### Late Phase 3 Development Pipeline

**Two NDA-Ready Assets**

<table>
<thead>
<tr>
<th>Research</th>
<th>Preclinical</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
<th>NDA</th>
<th>Commercial Rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Omadacycline</td>
<td>ABSSSI (Oral &amp; IV) – QIDP + SPA</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td>1Q '18</td>
<td>PARATEK® (Global)</td>
</tr>
<tr>
<td></td>
<td>CABP (Oral &amp; IV) – QIDP + SPA</td>
<td>✔️</td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>ABSSSI (Oral only) – QIDP</td>
<td>✔️</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td></td>
<td>UTI (Oral &amp; IV) – QIDP (cUTI / uUTI)</td>
<td>✔️</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Sarecycline</td>
<td>Inflammatory Acne</td>
<td>✔️</td>
<td></td>
<td></td>
<td>4Q '17</td>
<td>Allergan (U.S.)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>PARATEK® (ex-U.S.)</td>
</tr>
</tbody>
</table>

**Positive Studies**

- 1Q '18
- 4Q '17

---

10/18/2017 2
Omadacycline Life-Cycle Development Plans
Near-Term Focus on uUTI & cUTI Indications

- QIDP Status Granted by FDA for Complicated UTI (cUTI)
- New QIDP status granted for Uncomplicated UTI (uUTI)
  - Highlights the significant unmet need for treatment of uncomplicated urinary infections where some patients are difficult to treat, or currently available oral therapies are not adequate
  - Omadacycline has the potential to address this unmet need

UTI Phase 2 Program Strategy to pursue both uUTI and cUTI
  - cUTI – acute pyelonephritis
    - IV and Oral treatment regimens
  - uUTI - acute uncomplicated cystitis
    - Oral-only treatment regimens
  - Program initiation as early as Dec 2017
# Near-Term Flow of Key Milestones:
*Clinical Data and Regulatory Submissions*

<table>
<thead>
<tr>
<th>Omadacycline Events</th>
<th>Timing</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSSSI Phase 3 Data: IV and Oral</td>
<td>Q2 2016</td>
<td>Positive Phase 3 Data</td>
</tr>
<tr>
<td>UTI Phase 1b Data: PK/PD</td>
<td>Q4 2016</td>
<td>Proof-of-Principle</td>
</tr>
<tr>
<td>CABP Phase 3 Data: IV and Oral</td>
<td>Q2 2017</td>
<td>Positive Phase 3 Data</td>
</tr>
<tr>
<td>ABSSSI Phase 3 Data: Oral-Only</td>
<td>Q3 2017</td>
<td>Positive Phase 3 Data</td>
</tr>
<tr>
<td>UTI Phase 2 Initiation</td>
<td>As Early as Dec 2017</td>
<td>TBD</td>
</tr>
<tr>
<td>Initiate Rolling NDA Submission</td>
<td>Dec 2017</td>
<td>TBD</td>
</tr>
<tr>
<td>Complete NDA Submission</td>
<td>Q1 2018</td>
<td>TBD</td>
</tr>
<tr>
<td>Anticipated NDA Approval</td>
<td>Q4 2018</td>
<td>TBD</td>
</tr>
<tr>
<td>EMA MAA Submission</td>
<td>2H 2018</td>
<td>TBD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sarecycline Events(^{(1)})</th>
<th>Timing</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sarecycline Phase 3 Efficacy Studies</td>
<td>Q1 2017</td>
<td>Positive Phase 3 Data</td>
</tr>
<tr>
<td>Sarecycline NDA (Allergan) Submission</td>
<td>Q4 2017(^{(2)})</td>
<td>TBD</td>
</tr>
</tbody>
</table>

\(^{(1)}\) Allergan licensed U.S. development & commercial rights
\(^{(2)}\) As reported by Allergan (4Q2016 earnings call)
Today’s Speakers

George Zhanel, PharmD, PhD
Department of Medical Microbiology /Infectious Diseases
Canadian Antimicrobial Antimicrobial Resistance Alliance
Max Rady College of Medicine
University of Manitoba

George Sakoulas, MD
University of California, School of Medicine
Sharp Healthcare

Fredrick M. Abrahamian, DO
Clinical Professor of Medicine
David Geffen School of Medicine at UCLA
Los Angeles, California

Adam Woodrow, Chief Commercial Officer
Paratek Pharmaceuticals
Properties of Omadacycline
Selected MICROBIOLOGICAL Spectrum by Indication

