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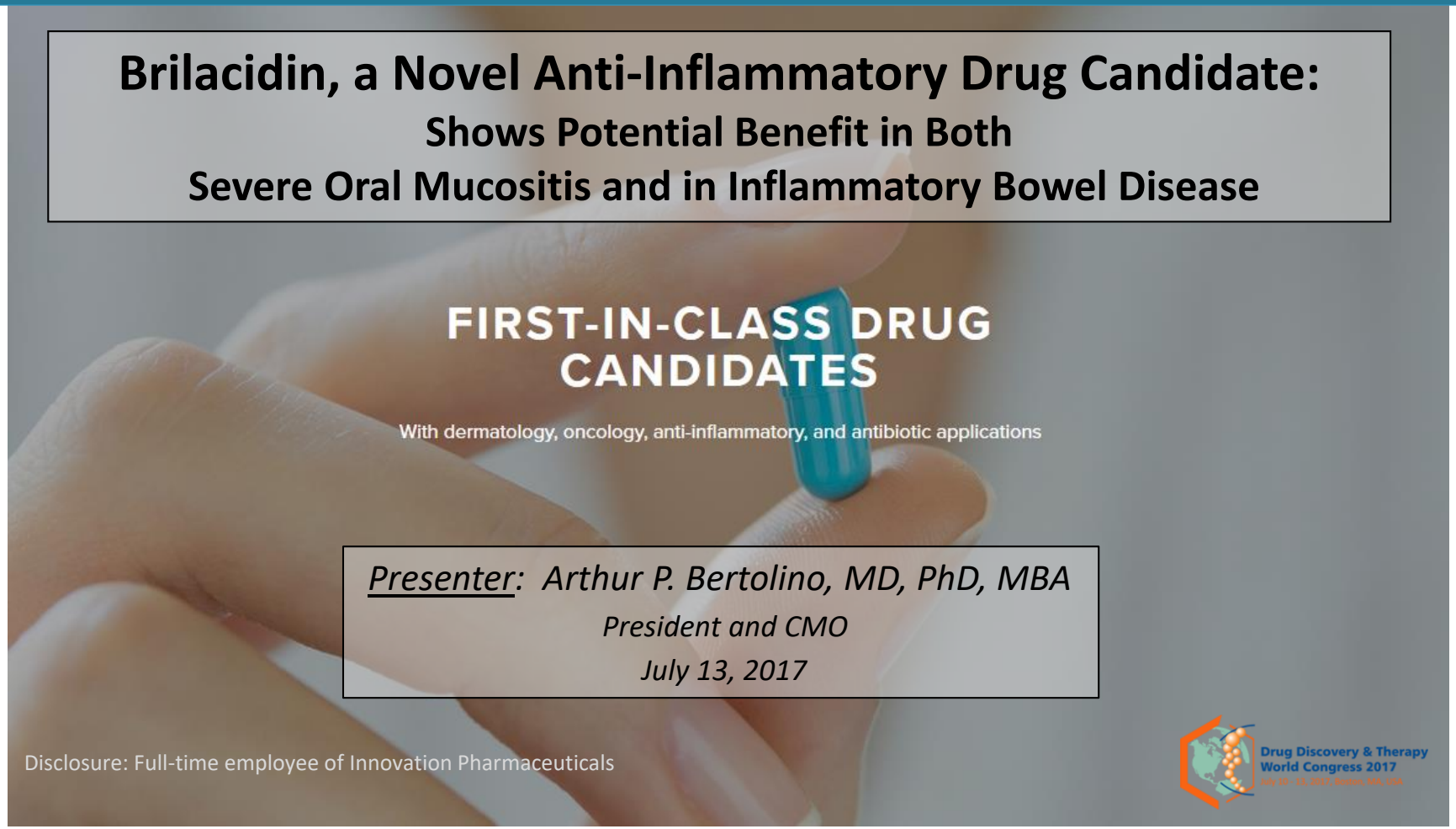
Brilacidin, a Novel Anti-Inflammatory Drug Candidate:
Shows Potential Benefit in Both
Severe Oral Mucositis and in Inflammatory Bowel Disease



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President and CMO
July 13, 2017

Disclosure: Full-time employee of Innovation Pharmaceuticals

Drug Discovery & Therapy World Congress 2017

100 Cummings Center, Beverly, MA

Ticker: IPIX

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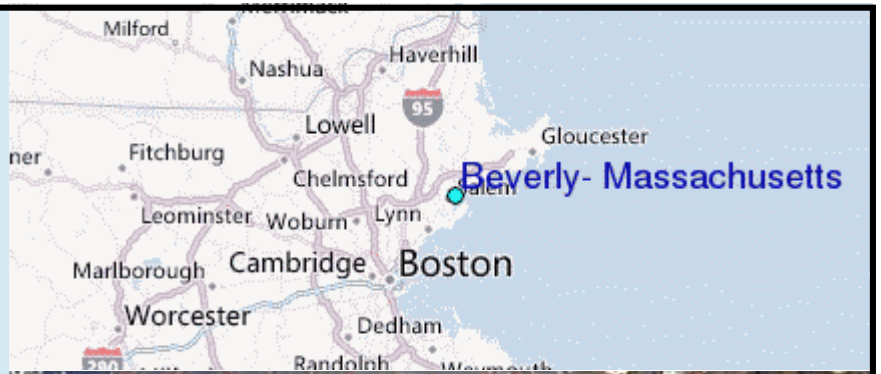
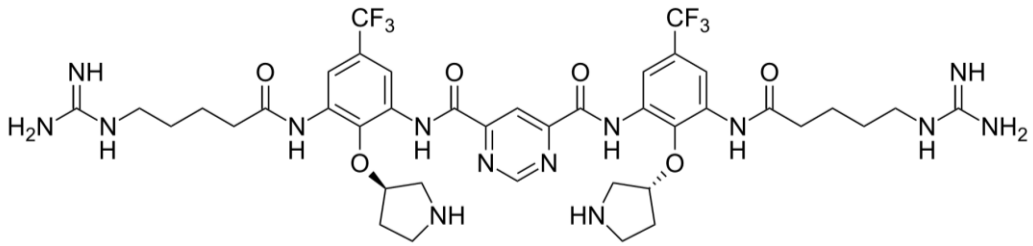


