Cellceutix Corporation
Beverly, MA USA
www.cellceutix.com

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A Randomized, Double-Blind Study Comparing Single-Dose and Short-Course Brilacidin to Daptomycin in the Treatment of Acute Bacterial Skin & Skin Structure Infections (ABSSSI)

Abstract 2969; Presentation 0195; Hall J, 4:00pm

April 27, 2015

A Randomized, Double-Blind Study Comparing Single-Dose and Short-Course Brilacidin to Daptomycin in the Treatment of Acute Bacterial Skin & Skin Structure Infections (ABSSSI)

Author Disclosures

Author	Category	Affiliation	Location
Daniel Jorgensen	Employee	Cellceutix Corporation	Beverly, MA, USA
Richard Scott	Consultant	Fox Chase Chemical Diversity Center	Doylestown, PA, USA
William O'Riordan	Consultant*	e-Study Site	San Diego, CA, USA
Kenneth Tack	Consultant	Celleceutix Corporation	Beverly, MA, USA

***Also PI in ABSSSI study**

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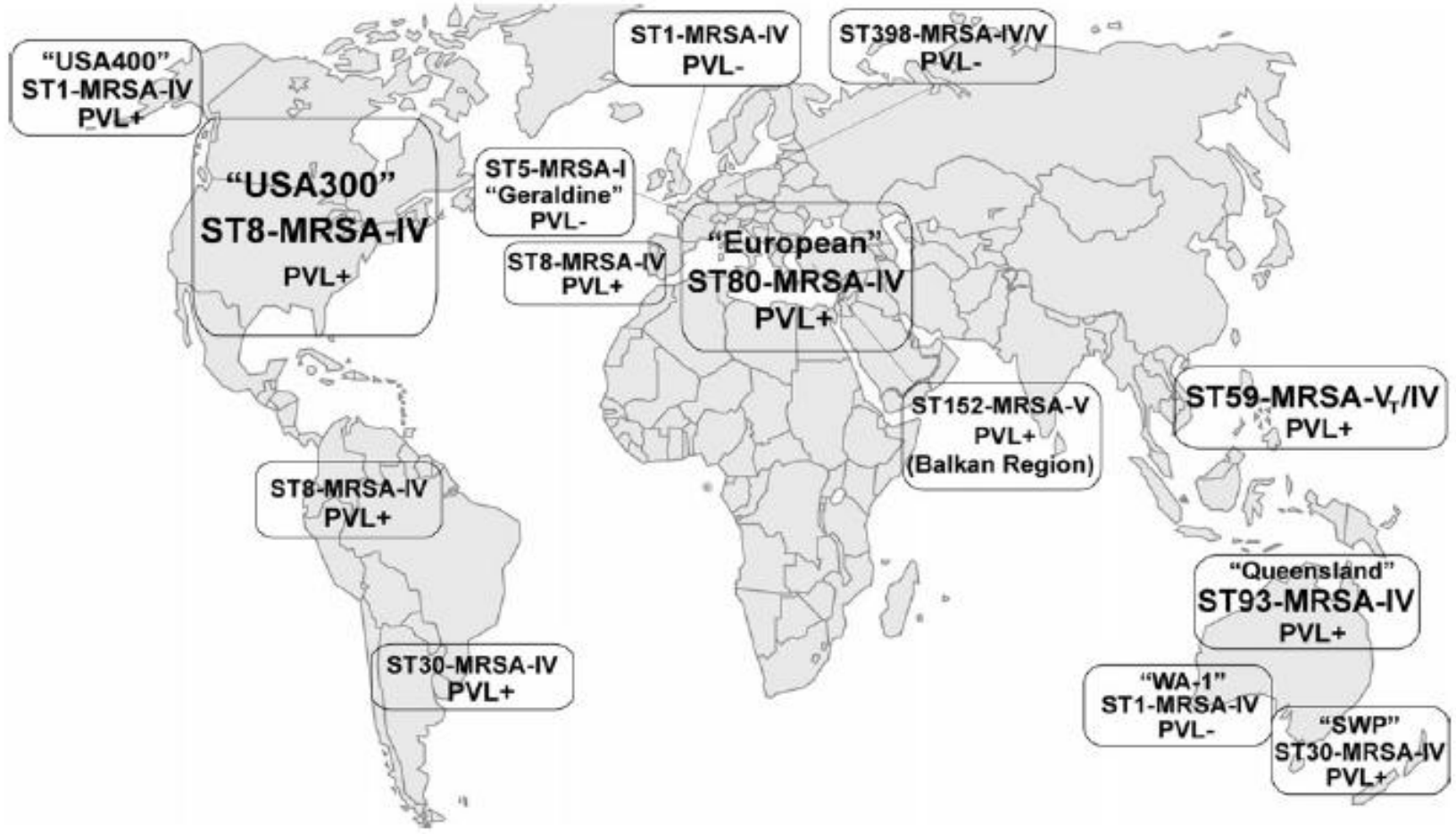
CA-MRSA—A Global Public Health Problem

Major Cause of Skin and Soft Tissue Infections



Global distribution of dominant community methicillin-resistant *Staphylococcus aureus* (MRSA) clones and Panton Valentine leukocidin (PVL)

