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

Presenter: Arthur P. Bertolino, MD, PhD, MBA
President and CMO
July 13, 2017

Disclosure: Full-time employee of Innovation Pharmaceuticals

100 Cummings Center, Beverly, MA
Ticker: IPIX
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100 Cummings Center
Suite 151B
Beverly, MA 01915
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 defense mimic) 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)

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**Duration of Severe Oral Mucositis**

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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

**Screening Period**

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<th>Week 1</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
<th>Week 7</th>
<th>End</th>
<th>Week 8</th>
<th>Week 9</th>
<th>Week 10</th>
<th>Week 11</th>
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<td>Day -45 to Day -1</td>
<td>V1</td>
<td>V1</td>
<td>V2</td>
<td>V2</td>
<td>V1</td>
<td>V2</td>
<td>V1</td>
<td>V2</td>
<td>V1</td>
<td>V1</td>
<td>FU1</td>
<td>FU2</td>
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**Double blind Treatment & Chemoradiation**

- Brilacidin (45 mg/15 mL WFI, *tid*)
- Placebo (15 mL WFI, *tid*)

**Follow-up Period**

- RT = Radiotherapy
- WFI = Water for Injection
- EOS = End of Study

CTIX-BRI-205: Oral Mucositis

Trial Design
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
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

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**

**Study Schematic:**

- **Cohort A**
  - Brilacidin 50 mg/60mL (n=6)

- **Cohort B**
  - Brilacidin 100 mg/60mL (n=6)

- **Cohort C**
  - Brilacidin 200 mg/60mL (n=5)

**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

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<tr>
<td>0</td>
<td>Normal number of stools per day for this subject</td>
<td>No blood seen</td>
<td>Normal</td>
<td>Normal or inactive disease</td>
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<tr>
<td>1</td>
<td>1 to 2 more stools than normal</td>
<td>Streaks of blood with stool less than half the time</td>
<td>Mild disease</td>
<td>Mild disease (erythema, decreased vascular pattern)</td>
</tr>
<tr>
<td>2</td>
<td>3 to 4 more stools than normal</td>
<td>Obvious blood with stool most of the time</td>
<td>Moderate disease</td>
<td>Moderate disease (marked erythema, absent vascular pattern, friability, erosions)</td>
</tr>
<tr>
<td>3</td>
<td>5 or more stools than normal</td>
<td>Blood alone passed</td>
<td>Severe disease</td>
<td>Severe disease (spontaneous bleeding, ulceration)</td>
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</table>
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)

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

**Clinically Important Improvement in SIBDQ**

- 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)

Analysis population: includes all subjects [all subjects have baseline and Day 42 assessment]
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); Σ=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 $C_{\text{max}}$ 215 ng/mL
- **Cohort C**
  - Maximum 1264 ng/mL
    - Average $C_{\text{max}}$ 743 ng/mL

In previous Brilacidin *ABSSSI study by intravenous (IV) dosing at 0.6 mg/kg and 0.8 mg/kg, $C_{\text{max}}$ 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*

<table>
<thead>
<tr>
<th>Incidence of Retention Times</th>
<th>Cohort A Brilacidin 50 mg</th>
<th>Cohort B Brilacidin 100 mg</th>
<th>Cohort C Brilacidin 200 mg</th>
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<tr>
<td></td>
<td>#990 201</td>
<td>#990 103</td>
<td>#990 218</td>
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<tr>
<td>&lt; 30 min</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>≥ 30 min to &lt; 1 h</td>
<td>0</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>≥1 h to &lt; 4 h</td>
<td>10</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>≥4 h</td>
<td>32</td>
<td>37</td>
<td>0</td>
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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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Clinical Team

Edward Walters, Kristine McGuigan - Innovation Pharmaceuticals

CROs

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