<table>
<thead>
<tr>
<th>Skin Pathogens</th>
<th>CABP Pathogens</th>
<th>UTI Pathogens</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>MIC&lt;sub&gt;90&lt;/sub&gt;</td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong></td>
<td>2,050</td>
<td>0.25</td>
</tr>
<tr>
<td>MRSA</td>
<td>920</td>
<td>0.25</td>
</tr>
<tr>
<td>Tetracycline-R</td>
<td>70</td>
<td>0.5</td>
</tr>
<tr>
<td>β-hemolytic strep</td>
<td>541</td>
<td>0.12</td>
</tr>
<tr>
<td>Viridans group strep</td>
<td>106</td>
<td>0.12</td>
</tr>
<tr>
<td>Enterococcus faecalis</td>
<td>328</td>
<td>0.25</td>
</tr>
<tr>
<td>Enterococcus faecium</td>
<td>167</td>
<td>0.12</td>
</tr>
<tr>
<td>VRE</td>
<td>112</td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Omadacycline Pharmacokinetics

- Oral (300 mg) and IV (100 mg) formulations
  - Oral bioequivalent to iv
- Once daily dosing
- Extensive tissue distribution (low protein binding)
- High concentration in lung (ELF, macrophages)
- Multiple routes of excretion (urine, bile and feces)
- No dose adjustments needed
  - Age and gender
  - Renal impairment
  - Hepatic impairment
- Low potential for drug interactions

Lung and Plasma Concentrations
Total Plasma, ELF, and AC Concentrations

<table>
<thead>
<tr>
<th>Site</th>
<th>Omadacycline $\text{AUC}_{0-\tau} \ (\text{mg}\cdot\text{h}/\text{L})$</th>
<th>Tigecycline $\text{AUC}_{0-\tau} \ (\text{mg}\cdot\text{h}/\text{L})$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma</td>
<td>11.73</td>
<td>1.83</td>
</tr>
<tr>
<td>ELF</td>
<td>17.23</td>
<td>3.16</td>
</tr>
<tr>
<td>AC</td>
<td>302</td>
<td>38.5</td>
</tr>
</tbody>
</table>

OMC: 100 mg intravenously q12h x 2 doses, then 100 mg q24h x 3 doses (4 days – steady-state conditions)
TIG: 100 mg intravenously x 1 dose, then 50 mg q12h x 6 doses$^a$ (4 days – steady-state conditions)

Omadacycline not associated with *Clostridium difficile* infection (CDI)

- Historically, tetracyclines have a low risk of *C. difficile* infection
- No reported cases of *C. difficile* infection in omadacycline treated patients
- Wilcox Gut simulation model:
  - No evidence of *C. difficile* germination, vegetative cell proliferation or toxin production were observed with omadacycline exposure

<table>
<thead>
<tr>
<th>Species</th>
<th>No. of Strains</th>
<th>Antibiotic</th>
<th>MIC Range</th>
<th>MIC&lt;sub&gt;90&lt;/sub&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>C. difficile</em></td>
<td>27</td>
<td>Omadacycline</td>
<td>0.06 – 0.12</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>Doxycycline</td>
<td>0.015 – 0.5</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>Omadacycline</td>
<td>0.25 - 8</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tigecycline</td>
<td>0.25 - 4</td>
<td>0.25</td>
</tr>
</tbody>
</table>

Tariq et al. CID 2017
Moura et al, SM Microbe 2017
# Perspective of this Agent: Microbiology and Pharmacology

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Omadacycline</th>
<th>Quinolones</th>
<th>Linezolid</th>
<th>Vancomycin</th>
<th>Ceftriaxone</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>S. pneumoniae</strong></td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Atypicals</td>
<td>yes</td>
<td>yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><em>Staphylococci</em> (MRSA)</td>
<td>yes</td>
<td>No</td>
<td>yes</td>
<td>yes</td>
<td>No</td>
</tr>
<tr>
<td><em>E. coli</em> MDR</td>
<td>yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>IV and PO</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Once Daily Dosing</td>
<td>yes</td>
<td>yes</td>
<td>No</td>
<td>No</td>
<td>yes</td>
</tr>
<tr>
<td>No Dosage Adjustment</td>
<td>yes</td>
<td>No</td>
<td>yes</td>
<td>No</td>
<td>yes</td>
</tr>
<tr>
<td>Low <em>C. difficile</em> Association</td>
<td>yes</td>
<td>No</td>
<td>yes</td>
<td>N/A</td>
<td>No</td>
</tr>
<tr>
<td>Low Drug Interactions</td>
<td>yes</td>
<td>yes</td>
<td>No</td>
<td>No</td>
<td>yes</td>
</tr>
</tbody>
</table>
Omadacycline Potentially Addresses Microbiology and Pharmacology Needs