Clinical Infectious Diseases 2011;52(1):99–114

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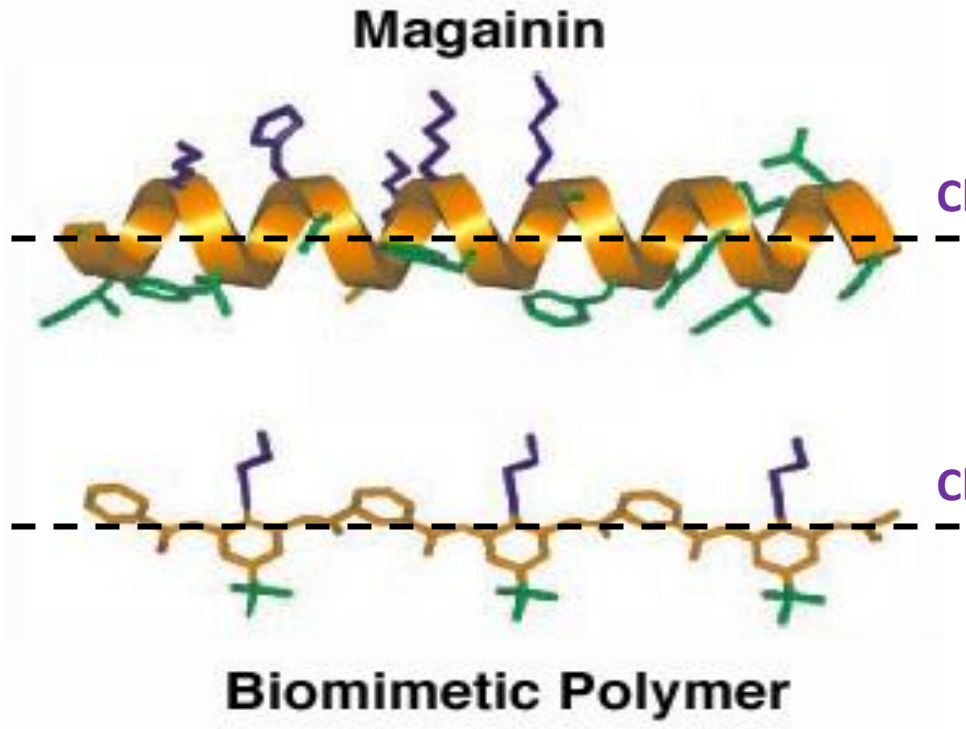
Background & Rationale

Design Approach

The biological activities of host defense proteins depend on an *amphiphilic helix*



Capture structural and biological properties of HDPs using fully synthetic, nonpeptidic scaffolds and sidechains

Not peptidomimetics

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Background & Rationale

- **Develop small non-peptidic, fully synthetic mimics of Host Defense Proteins (HDPs) as systemic and topical agents**
  -Novel approach for bactericidal activity
- **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 bacterial invasion**
  -Part of innate immunity
  -Maintenance of epithelial barrier function
  -Regulate microbiota
  -Immuno-modulatory activities – link innate and adaptive immunity
- **HDP dysfunction implicated in inflammatory disorders of skin and mucosal surfaces**
  -Inflammatory bowel disease (BID), atopic dermatitis, acne, skin infections, cystic fibrosis…
- **Clinical lead (Gram-positive program):** **Brilacidin**

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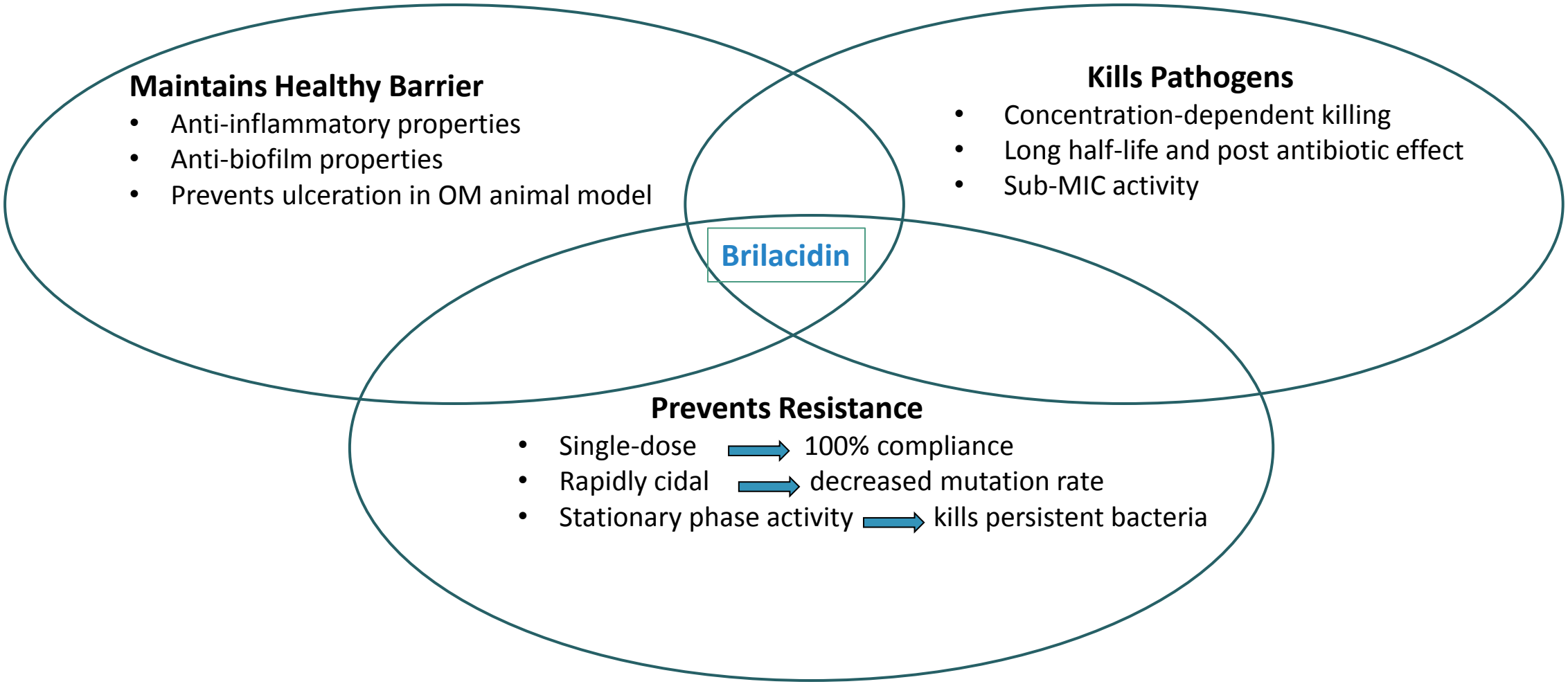
Lead Compound--Brilacidin



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Brilacidin Clinical Experience

- Phase 1 studies completed
  - Ascending single-dose (PMX63-101), multiple-dose x 5 days (PMX63-102), and fixed-dose x 14 days (PMX63-103)
  - IV infusions q48H, q24H, and q12H
- Pharmacokinetics
  - Consistent and linear pharmacokinetics in plasma with half-life of ~ 15-23 hours.
- Ex-vivo efficacy
  - Long lasting bactericidal and inhibitory activity vs. MSSA and MRSA in serum from human subjects after doses as low as 0.1 mg/kg
- Safety
  - Mild paraesthesia and hypoaesthesia (numbness and tingling) with acute onset and rapid resolution No neurotoxicity evident in human subjects or animal safety studies
  - Transient blood pressure elevation
    - Dose-dependent; reversible after treatment discontinuation
- Phase 2 in ABSSSI
  - Brilacidin dosed in > 300 patients
  - Effective; Generally safe and well-tolerated
  - Phase 2a data presented at ICAAC, 2012
  - PK/PD data presented at ECCMID, 2013
  - Phase 2b data presented at ECCMID, 2015

