- Phase 2, Multi-center, Randomized, Double-blind, Placebo-controlled (10 sites in US expanding to up to 20)
- 60 subjec***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 ≥ 3)
- Safety and tolerability of topically-applied Brilacidin administered three times daily for approximately 7 weeks
- ts – 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

For pre-clinical work, see http://cellceutix.com/wp-content/uploads/2013/11/ECCMID-2015-OM-poster.pdf
For study details, see https://clinicaltrials.gov/ct2/show/NCT02324335

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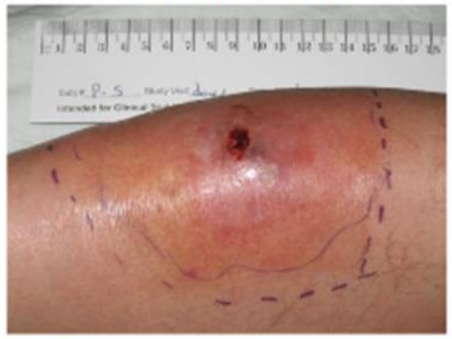
Brilacidin

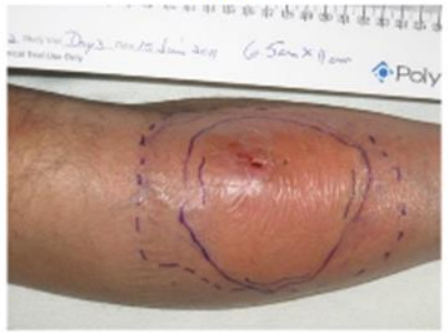
ABSSSI Phase 2b Clinical Trial Results

	Brilacidin 0.6 mg/kg IV x 1 day (N=53)	Brilacidin 0.8 mg/kg IV x 1 day (N=53)	Brilacidin x 3 days (N=53)	Daptomycin x 7 days (N=50)
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)

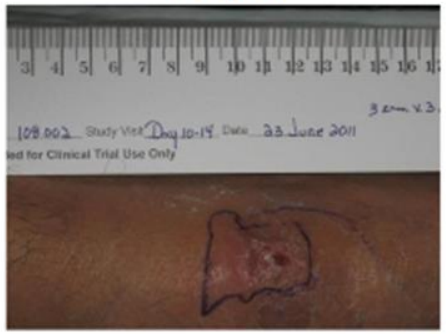
Pre-treatment



Day 3



Day 10



Current Perspectives

- **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 patient non-compliance as driver of resistance
- **Phase 3 planning in progress**
  - Response to Special Protocol Assessment (SPA) comments from FDA underway

*Acute Bacterial Skin and Skin Structure Infection

For the Phase 2b clinical trial of Brilacidin in ABSSSI, see https://clinicaltrials.gov/ct2/show/NCT02052388
Also see: Comparative Mechanistic Studies of Brilacidin, Daptomycin, and the Antimicrobial Peptide LL16

Intellectual Property and Patents

Strong Protections Across All Drug Candidates and Related Compounds

- #US Patents granted
  - 1
- Prurisol Mfg method
  - Prov. pending
- Countries Granted
  - Various EU
  - Japan
  - Others

- # US Patents granted
  - 1
- # Patents pending
  - Others
- Countries Granted
  - Various EU
  - Japan
  - Others

- # US Patents granted
  - 9
- Brilacidin Mfg method
  - In-process
- Countries Granted
  - Various EU
  - Japan
  - Others

Join Cellceutix in Reaching Milestones

2017 Goals = A Focus On Partnering Opportunities

Successfully Complete

- **Phase 2b Trial of Prurisol for Psoriasis**
- **Phase 2a Trial of Brilacidin for UP/UPS (IBD)**
- **Phase 2 Trial of Brilacidin for Oral Mucositis**
- **Phase 2a Trial of Kevetrin for Ovarian Cancer**
- **FDA Meetings**
  - ❖ **EoP2 for Psoriasis**
  - ❖ **SPA for Brilacidin in ABSSSI**

Meeting 2017 Milestones Sets the Stage to Potentially Initiate 5 Registration Studies in 2018!

OTCQB(symbol): CTIX; **Share Price:** ~$1.20; **Market Cap:** ~$150M;
Avg. Daily Vol: ~145k; **Shares Outstanding:** ~ 124M

Cellceutix Corporation

100 Cummings Center
Beverly, MA

January 2017

Ticker: CTIX