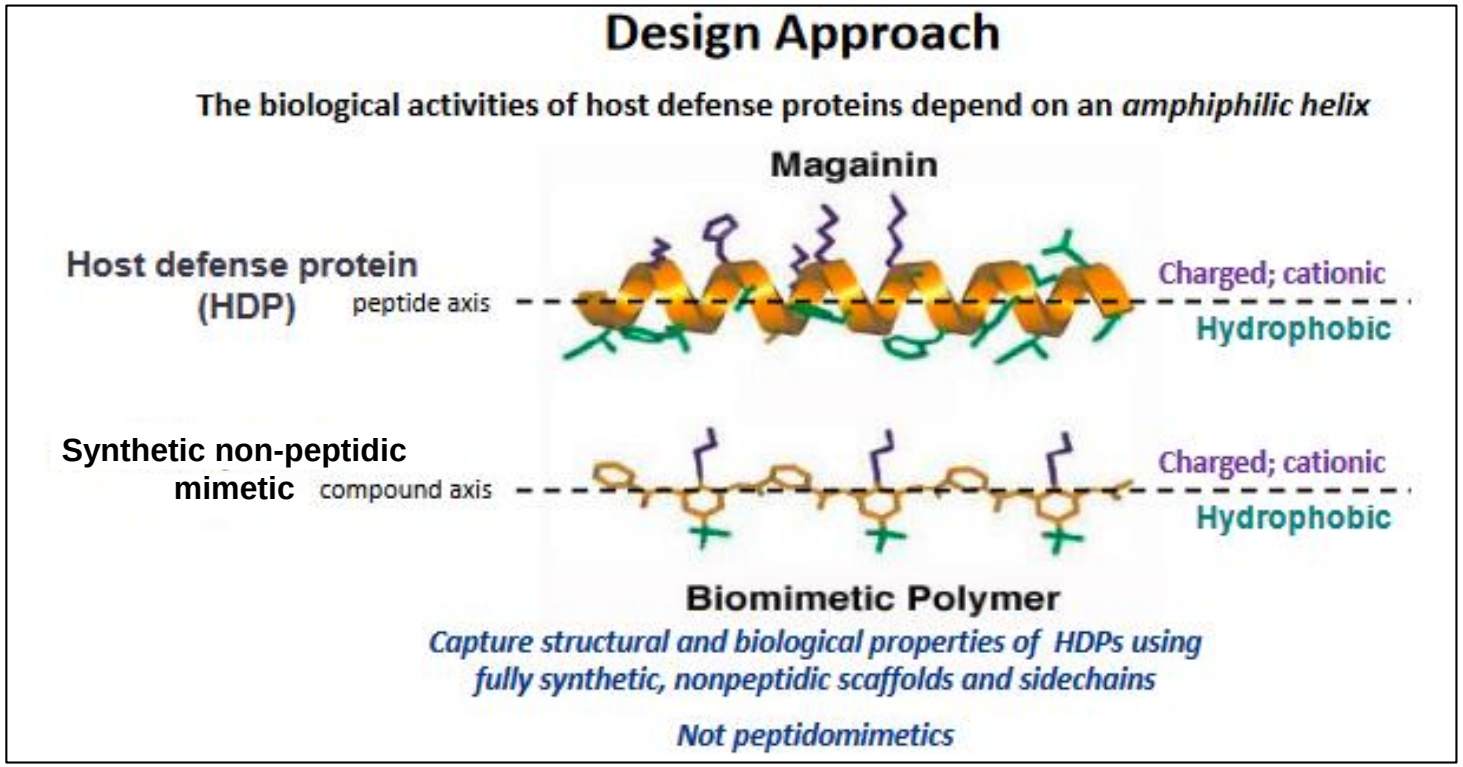
Brilacidin

Chemical Properties and Design



Formula $C_{40}H_{50}F_6N_{14}O_6$

Molar Mass 936.9 g/mol



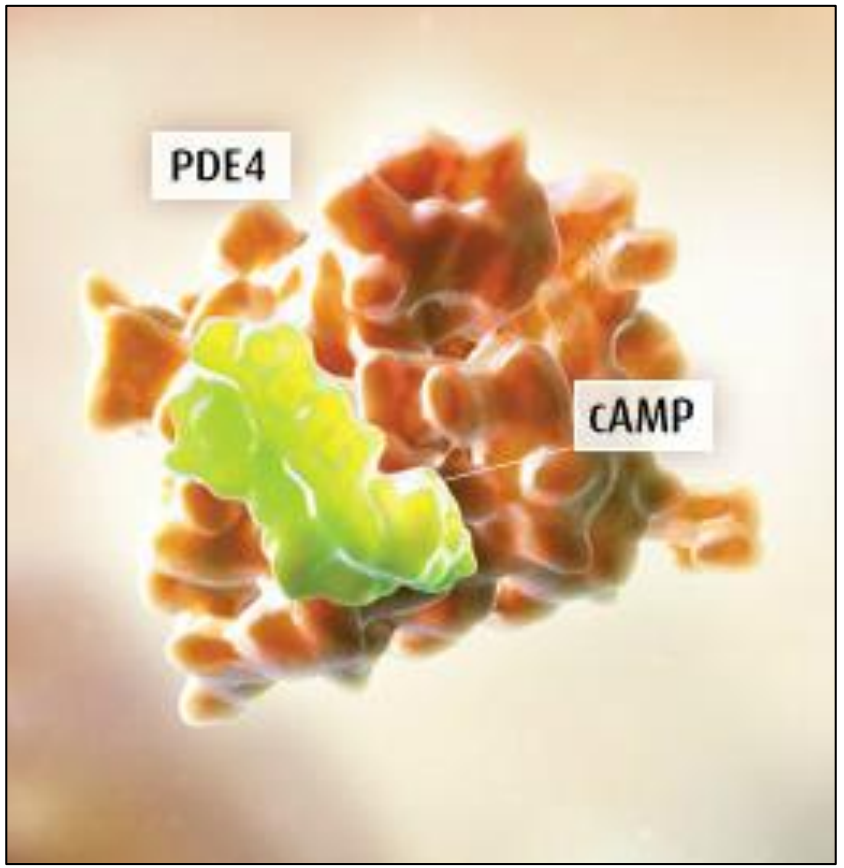
Brilacidin—Mechanism of Action

Immunomodulatory: *Inhibits PDE4*

Brilacidin as a novel anti-inflammatory candidate acts through inhibition of PDE4

- **Being developed as a localized treatment agent for inflammatory diseases**
- **Anti-inflammatory properties**
  - Functions through the cyclic AMP/cyclic GMP pathways
  - Suppresses pro-inflammatory mediators and increases anti-inflammatory mediators

Effectiveness as an antibacterial (host defensin mimetic) already demonstrated in a successful Ph2b *ABSSSI clinical trial [see CTIX-BRI-204]



*ABSSSI - Acute Bacterial Skin and Skin Structure Infection

Brilacidin for Oral Mucositis (OM)

A Painful and Common Complication of Chemoradiation

Clinical Overview

- Frequent complication of chemoradiation for **Head and Neck Cancer**
- Painful and debilitating inflammation & ulceration; increases susceptibility to bacterial infections
- 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
- **No currently approved medications for prevention of OM in this population**