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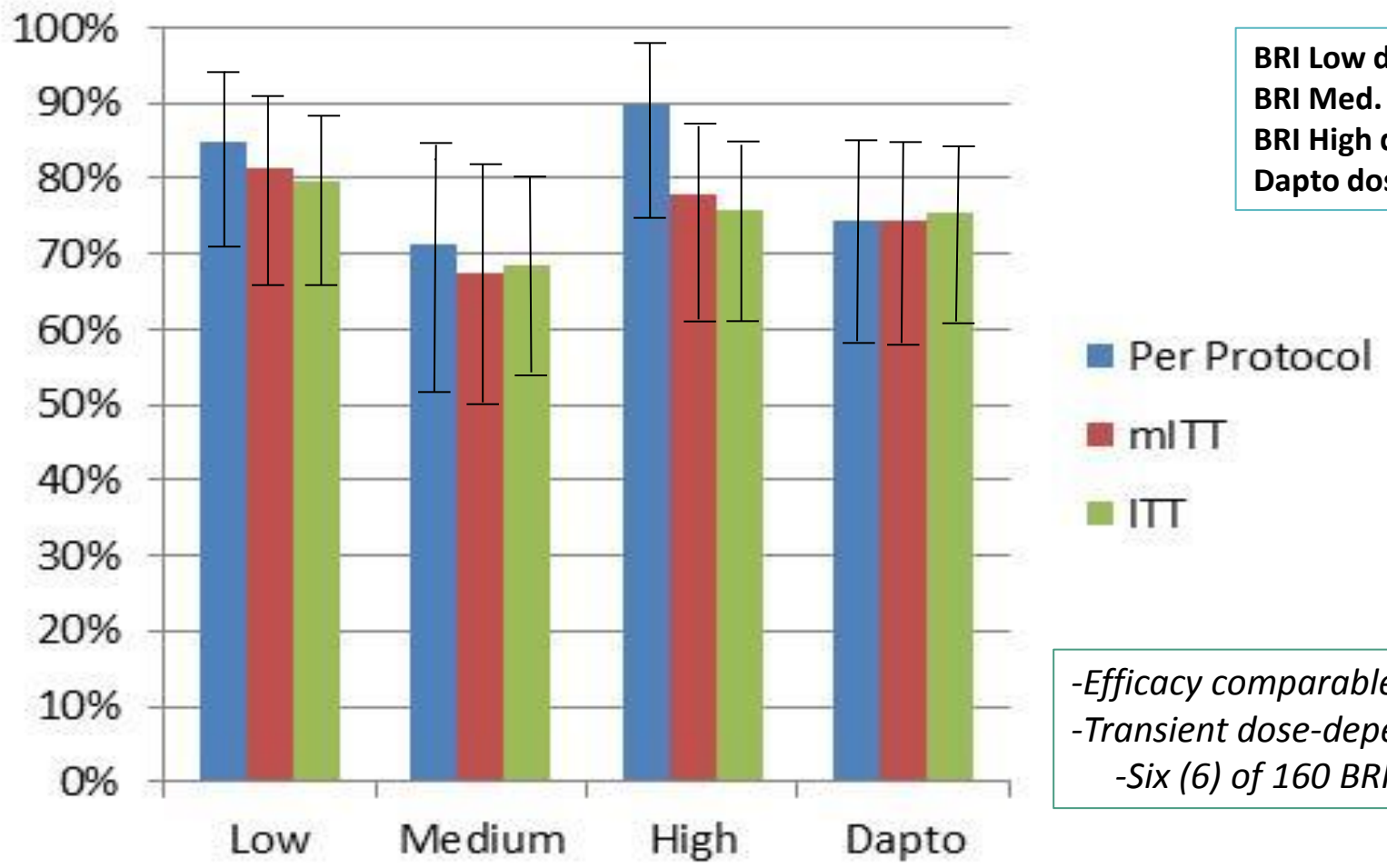
Previous Study (Phase 2a)

FDA-Defined Clinical Response – Day 2-3



% Clinical Success

Dosing Regimens

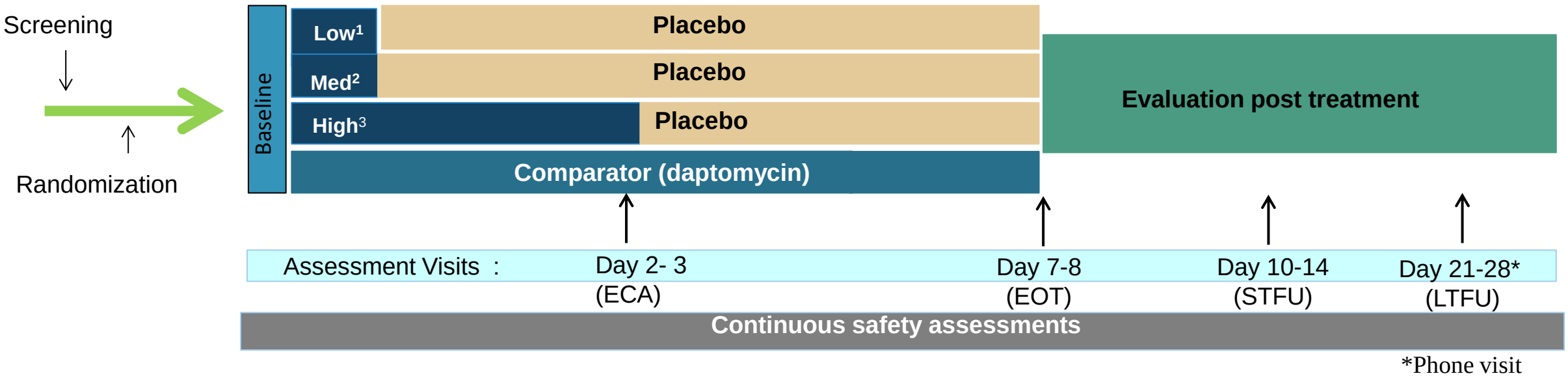
BRI Low dose: 1.60 mg/kg over 5 days
BRI Med. dose: 2.15 mg/kg over 5 days
BRI High dose: 2.40 mg/kg over 5 days
Dapto dose: 4 mg/kg QD x 7 days