- **Community acquired bacterial pneumonia (CABP):**
  - Alternative to:
    - Ceftriaxone/macrolide and fluoroquinolones
  - Covers *S. aureus* and atypicals as well as drug resistant *S. pneumoniae*

- **Acute Bacterial Skin and Skin Structure Infections (ABSSSI):**
  - Alternative to vancomycin and linezolid

- **Potential to treat Urinary tract Infections (UTI):**
  - Potential if ESBL or MDR *E. coli* are suspected

- **Other:**
  - MDR ESBL *E. coli* in other sites (IV/PO)
  - Oral step down therapy—early discharge (ER)
  - Bad renal function
  - Replace tigecycline (IV/PO, less AE)
Omadacycline: A Potential New Antibiotic for Community Acquired Infections

George Sakoulas, MD
Associate Professor
University Of California, School of Medicine
Infectious Disease Consultant, Sharp Healthcare
San Diego, California
Key Clinical Attributes of Omadacycline

- Once Daily Dosing
- IV and Oral Administration Options
- No Anticipated Dosage Modifications
  - age
  - weight/BMI
  - hepatic impairment
  - renal impairment
- *In vitro* activity against common CABP & ABSSSI pathogens
  - Retained Activity Against Tetracycline-resistant Pathogens
  - Activity against drug resistant ABSSSI and CABP pathogens (e.g. MRSA, PRSP)
- Demonstrated efficacy in CABP and ABSSSI
- Low potential for Drug-Drug Interactions
- Safe and Tolerable Profile
- Anticipated low propensity to induce *C. difficile* (tetracycline class)
Omadacycline Efficacy in ABSSSI and CABP

Early Clinical Response - FDA Primary Endpoint

CABP (ITT)
- Omadacycline: 81.1%
- Moxifloxacin: 82.7%

ABSSSI (mITT)
- Omadacycline: 84.8%
- Moxifloxacin: 85.5%
- Linezolid: 87.5%

OPTIC
- Delta (95% CI): 
  Omadacycline: -1.6 (-7.1, 3.8)

OASIS-1 (IV to Oral)
- Delta (95% CI): 
  Omadacycline: -0.7 (-6.3, 4.9)

OASIS-2 (Oral)
- Delta (95% CI): 
  Omadacycline: +5.0 (-0.2, 10.3)
Omadacycline Efficacy in ABSSSI and CABP

PTE - EMA Primary Endpoint

**CABP**

- **OPTIC**
  - ITT: 88.4 vs 85.2, Delta (97.5% CI) +3.3 (-2.7, 9.3)
  - CE: 92.5 vs 90.5, Delta (97.5% CI) +2.0 (-3.2, 7.4)

**ABSSSI**

- **OASIS-1**
  - mITT: 86.1 vs 83.6, Delta (97.5% CI) +3.3 (-2.2, 9.0)
  - CE: 96.3 vs 93.5, Delta (95% CI) +2.3 (-0.5, 5.8)
- **OASIS-2**
  - mITT: 84.2 vs 80.8, Delta (97.5% CI) +2.0 (-3.2, 7.4)
  - CE: 97.9 vs 95.5, Delta (95% CI) +2.8 (-1.0, 6.9)
# Common TEAEs in the OPTIC, OASIS-1, and OASIS-2 Studies

## OPTIC Study (CABP)

<table>
<thead>
<tr>
<th></th>
<th>Omadacycline (N=382) %</th>
<th>Moxifloxacin (N=388) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with any TEAE</td>
<td>41.1</td>
<td>48.5</td>
</tr>
<tr>
<td>ALT increased</td>
<td>3.7</td>
<td>4.6</td>
</tr>
<tr>
<td>Hypertension</td>
<td>3.4</td>
<td>2.8</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2.6</td>
<td>1.5</td>
</tr>
<tr>
<td>Nausea</td>
<td>2.4</td>
<td>5.4</td>
</tr>
<tr>
<td>Headache</td>
<td>2.1</td>
<td>1.3</td>
</tr>
<tr>
<td>AST increased</td>
<td>2.1</td>
<td>3.6</td>
</tr>
<tr>
<td>Diarrhea b</td>
<td>1.0</td>
<td>8.0</td>
</tr>
</tbody>
</table>