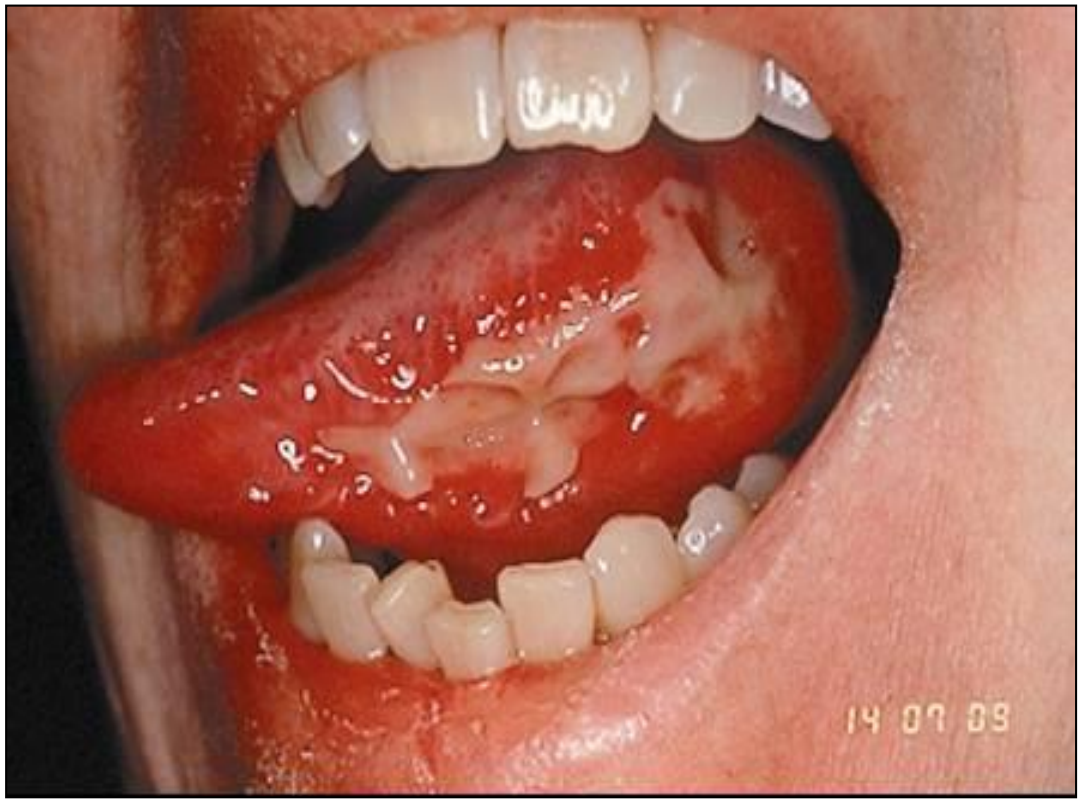


Photo: courtesy of S. Sonis

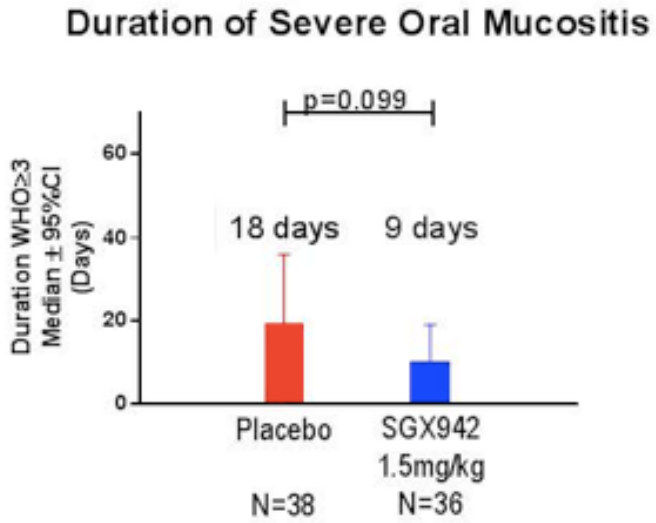
Brilacidin for OM

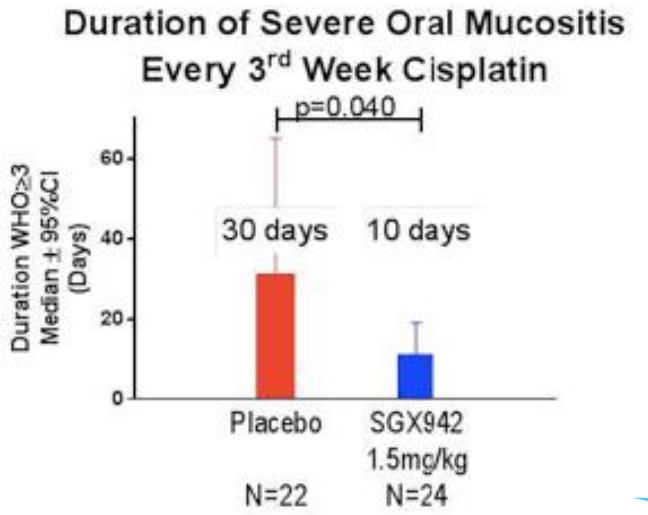
Current Treatments; Largely Palliative in Nature (Symptom Relief)

Current Treatments

- Only one drug treatment available
  - Kepivance for IV infusion
    - Limited label (HSCT)
  - Some medical devices
    - No or little relevant efficacy data (*e.g.*, Gelclair)
- In development
  - Soligenix (IV-admin)
  - Galera (IV-admin)
  - Onxeo (buccal pad)

Product	Company	Phase	Indication	Comment / Issue
Kepivance	Amgen	Approved (drug)	Prevent OM-HSCT	Inconvenient IV dosing 3x pre + 3x post chemo, over priced
Gelclair	DARA	Approved (device)	Palliation	Poor reimbursement, poor data
Mucotrol	Edwards Pharmaceutical	Approved (device)	Palliation	Poor reimbursement, poor data
Caphosol	EUSA	Approved (device)	Palliation	Poor reimbursement, poor data
Episil	Camurus	Approved (device)	Palliation	
Mugard	Access	Approved (device)	Palliation	Poor reimbursement; recent controlled study confirmed activity as a palliative agent





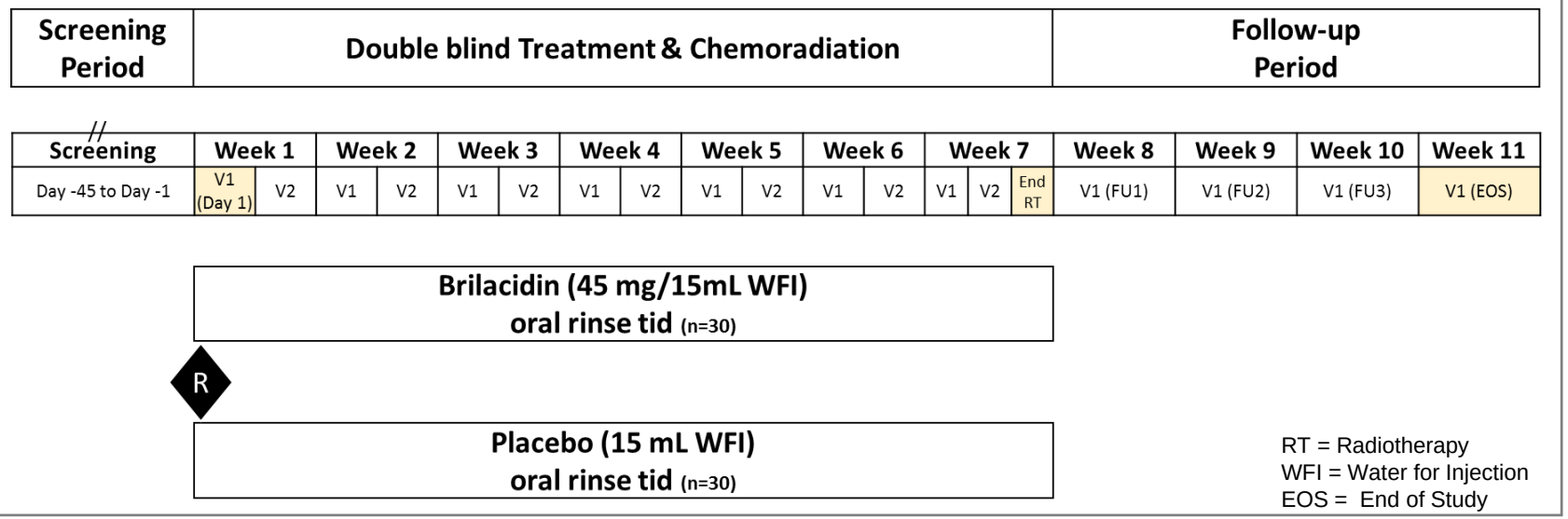
CTIX-BRI-205: Oral Mucositis

Trial Design

- **Phase 2, multi-center (USA), randomized, double-blind, placebo-controlled study**
- Efficacy and Safety of Brilacidin oral rinse administered *tid* for 7 weeks (49 days)
- Daily treatment aimed at attenuating Oral Mucositis (OM) in subjects with Head and Neck Cancer receiving concurrent chemoradiation therapy