-Efficacy comparable to 7 days of daptomycin
-Transient dose-dependent elevation of BP
-Six (6) of 160 BRI subjects with SBP ≥ 180 mmHg

Data presented at ICAAC, Sept. 2012

CTIX-BRI-204 Study (Phase 2b)

Study Design



[1]**Low** (0.6mg/kg single dose)
[2]**Med** (0.8mg/kg single dose)
[3]**High** (0.6 mg/kg D1; 0.3 mg/kg D2 & D3)*

**Highest total dose of 1.2 mg/kg is less than lowest total dose of 1.6 mg/kg in phase 2a study*

- **Trial conducted at 4 sites in U.S.**
- **Dosing: IV infusion 1x/day for 7 days**
  - 1or 3 days on BRI + 4 or 6 days on placebo; or 7 days on daptomycin
- **215 patients, 4 arms, ~50 patients per arm**
- **ABSSSI definition (FDA Guidance, Oct 2013)**
  - ≥ 75 sq. cm^2 (redness, edema, and/or induration)
  - Wound, major cutaneous abscess, cellulitis/erysipelas
- **Early Clinical Response (48-72 hours)—FDA endpoint**
- **Clinical Response (Day 7-8; Day 10-14)—EMA endpoint**

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Study Analysis Populations

Definition	Number (%) of Subjects [a]				
	Brilacidin (mg/kg IV)				
	0.6 1 day	0.8 1 day	0.6/0.3 3 days	Daptomycin 7 days	Overall
Intent-to-Treat (ITT)	54	53	54	54	215
All Treated/Safety	53	53	53	50	209
Microbiological ITT (MITT)	31 (58.5)	35 (66.0)	29 (54.7)	38 (76.0)	133 (63.6)
Clinical Evaluable – EOT (CE-EOT)	48 (90.6)	46 (86.8)	49 (92.5)	47 (94.0)	190 (90.9)
Clinical Evaluable – STFU (CE-STFU)	49 (92.5)	42 (79.2)	45 (84.9)	46 (92.0)	182 (87.1)
Microbiological Evaluable – EOT (ME-EOT)	29 (54.7)	28 (52.8)	26 (49.1)	35 (70.0)	118 (56.5)
Microbiological Evaluable – STFU (ME-STFU)	29 (54.7)	24 (45.3)	23 (43.4)	34 (68.0)	110 (52.6)

Source: Section 14, Table 14.1.2.1.

(a) Percentages are based on the number of subjects who received at least 1 dose of study treatment in each treatment group.

FDA Early Endpoint & Safety

EMA Endpoints at EOT and STFU

- ATS Population = All subjects who received any amount of study drug
- mITT Population = All ATS subjects with ABSSSI pathogen isolated at baseline

Primary Endpoint--United States
Early Clinical Response at 48-72 hours

FDA ABSSSI Guidance (Oct, 2013):

> *"Clinical response should be based on the percent reduction in the lesion size at 48 to 72 hours compared to baseline, measured in patients who did not receive rescue therapy and are alive. A clinical response in a patient generally is defined as a percent reduction in lesion size greater than or equal to 20 percent compared to baseline".*

"Clinical Response" if all of the below criteria are fulfilled:

- Did not receive rescue therapy
- Alive
- ≥ 20% reduction in lesion area (lesion length x lesion width)

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Primary Endpoint--United States

Early Clinical Response at 48-72 hours

	0.6 mg/kg IV x 1 day (N=53)	0.8 mg/kg IV x 1 day (N=53)	Brilacidin x 3 days (N=53)	Daptomycin (N=50)
N 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 (Oct, 2013)

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Primary Endpoint—Europe

Investigator Clinical Response at EOT and STFU

Study Timepoint		0.6 mg/kg IV x 1 day	0.8 mg/kg IV x 1 day	Brilacidin x 3 days	Daptomycin
EOT	N assessed	30	31	29	38
(D7-8)	Clinical Response (%)	29 (96.7)	26 (83.9)	26 (89.7)	35 (92.1)
	95% C.I.	(90.2, 100)	(70.9, 96.8)	(78.6, 100)	(83.5, 100)
	Non-clinical Response*	1	5	3	3
STFU	N assessed	30	29	25	36
(D10-14)	Clinical Response (%)	29 (96.7)	24 (82.8)	24 (96.0)	34 (94.4)
	95% C.I.	(90.2, 100)	(69.0, 96.5)	(88.3, 100)	(87.0, 100)
	Non-clinical Response*	1	5	1	2

mITT Population

*Includes PI response of “Clinical Failure” and “Indeterminate”

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Investigator Clinical Response at EOT and STFU

--By Baseline Pathogen

Baseline Pathogen	PI Clinical Assessment at Day 7/8: EOT				PI Clinical Assessment at Day 10-14: STFU			
	Brilacidin				Brilacidin			
	0.6 1 day	0.8 1 day	0.6/0.3 3 days	Daptomycin 7 days	0.6 1 day	0.8 1 day	0.6/0.3 3 days	Daptomycin 7 days
Staphylococcus aureus								
MSSA only	16/17 (94.1)	15/18 (83.3)	12/13 (92.3)	11/13 (84.6)	16/17 (94.1)	14/17 (82.4)	12/12 (100.0)	11/12 (91.7)
+ *S. lugdunensis*	1/1 (100.0)		1/1 (100.0)		1/1 (100.0)		1/1 (100.0)	
+ *S. anginonsus-milleri*		1/1 (100.0)	1/1 (100.0)			1/1 (100.0)	1/1 (100.0)	
+ *S. pyogenes*				2/2 (100.0)				2/2 (100.0)
MRSA only	9/9 (100.0)	7/8 (87.5)	10/11 (90.9)	12/13 (92.3)	9/9 (100.0)	6/7 (85.7)	8.8 (100.0)	11/12 (91.7)
+ *E. faecalis*				1/1 (100.0)				1/1 (100.0)
+ *S. agalactiae*				1/1 (100.0)				1/1 (100.0)
Streptococcus								
agalactiae				1/1 (100.0)				1/1 (100.0)
anginonsus-milleri	2/2 (100.0)	2/3 (66.7)	2/3 (66.7)	3/3 (100.0)	2/2 (100.0)	2/3 (66.7)	2/3 (66.7)	3/3 (100.0)
pyogenes	1/1 (100.0)				1/1 (100.0)			
Staphylococcus								
lugdunensis		1/1 (100.0)		1/1 (100.0)		1/1 (100.0)		1/1 (100.0)
Enterococcus								
faecalis				1/1 (100.0)				1/1 (100.0)
Group C Beta-hemoloytic streptococci				2/2 (100.0)				2/2 (100.0)

mITT Population

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Brilacidin MIC by Baseline Pathogen

Pathogen [(a)]	Brilacidin MIC (µg/ml)				
	$N_{isolates}$	Range		MIC_{50}	MIC_{90}
		Minimum	Maximum		
S. aureus	113	0.50	2.00	1.00	1.00
MSSA	65	1.00	2.00	1.00	1.00
MRSA	48	0.5	2.00	1.00	1.00
S. pyogenes	2	2.00	2.00	-	-
S. agalactiae	2	2.00	2.00	-	-
Group C Beta- haemolytic streptococci	1	2.00	2.00	-	-
S. anginonsus-milleri group	3	0.25	4.00	2.00	4.00
E. faecalis	3	4.00	8.00	4.00	8.00
S. lugdunensis	4	1.00	1.00	1.00	1.00

(a) Based on central laboratory results.

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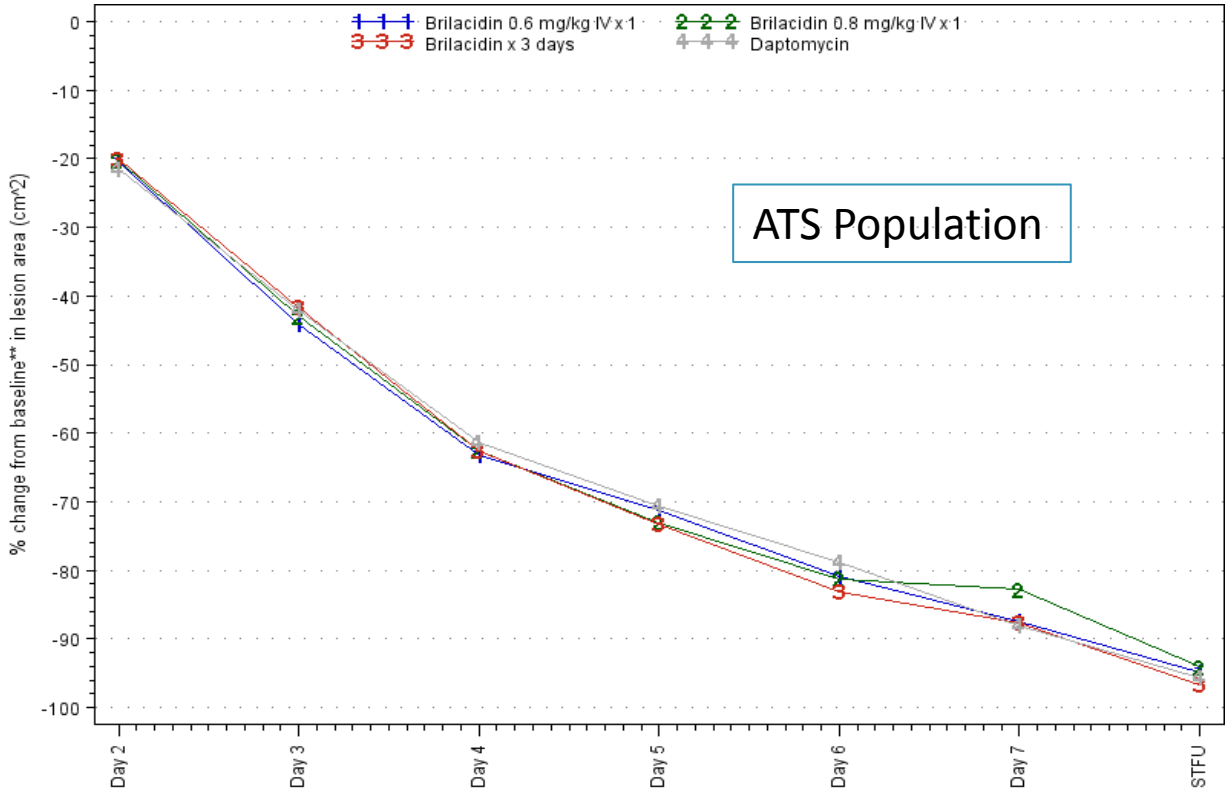
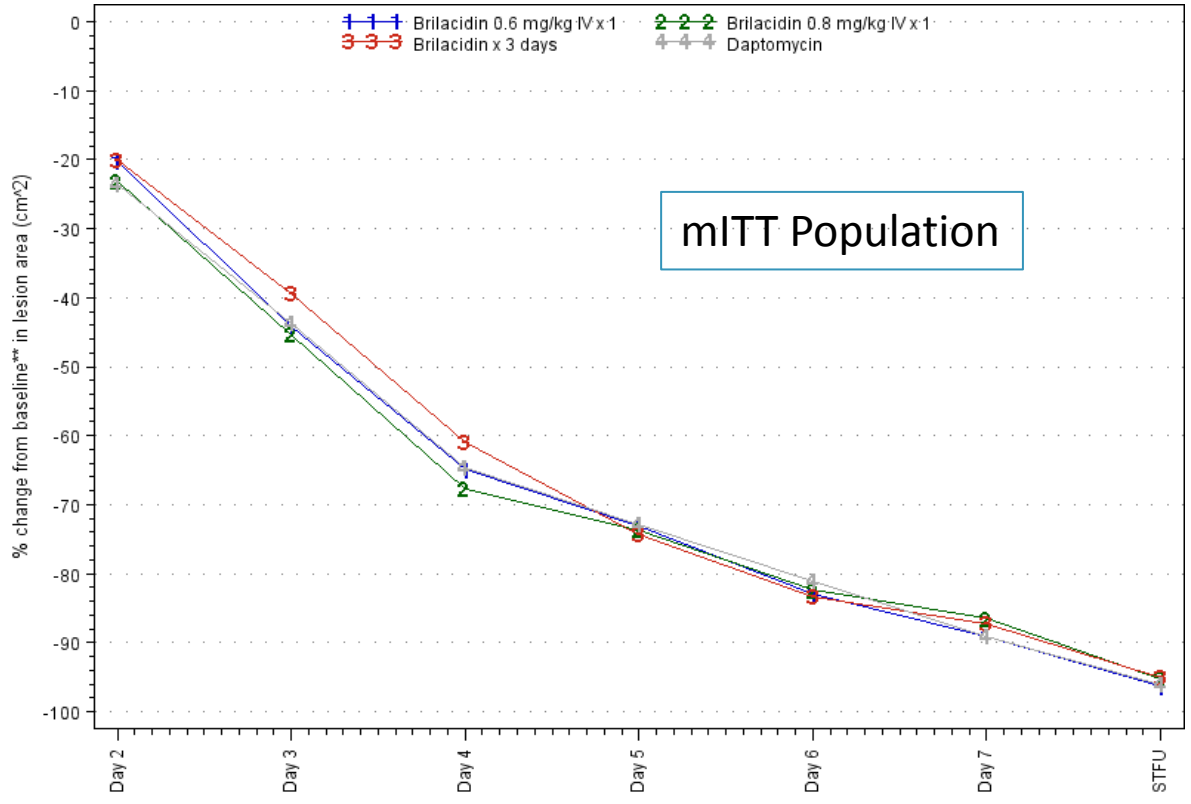
Early and Sustained Clinical Response