Trial Design

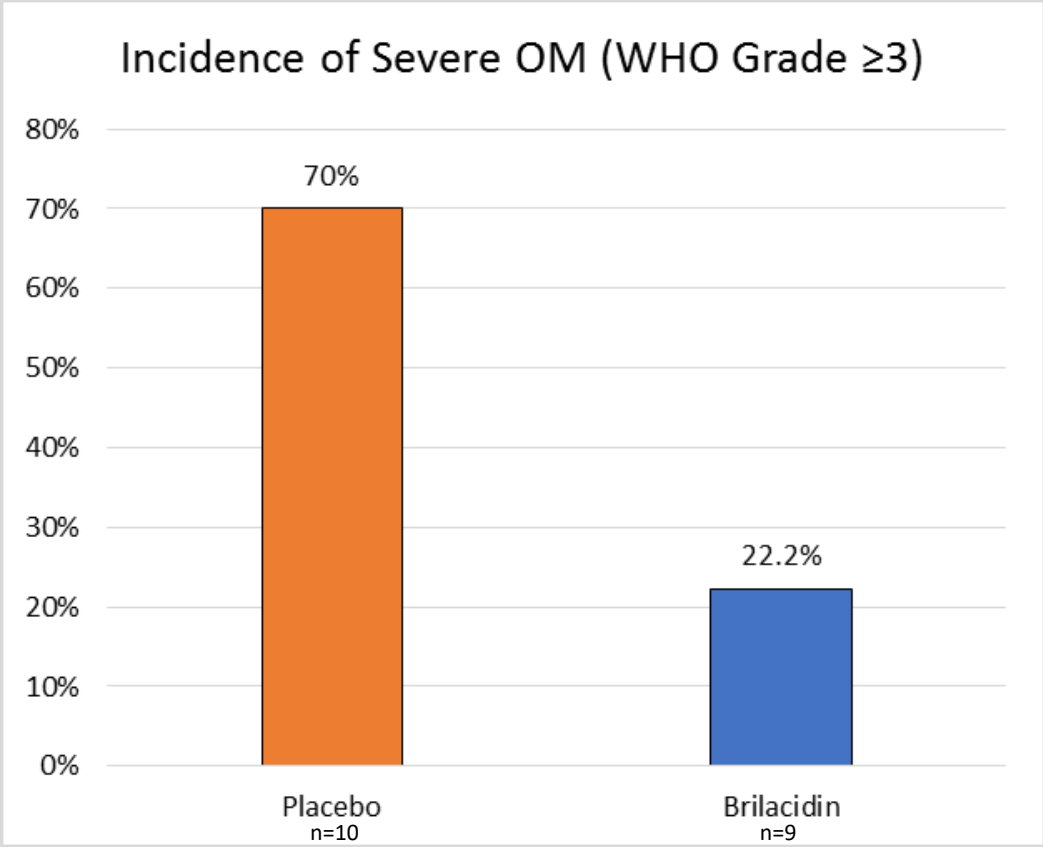
- 7 weeks of treatment, with two visits per week
- 2 treatment arms:
  - Brilacidin (45 mg/15 mL WFI, tid)
  - Placebo (15 mL WFI, tid)
- Oral rinse (15 mL); "swish" for 1 min, then "spit" out
- 3 x daily oral rinse (tid), approximately 6 hours apart



CTIX-BRI-205 (OM): Efficacy Data

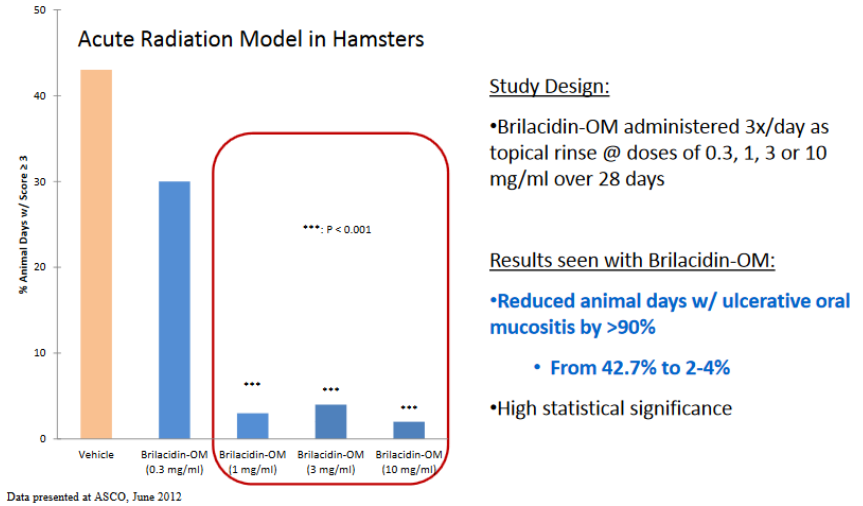
Positive Results: *Ad-Hoc* ***Interim Analysis***

- **Brilacidin markedly reduced the Incidence of Severe OM (WHO Grade ≥ 3)** experienced during chemoradiation therapy by subjects with Head and Neck Cancer receiving a **cumulative radiation dose of at least 55 Gy and reached or passed 5 weeks on study** (n= 19 subjects)



- **7 of 10 subjects (70%) in the placebo treatment arm** experienced at least one score of WHO Grade ≥3
- **2 of 9 subjects (22.2%) in the Brilacidin treatment arm** experienced at least one score of WHO Grade ≥3

Clinical results consistent with preclinical animal model



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

CTIX-BRI-205 (OM): Safety Data/PK

*Brilacidin was **Generally Well-Tolerated** with No Measurable Systemic Exposure*

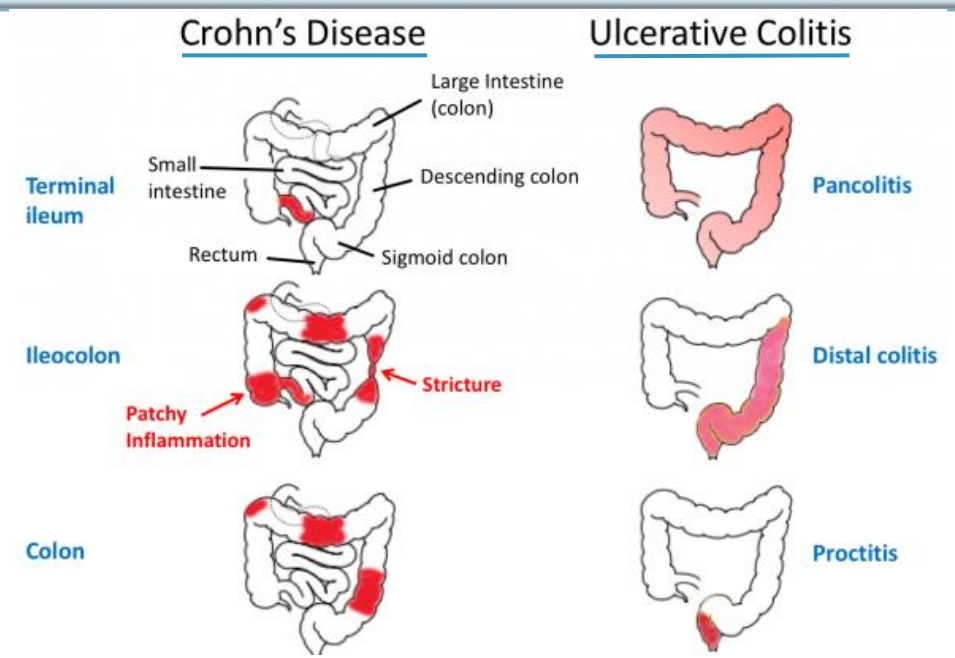
- **Adverse Events**
  - Majority of Treatment-Emergent AEs (TEAEs) related to chemoradiation or underlying indication
  - Nine (9) SAEs reported; No Deaths. SAEs typical for subject population
- **Safety Monitoring**
  - No treatment group differences apparent on vital signs and clinical laboratory safety tests
- **Concomitant Medications**
  - No treatment group differences apparent