All Study Visits

Mean % Change from Baseline in Lesion Area by Study Visit—Days 1-7, EOT, and STFU



*As-treated
** Baseline is Screening or Day 1 measurement, whichever is closer and prior to first study drug administration.



*As-treated
** Baseline is Screening or Day 1 measurement, whichever is closer and prior to first study drug administration.

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PK-PD Modeling and Dose Selection

ICPD® INSTITUTE FOR CLINICAL PHARMACODYNAMICS

Efficacy predictions consistent across two PK/PD models for microbiologically evaluable subjects

Data on File (2015)

ICPD, ECCMID (2013)*

Brilacidin Single Dose (mg/kg)	Average predicted % probability of Sponsor-defined clinical success (2015 pooled analysis, Studies 203 & 204)		Average predicted % probability of Sponsor-defined clinical success (2012 analysis for Study 203 alone)	
	EOT	TOC/SFTU	EOT	TOC
0.4	84.33	86.40	89.0	88.8
0.6	88.92	89.23	91.6	90.9
0.8	92.03	91.40	93.5	92.6
1.0	94.16	93.08	94.9	93.9

* Use of Pharmacokinetics-Pharmacodynamics and Monte Carlo Simulation Analyses to Support Brilacidin Dose Selection for Patients with Acute Bacterial Skin and Skin Structure Infections

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Summary of Adverse Events
All Treated/Safety Population

	Brilacidin: 0.6 mg/kg single dose	Brilacidin: 0.8 mg/kg single dose	Brilacidin: 3-day regimen	Daptomycin
No. of Subjects	53	53	53	50
No. of Treatment-Emergent AEs	90	114	149	61
Subjects with at least 1 TEAE, n (%)	42 (79.2)	43 (81.1)	49 (92.5)	23 (46.0)
Subjects with AE leading to study withdrawal, n (%)	3 (5.7)	1 (1.9)	2 (3.8)	1 (2.0)
Subjects with at least 1 TR AE, n (%)	35 (66.0)	37 (69.8)	47 (88.7)	17 (34.0)
-Subjects with AE of numbness or tingling (N/T), n (%)	31 (58.5)	33 (62.3)	39 (73.6)	4 (8.0)
-Excluding N/T, subjects with at least 1 TRAE, n (%)	4 (7.5)	4 (7.5)	8 (15.1)	13 (26.0)
Subjects with at least 1 SAE, n (%)	3 (5.7)	1 (1.9)	2 (3.8)	0 (0.0)
Subjects with AE leading to death, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Subjects reported with AE of hypertension or BP increased, ≥ 160 mmHg , n (%)	2 (3.8)	9 (17.0)	14 (26.4)	5 (10.0)

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CTIX-BRI-204 Study
Conclusions (1)--Efficacy

- Brilacidin is a potent anti-staphylococcal compound, with high activity vs. MRSA
- Single-dose brilacidin was effective in a phase 2b ABSSSI study
- Efficacy rates were--
  - High across all brilacidin treatment groups, including both single-dose regimens
  - High in all analysis populations, including microbiologically evaluable populations
  - High at early FDA timepoint (Day 2-3), indicating immediate clinical response
  - High at later EMA timepoints (Days 7-8; 10-14), indicating a sustained clinical response
  - Similar to 7 days of active comparator (daptomycin)
- PK/PD model correctly predicted high efficacy using single doses

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CTIX-BRI-204 Study
Conclusions (2)--Safety

- Single-dose brilacidin was safe and well tolerated in a phase 2b ABSSSI study
  - Reduction in total dose decreases the frequency, severity, and duration of adverse events, vs. phase 2a study
  - Blood pressure events low in 0.6 mg/kg single-dose regimen, similar to or better than daptomycin (active control)
  - There were no treatment-related SAEs or hypertension-related SAEs
  - Numbness/Tingling mild, transient, and decreased in frequency and severity, vs. phase 2a study
- PK/PD model correctly predicted decrease in AEs with lower total dose, particularly low single-dose regimens

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CTIX-BRI-204 Study
Overall Summary

- Brilacidin was safe and effective in two 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

Other Cellceutix Presentations
ECCMID 2015

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Cellceutix Corporation
Beverly, MA USA
www.cellceutix.com

ECMIID 2015
Copenhagen, Denmark
25 – 28 April 2015

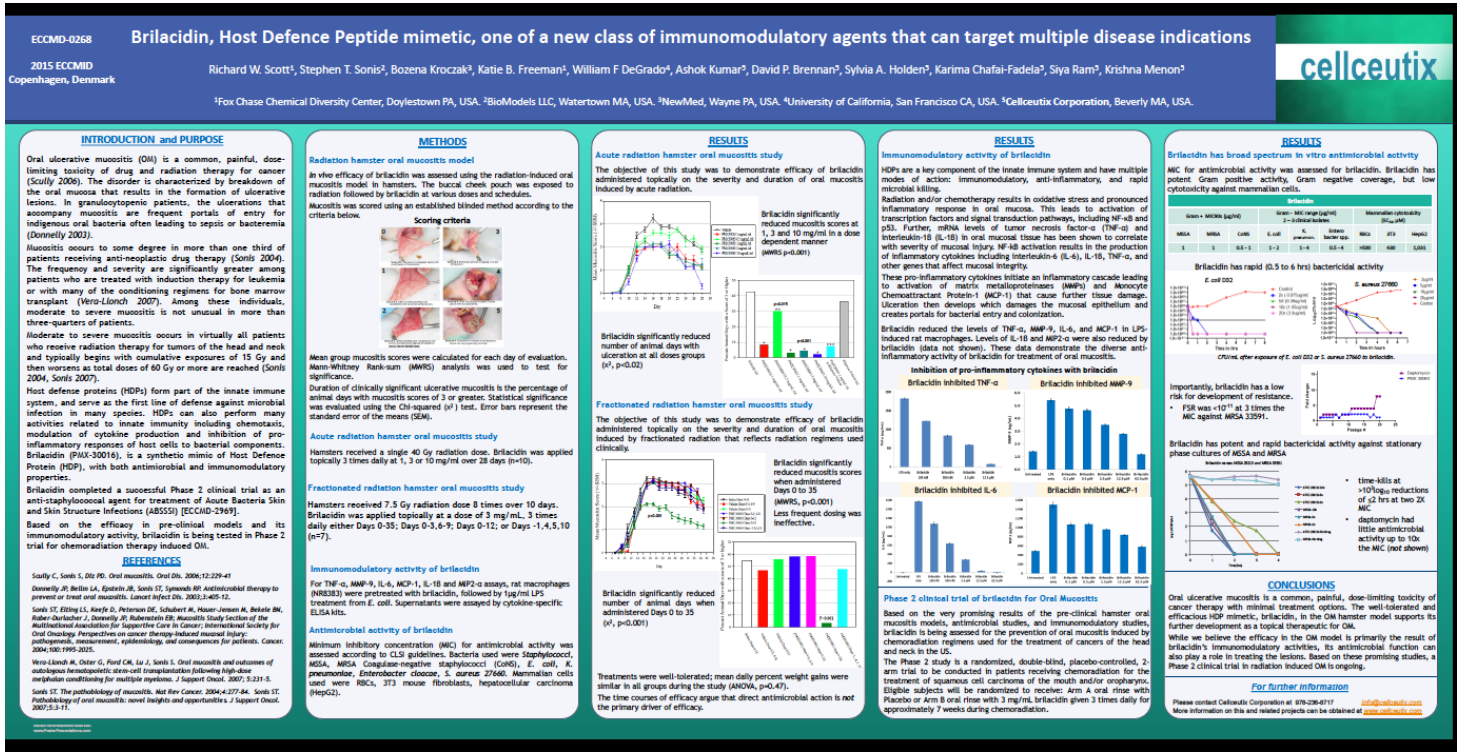
Synthetic Novel Host Defense Protein Mimetics for the Treatment of Gram-Negative Bacterial Infections

Presentation 0169, Hall C, 12:00pm

April 26, 2015

Oral Presentation #0082

e-Poster #EV0201



ECCMD-0268

2015 ECCMID
Copenhagen, Denmark

Brilacidin, Host Defence Peptide mimetic, one of a new class of immunomodulatory agents that can target multiple disease indications

Richard W. Scott[1], Stephen T. Sonis[2], Bozena Kroczak[3], Katie B. Freeman[1], William F DeGrado[4], Ashok Kumar[5], David P. Brennan[5], Sylvia A. Holden[5], Karima Chafai-Fadela[5], Siya Ram[5], Krishna Menon[5]

[1]Fox Chase Chemical Diversity Center, Doylestown PA, USA. [2]BioModels LLC, Watertown MA, USA. [3]NewMed, Wayne PA, USA. [4]University of California, San Francisco CA, USA. [5]**Cellceutix Corporation**, Beverly MA, USA.

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INTRODUCTION and PURPOSE

Oral ulcerative mucositis (OM) is a common, painful, dose-limiting toxicity of drug and radiation therapy for cancer (*Scully 2006*). The disorder is characterized by breakdown of the oral mucosa that results in the formation of ulcerative lesions. In granulocytopenic patients, the ulcerations that accompany mucositis are frequent portals of entry for indigenous oral bacteria often leading to sepsis or bacteremia (*Donnelly 2003*).

Mucositis occurs to some degree in more than one third of patients receiving anti-neoplastic drug therapy (*Sonis 2004*). The frequency and severity are significantly greater among patients who are treated with induction therapy for leukemia or with many of the conditioning regimens for bone marrow transplant (*Vera-Llonch 2007*). Among these individuals, moderate to severe mucositis is not unusual in more than three-quarters of patients.

Moderate to severe mucositis occurs in virtually all patients who receive radiation therapy for tumors of the head and neck and typically begins with cumulative exposures of 15 Gy and then worsens as total doses of 60 Gy or more are reached (*Sonis 2004, Sonis 2007*).

Host defense proteins (HDPs) form part of the innate immune system, and serve as the first line of defense against microbial infection in many species. HDPs can also perform many activities related to innate immunity including chemotaxis, modulation of cytokine production and inhibition of pro-inflammatory responses of host cells to bacterial components. Brilacidin (PMX-30016), is a synthetic mimic of Host Defence Protein (HDP), with both antimicrobial and immunomodulatory properties.

Brilacidin completed a successful Phase 2 clinical trial as an anti-staphylococcal agent for treatment of Acute Bacteria Skin and Skin Structure Infections (ABSSSI) [ECCMD-2969].

Based on the efficacy in pre-clinical models and its immunomodulatory activity, brilacidin is being tested in Phase 2 trial for chemoradiation therapy induced OM.

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Vera-Llonch M, Oster G, Ford CM, Lu J, Sonis S. Oral mucositis and outcomes of autologous hematopoietic stem-cell transplantation following high-dose melphalan conditioning for multiple myeloma. J Support Oncol. 2007; 5:231-5.

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METHODS

Radiation hamster oral mucositis model

In vivo efficacy of brilacidin was assessed using the radiation-induced oral mucositis model in hamsters. The buccal cheek pouch was exposed to radiation followed by brilacidin at various doses and schedules.

Mucositis was scored using an established blinded method according to the criteria below.

Scoring criteria

Mean group mucositis scores were calculated for each day of evaluation. Mann-Whitney Rank-sum (MWRS) analysis was used to test for significance.

Duration of clinically significant ulcerative mucositis is the percentage of animal days with mucositis scores of 3 or greater. Statistical significance was evaluated using the Chi-squared (x^2) test. Error bars represent the standard error of the means (SEM).