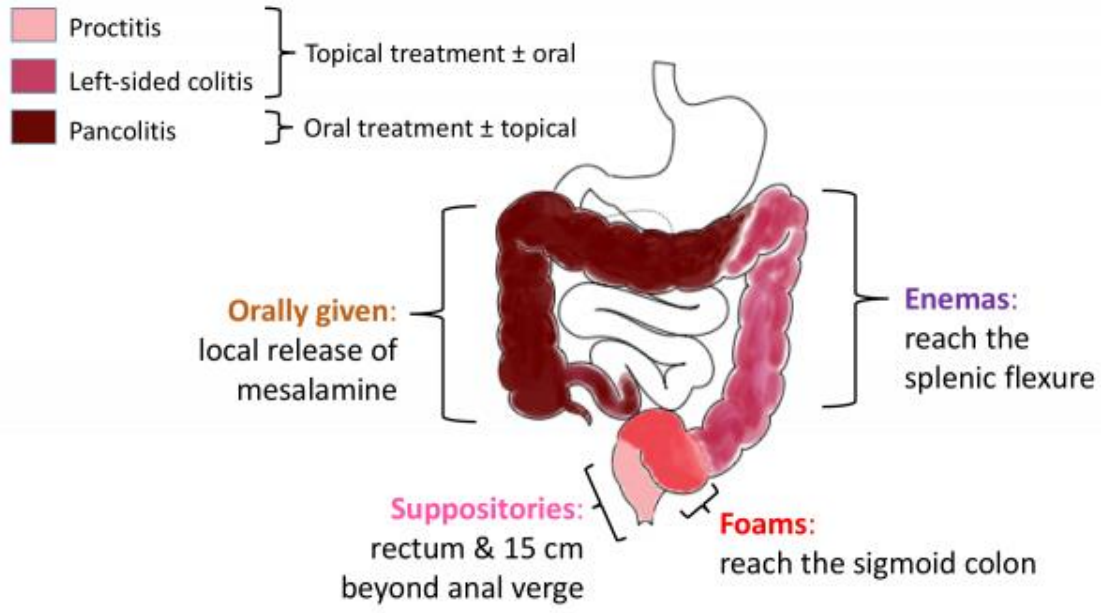
- **Pharmacokinetics (PK): No Measurable Brilacidin Concentrations in Plasma**
  - Plasma samples analyzed from 6 subjects treated with Brilacidin; samples collected once weekly
  - All Brilacidin concentrations were below the lower limit of quantification (LLOQ), < 10 ng/mL

Inflammatory Bowel Disease (IBD)

A Hard-to-Treat Chronic Condition That Affects Over a Million People in the U.S.

- **Group of Inflammatory Conditions of Colon & Small Intestine**
  Principle types: *Crohn's disease (CD) and Ulcerative colitis (UC)* **[(Ulcerative Proctitis (UP) and Ulcerative Proctosigmoiditis (UPS) are subcategories of UC)]**
- **Autoimmune Etiology**
- **Main GI Symptoms:** abdominal pain, vomiting, diarrhea, rectal bleeding, severe internal abdominal/pelvic cramps/muscle spasms and weight loss
- **Recurrences Frequent**: disease also associated with increased risk of co-morbidities
- **Medications for Treatment Include**: aminosalicylates, corticosteroids, immunomodulators , antibiotics and biologics, including anti-TNF agents, anti-integrin agents and IL12/23 inhibitors which have high initial treatment failure rates and loss-of-response rates (up to 1/3rd of patients for each); treatment non-adherence occurs in up to 50 percent of IBD patients
- **Common, Costly**: in the U.S., 70,000 newly diagnosed IBD cases each year; total annual financial burden of IBD estimated to be $14.6 to $31.6 billion





Sources: http://tmedweb.tulane.edu/pharmwiki/doku.php/inflammatory_bowel_disease_ibd; http://www.slideshare.net/afzalhaqasif/inflammatory-bowel-disease2014; http://online.ccfa.org/site/DocServer/CCFA_Ingle_5_2016_--_What_s_New_IBD.pdf; Innovation Pharmaceuticals research

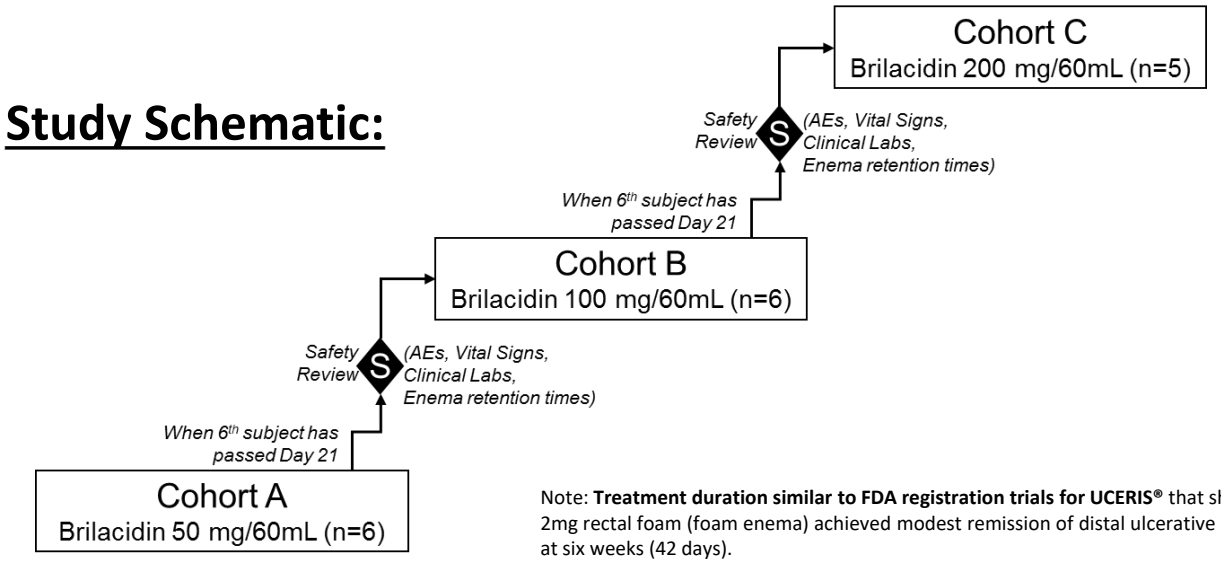
CTIX-BRI-206: Ulcerative Proctitis/Ulcerative Proctosigmoiditis (UP/UPS)

Proof-of-Concept Trial Design

- **Phase 2, Open Label, Dose-Escalation Trial**
- **Active Mild-to-Moderate Ulcerative Proctitis (UP) or Ulcerative Proctosigmoiditis (UPS)**
  - Treated 17 subjects
    - Six (6) Subjects in each of Cohorts A and B (Brilacidin 50 mg and 100 mg, respectively), 5 Subjects in Cohort C (Brilacidin 200 mg)
- **Efficacy, Safety and PK of 3 Dose Levels**

Trial conducted at 3 sites, ex-US

Study Schematic:



Note: **Treatment duration similar to FDA registration trials for UCERIS®** that showed 2mg rectal foam (foam enema) achieved modest remission of distal ulcerative colitis at six weeks (42 days).