Acute radiation hamster oral mucositis study

Hamsters received a single 40 Gy radiation dose. Brilacidin was applied topically 3 times daily at 1, 3 or 10 mg/ml over 28 days (n=10).

Fractionated radiation hamster oral mucositis study

Hamsters received 7.5 Gy radiation dose 8 times over 10 days. Brilacidin was applied topically at a dose of 3 mg/mL, 3 times daily either Days 0-35; Days 0-3,6-9; Days 0-12; or Days -1,4,5,10 (n=7).

Immunomodulatory activity of brilacidin

For TNF-α, MMP-9, IL-6, MCP-1, IL-1β and MIP2-α assays, rat macrophages (NR8383) were pretreated with brilacidin, followed by 1μg/ml LPS treatment from *E. coli*. Supernatants were assayed by cytokine-specific ELISA kits.

Antimicrobial activity of brilacidin

Minimum inhibitory concentration (MIC) for antimicrobial activity was assessed according to CLSI guidelines. Bacteria used were *Staphylococci*, MSSA, MRSA Coagulase-negative staphylococci (CoNS), *E. coli*, *K. pneumoniae*, *Enterobacter cloacae*, *S. aureus* 27660. Mammalian cells used were RBCs, 3T3 mouse fibroblasts, hepatocellular carcinoma (HepG2).

RESULTS

Acute radiation hamster oral mucositis study

The objective of this study was to demonstrate efficacy of brilacidin administered topically on the severity and duration of oral mucositis induced by acute radiation.

Brilacidin significantly reduced mucositis scores at 1, 3 and 10 mg/ml in a dose dependent manner (MWRS p<0.001)

Brilacidin significantly reduced number of animal days with ulceration at all doses groups (x^2, p<0.02)

Fractionated radiation hamster oral mucositis study

The objective of this study was to demonstrate efficacy of brilacidin administered topically on the severity and duration of oral mucositis induced by fractionated radiation that reflects radiation regimens used clinically.

Brilacidin significantly reduced mucositis scores when administered Days 0 to 35 (MWRS, p<0.001)

Less frequent dosing was ineffective.

Brilacidin significantly reduced number of animal days when administered Days 0 to 35 (x^2, p<0.001)

Treatments were well-tolerated; mean daily percent weight gains were similar in all groups during the study (ANOVA, p=0.47).

The time courses of efficacy argue that direct antimicrobial action is *not* the primary driver of efficacy.

RESULTS

Immunomodulatory activity of brilacidin

HDPs are a key component of the innate immune system and have multiple modes of action: immunomodulatory, anti-inflammatory, and rapid microbial killing.

Radiation and/or chemotherapy results in oxidative stress and pronounced inflammatory response in oral mucosa. This leads to activation of transcription factors and signal transduction pathways, including NF-κB and p53. Further, mRNA levels of tumor necrosis factor-α (TNF-α) and interleukin-1β (IL-1β) in oral mucosal tissue has been shown to correlate with severity of mucosal injury. NF-kB activation results in the production of inflammatory cytokines including interleukin-6 (IL-6), IL-1β, TNF-α, and other genes that affect mucosal integrity.

These pro-inflammatory cytokines initiate an inflammatory cascade leading to activation of matrix metalloproteinases (MMPs) and Monocyte Chemoattractant Protein-1 (MCP-1) that cause further tissue damage. Ulceration then develops which damages the mucosal epithelium and creates portals for bacterial entry and colonization.

Brilacidin reduced the levels of TNF-α, MMP-9, IL-6, and MCP-1 in LPS-induced rat macrophages. Levels of IL-1β and MIP2-α were also reduced by brilacidin (data not shown). These data demonstrate the diverse anti-inflammatory activity of brilacidin for treatment of oral mucositis.

Inhibition of pro-inflammatory cytokines with brilacidin

Phase 2 clinical trial of brilacidin for Oral Mucositis

Based on the very promising results of the pre-clinical hamster oral mucositis models, antimicrobial studies, and immunomodulatory studies, brilacidin is being assessed for the prevention of oral mucositis induced by chemoradiation regimens used for the treatment of cancers of the head and neck in the US.

The Phase 2 study is a randomized, double-blind, placebo-controlled, 2-arm trial to be conducted in patients receiving chemoradiation for the treatment of squamous cell carcinoma of the mouth and/or oropharynx. Eligible subjects will be randomized to receive: Arm A oral rinse with Placebo or Arm B oral rinse with 3 mg/mL brilacidin given 3 times daily for approximately 7 weeks during chemoradiation.

RESULTS

Brilacidin has broad spectrum in vitro antimicrobial activity

MIC for antimicrobial activity was assessed for brilacidin. Brilacidin has potent Gram positive activity, Gram negative coverage, but low cytotoxicity against mammalian cells.

Brilacidin							
Gram + MICROS (μg/ml)			Gram – MIC range (μg/ml) 2 – 5 clinical isolates			Mammalian cytotoxicity (IC_{50} μM)	
MSSA	MRSA	CoNS	E. coli	K. pneumon.	Entero bacter spp.	RBCs	3T3	HepG2
1	1	0.5 – 1	1 – 2	1 – 4	0.5 – 4	>500	400	1,000

Brilacidin has rapid (0.5 to 6 hrs) bactericidal activity

CFU/mL after exposure of *E. coli* 032 or *S. aureus* 27660 to brilacidin.

Importantly, brilacidin has a low risk for development of resistance.

- FSR was <10^{-11} at 3 times the MIC against MRSA 33591.

Brilacidin has potent and rapid bactericidal activity against stationary phase cultures of MSSA and MRSA

- time-kills at >$10^3$$\log_{10}$ reductions of ≤2 hrs at two 2X MIC
- daptomycin had little antimicrobial activity up to 10x the MIC (*not shown*)

CONCLUSIONS

Oral ulcerative mucositis is a common, painful, dose-limiting toxicity of cancer therapy with minimal treatment options. The well-tolerated and efficacious HDP mimetic, brilacidin, in the OM hamster model supports its further development as a topical therapeutic for OM.

While we believe the efficacy in the OM model is primarily the result of brilacidin's immunomodulatory activities, its antimicrobial function can also play a role in treating the lesions. Based on these promising studies, a Phase 2 clinical trial in radiation induced OM is ongoing.

For further information

Please contact Cellceutix Corporation at 978-296-8717 info@cellceutix.com
More information on this and related projects can be obtained at www.cellceutix.com