- **Brilacidin Retention Enema** (60 mL; 2 oz)
  - Once daily at bedtime for 6 weeks (42 days); with attempt to retain through the night/minimally retain for 30 (± 5) mins
- **Endoscopic Evaluation**
  - Investigator assessment of rectal and sigmoid mucosa up to 40 cm from anal verge at screening and at end of treatment /Day 42 (± 3 days)
- **Primary Endpoint**
  - Uses Modified Mayo Disease Activity Index (**MMDAI**) scoring

CTIX-BRI-206 (UP/UPS): Proof of Concept

Efficacy Endpoints

Primary Efficacy Endpoint: Clinical Remission at Day 42/Week 6, defined by Modified Mayo scoring

Endoscopy Findings [E] subscore ≤ 1 AND **Rectal Bleeding [RB] subscore = 0** AND **Stool Frequency [SF] subscore** improvement or no change from baseline

Modified Mayo Disease Activity Index (MMDAI) scoring

Score	Stool (Bowel) Frequency [SF]	Rectal Bleeding [RB]	Physician's Global Assessment [PGA]	Endoscopy Findings [E]
0	Normal number of stools per day for this subject	No blood seen	Normal	Normal or inactive disease
1	1 to 2 more stools than normal	Streaks of blood with stool less than half the time	Mild disease	Mild disease (erythema, decreased vascular pattern)
2	3 to 4 more stools than normal	Obvious blood with stool most of the time	Moderate disease	Moderate disease (marked erythema, absent vascular pattern, friability, erosions)
3	5 or more stools than normal	Blood alone passed	Severe disease	Severe disease (spontaneous bleeding, ulceration)

CTIX-BRI-206 (UP/UPS): Efficacy Data

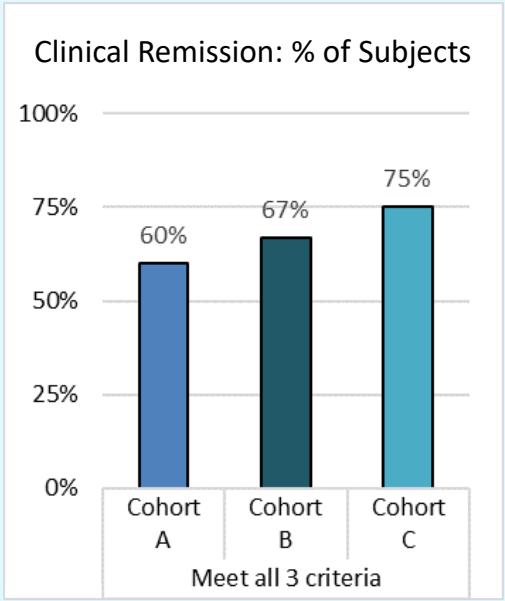
Primary Efficacy Endpoint, Topline Results

Clinical Remission in > 50% subjects (Day 42)

Similar across cohorts

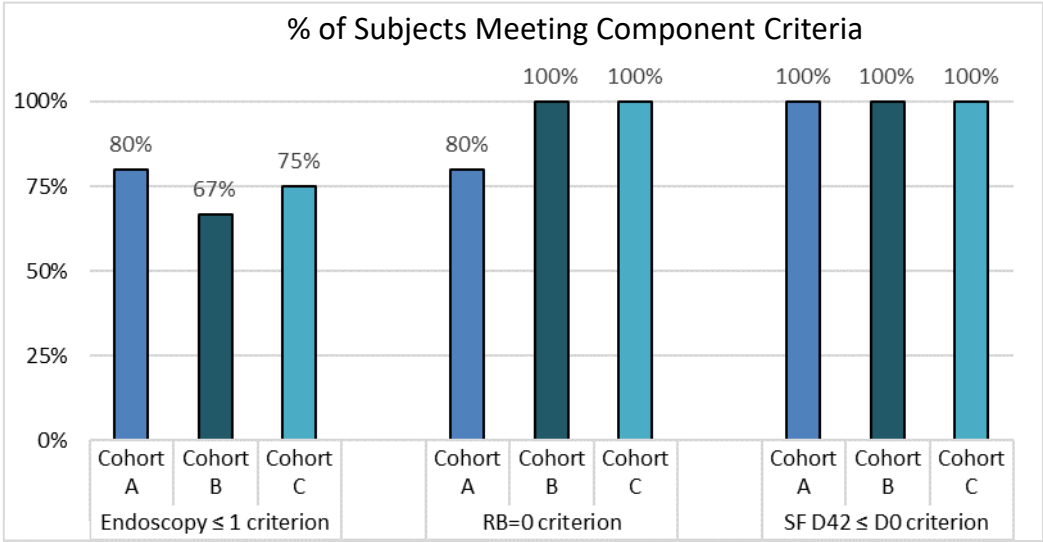
- 60% Cohort A (3 of 5)
- 67% Cohort B (4 of 6)
- 75% Cohort C (3 of 4)

Analysis population: Includes subjects with Endoscopy, Rectal Bleeding and Stool Frequency subscores at baseline and Day 42; one subject in Cohort A and one subject in Cohort C are not included due to no Day 42 endoscopy (subjects declined)



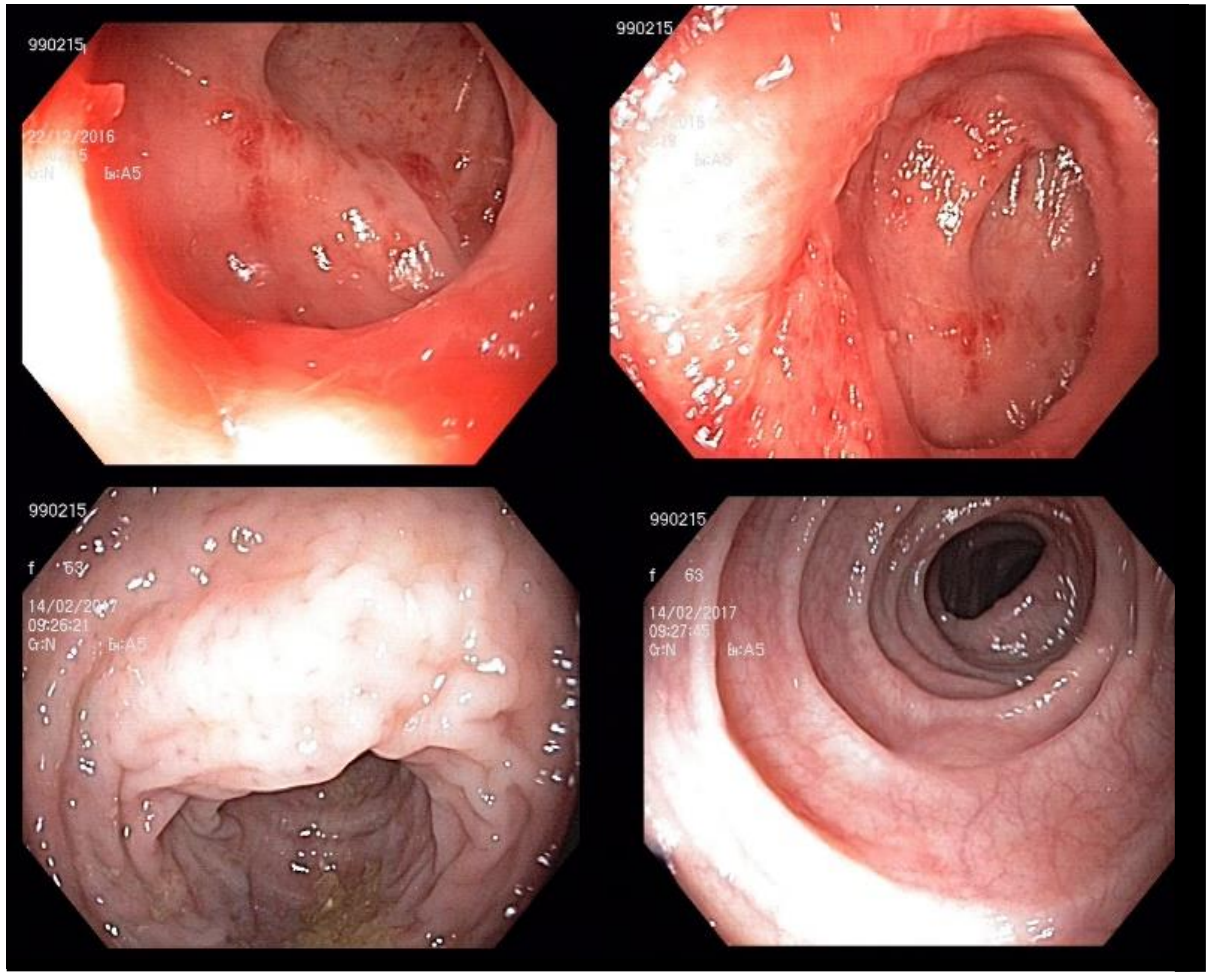
Clinical Remission is defined as:

- Endoscopy subscore ≤ 1
- Rectal Bleeding subscore of 0
- Stool Frequency subscore improvement or no change from baseline



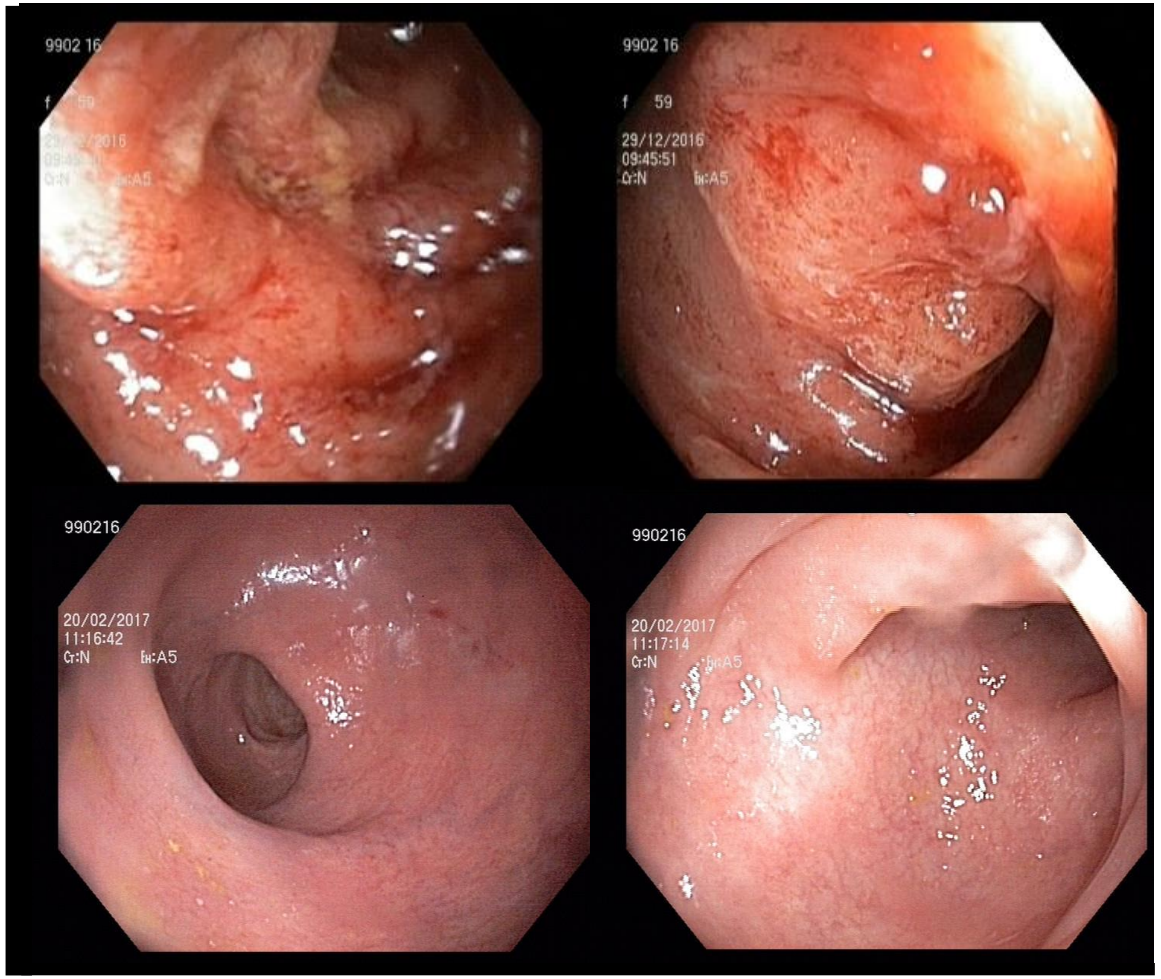
CTIX-BRI-206 (UP/UPS): Endoscopy

Examples Clinical Remission; Treated with Brilacidin 100mg (Cohort B)



Baseline

D42



Subject 990216 (rectum)

Subject 990215 (rectum)

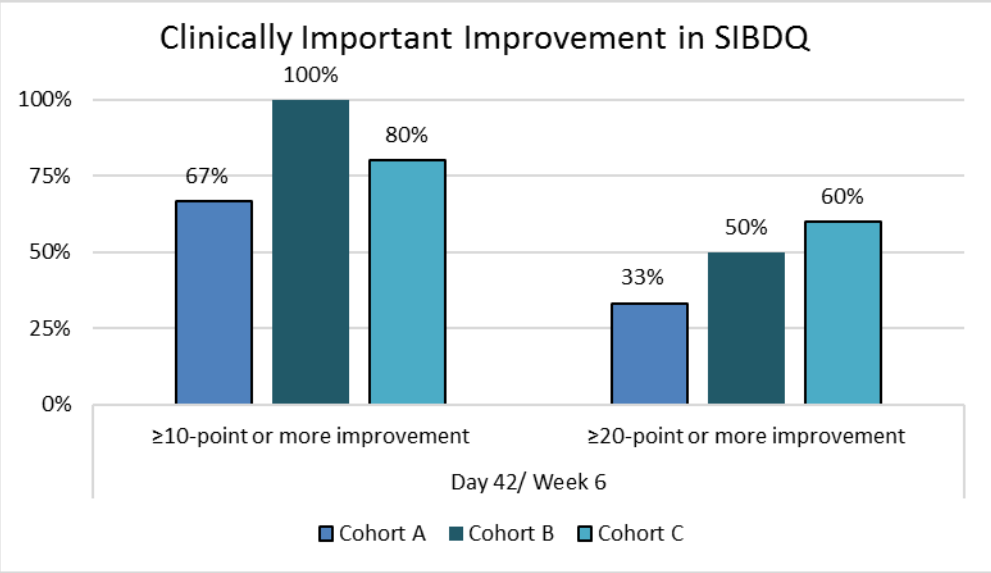
Note: Baseline/ D42(After Treatment) series not necessarily identical anatomical positions

CTIX-BRI-206 (UP/UPS): Patient Quality-of-Life

Quality-of-Life Better Overall

Improvement in **Quality-of-Life (QoL)** reported by **16 of 17 subjects** after six weeks of treatment

- **QoL instrument** used was Short Inflammatory Bowel Disease Questionnaire [SIBDQ]
- **Clinically Important Change in Disease Activity = approximately 10 points change on SIBDQ**
- **At Day 42:**
  - **More than 60% subjects in each cohort achieved ≥10-point or more improvement**
  - At least half of subjects in cohorts B and C also showed ≥20-point or more improvement
  - >50-point improvement observed for one subject in Cohort B



Analysis population: includes all subjects [all subjects have baseline and Day 42 assessment]

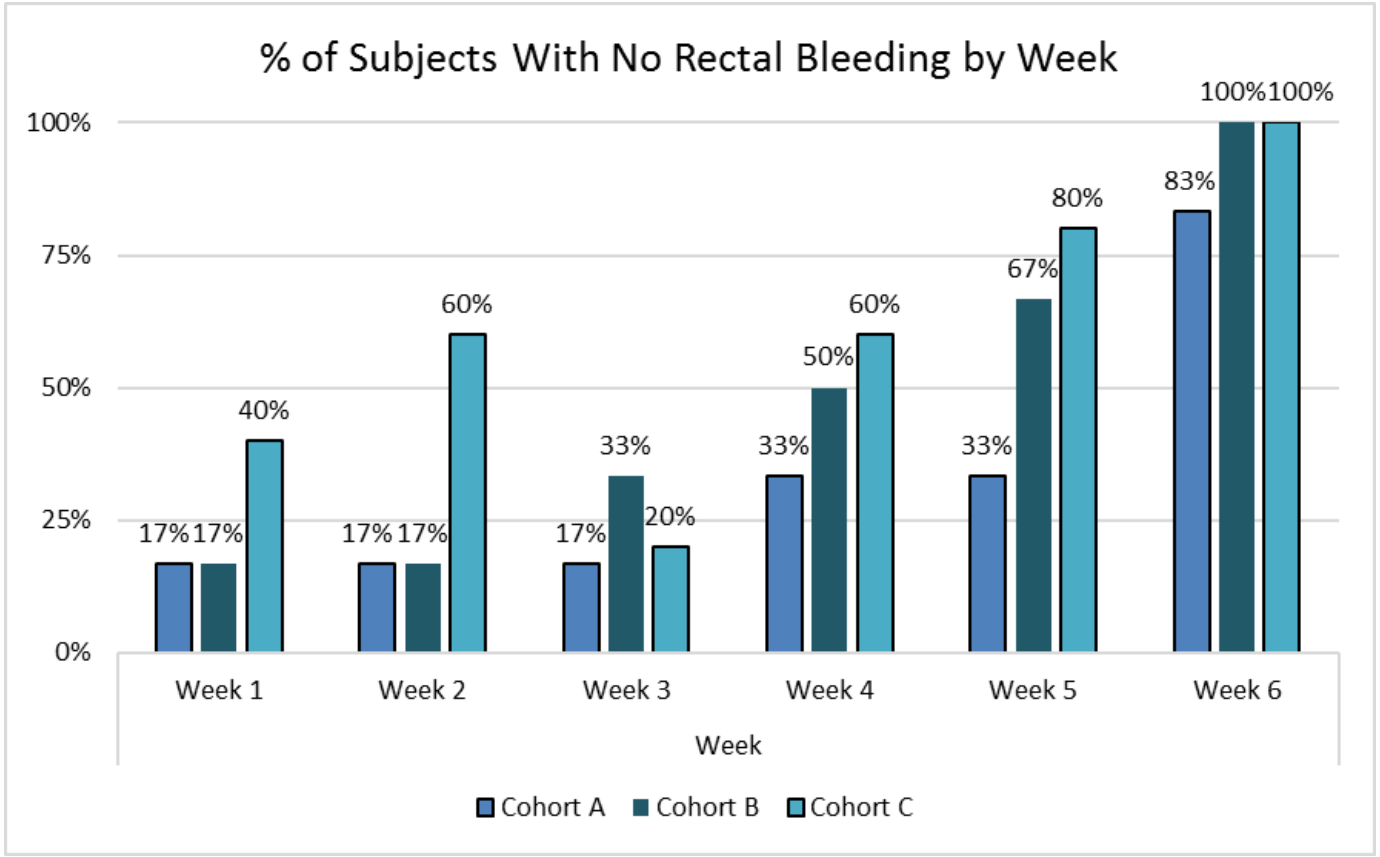
- SIBDQ is sum of scores from 10 questions, each on 7-point Likert Scale where 1 = worst health, 7 = best health ; Total score ranges from 10 (worst health) to 70 (best health)
- Higher scores represent better overall Quality of Life
- Clinically important change in disease activity, ~10-point change in SIBDQ (Jowett et al, AJG 2001;96(10):2921-28)

CTIX-BRI-206 (UP/UPS): Efficacy Data

Rectal Bleeding Response Shows Marked Improvement

Rectal Bleeding (RB) subscore

- Improved for all subjects, all cohorts
- No rectal bleeding (RB=0) at Day 42
  - 5 of 6 subjects Cohort A
  - All 6 subjects Cohort B
  - All 5 subjects Cohort C



Analysis population: includes all subjects [all subjects have baseline and Day 42 assessment]

CTIX-BRI-206 (UP/UPS): Safety Data

Brilacidin was Generally Well-Tolerated

- **Adverse Events**
  - No Serious Adverse Events (SAEs)
  - No severe adverse events; all AEs mild or moderate severity
  - Treatment-emergent AEs, experienced by 8 subjects
    - Investigator Causality: Possibly Related (1); Unlikely Related (16); Not Related (1); ∑=18
      - Possibly Related event was of abdomen pain, start/stop on Day 2, for Cohort C subject
    - None resulted in treatment withdrawal/dose change or study withdrawal
- **Clinical Laboratory Review**
  - No apparent clinically significant trends observed for blood chemistry, hematology, urinalysis
- **Vital Signs**
  - No clinically significant trends observed

CTIX-BRI-206 (UP/UPS): Pharmacokinetics

Systemic Exposure is Limited (when administered by Rectal Enema)

Brilacidin Concentrations (plasma) by Cohort

- **Cohort A**
  - All subjects <100 ng/mL
- **Cohort B**
  - Maximum 605 ng/mL
    - Average C_{max} 215 ng/mL
- **Cohort C**
  - Maximum 1264 ng/mL
    - Average C_{max} 743 ng/mL

In previous Brilacidin *ABSSSI study by intravenous (IV) dosing at 0.6 mg/kg and 0.8 mg/kg, C_{max} was approximately 9,000 ng/mL and 12,000 ng/mL, respectively [*Study CTIX-BRI-204*]

*ABSSSI - Acute Bacterial Skin and Skin Structure Infection

CTIX-BRI-206 (UP/UPS): Enema Retention Times

Enemas Well-Retained

Overall, good retention for a water-based enema

Most prevalent retention time category per subject highlighted in green

Incidence of Retention Times	Cohort A Brilacidin 50 mg						Cohort B Brilacidin 100 mg						Cohort C Brilacidin 200 mg				
	#990 201	#990 202	#990 204	#990 205	#990 209	#990 210	#990 103	#990 213	#990 215	#990 216	#990 217	#990 305	#990 218	#990 306	#990 308	#990 105	#990 311
< 30 min	0	6	1	1	0	0	0	0	4	3	1	0	5	7	1	0	18
≥ 30 min to < 1 h	0	5	3	0	0	16	0	33	37	30	34	0	31	3	2	3	8
≥1 h to < 4 h	10	3	11	15	13	19	5	8	1	9	7	6	6	4	16	3	1
≥4 h	32	28	27	26	29	7	37	1	0	0	0	36	0	28	23	36	14

Cohort A, majority of enemas retained by all 6 subjects for at least 1 hour or more

Cohorts B and C: 4 of 6 subjects in Cohort B, and 2 of 5 subjects in Cohort C, recorded shorter duration retention times (range 14 to 59 mins) most frequently

- 42 dosing enemas per subject [except Cohort C subject #990311 with 41- last enema omitted due to scheduling]
- What is recorded? Time of "Enema Evacuation or Next Stool" after enema administration. Time is recorded in patient diary for out-patient visits (from D6 to D41/42)

Perspectives on CTIX-BRI-205 and CTIX-BRI-206 Trial Results

- **Brilacidin efficacy favorable in chemoradiation-induced Severe Oral Mucositis (SOM)**
  - Markedly reduced rate of Severe OM (WHO Grade ≥ 3) [**interim analysis**]
    - Active Arm (BRI): 2 of 9 subjects (22.2 percent); Control Arm (Placebo): 7 of 10 subjects (70 percent)
- **Brilacidin efficacy favorable in UP/UPS (IBD) across 3 dose escalation cohorts (50mg, 100mg, 200mg as retention enema)**
  - Proof-of-Concept achieved with current simple water formulation*
  - Clinical Remission (with endoscopic response) in at least half of subjects in each cohort
  - Improved Quality-of-Life
- **Safety data show Brilacidin well-tolerated in both indications**
- **PK demonstrates limited systemic absorption by both routes of administration**

Data support Brilacidin clinical efficacy with local treatment in 2 clinical indications

* Formulation development plans for Brilacidin include tablets for oral dosing of more extensive UC and Crohn's disease and foam and/or gel for UP/UPS

Acknowledgments

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CROs

Clinical Assistance Programs (OM)
SPRI Clinical Trials (UP/UPS)

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