## OASIS-1 Study (ABSSSI)

<table>
<thead>
<tr>
<th></th>
<th>Omadacycline (N=323) %</th>
<th>Linezolid (N=322) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with any TEAE</td>
<td>48.3</td>
<td>45.7</td>
</tr>
<tr>
<td>Nausea</td>
<td>12.4</td>
<td>9.9</td>
</tr>
<tr>
<td>Infusion site extravasation a</td>
<td>8.7</td>
<td>5.9</td>
</tr>
<tr>
<td>Subcutaneous abscess</td>
<td>5.3</td>
<td>5.9</td>
</tr>
<tr>
<td>Vomiting</td>
<td>5.3</td>
<td>5.0</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>4.6</td>
<td>4.7</td>
</tr>
<tr>
<td>Headache</td>
<td>3.1</td>
<td>4.0</td>
</tr>
<tr>
<td>ALT increased</td>
<td>2.8</td>
<td>4.3</td>
</tr>
<tr>
<td>AST increased</td>
<td>2.5</td>
<td>3.7</td>
</tr>
<tr>
<td>Wound infection</td>
<td>2.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>2.2</td>
<td>3.1</td>
</tr>
</tbody>
</table>

a Events were reported as IV site infiltration, typically due to difficulty in finding reliable venous access sites. All events were mild. Among these subjects, 79% in each treatment group had ABSSSI considered related to intravenous drug use.

b In addition to diarrhea, 7 cases of *C. difficile* colitis and 1 case of pseudomembranous colitis were reported, all cases were in the moxifloxacin arm of the study.

## OASIS-2 Study (ABSSSI)

<table>
<thead>
<tr>
<th></th>
<th>Omadacycline (N=368) %</th>
<th>Linezolid (N=367) %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with any TEAE</td>
<td>53.5</td>
<td>37.3</td>
</tr>
<tr>
<td>Nausea</td>
<td>30.2</td>
<td>7.6</td>
</tr>
<tr>
<td>Vomiting</td>
<td>16.8</td>
<td>3.0</td>
</tr>
<tr>
<td>Wound infection</td>
<td>6.0</td>
<td>4.6</td>
</tr>
<tr>
<td>ALT increased</td>
<td>5.2</td>
<td>3.0</td>
</tr>
<tr>
<td>AST increased</td>
<td>4.6</td>
<td>3.3</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>4.1</td>
<td>2.7</td>
</tr>
<tr>
<td>Headache</td>
<td>3.5</td>
<td>2.2</td>
</tr>
<tr>
<td>Cellulitis</td>
<td>3.3</td>
<td>2.5</td>
</tr>
</tbody>
</table>

1 Nausea: Omadacycline = 75% mild and 25% moderate. Linezolid = 78.1% mild and 21.9% moderate. One patient on omadacycline arm discontinued due to nausea and vomiting.
Premature Discontinuations from Pivotal Phase 3 Studies

### OPTIC
#### CABP
- Omadacycline: 8.8%
- Moxifloxacin: 10.8%

### OASIS-1
#### ABSSSI
- Omadacycline: 10.0%
- Linezolid: 11.7%

### OASIS-2
#### ABSSSI
- Omadacycline: 10.9%
- Linezolid: 14.2%

**Notes:**
- **1** All Other: Lost to Follow-up, Withdrawal by Subject, Physician Decision, Death, Other
• Robust and Consistent Efficacy Observed for Omadacycline Across All Three Studies
  – Omadacycline met primary FDA and EMA endpoints in each study

• Omadacycline Was Generally Safe and Well Tolerated
  – Overall, good tolerability with acceptable severity and rate of nausea, vomiting, and diarrhea
  – Low discontinuation rate for patients on omadacycline and comparators
  – Post-baseline changes in liver chemistries similar for omadacycline and comparators
Community Acquired Pneumonia (CAP) Carries a High Disease Burden

**Impact of CAP**

- Pneumonia carries a high disease burden
  - Approximately 4.5 million ambulatory visits
  - Approximately 1.1 million hospitalizations
  - Eighth leading cause of death
    - Approximately 60,000 deaths annually
    - 85% occurred in patients aged ≥ 65

**Impact of *S. pneumoniae***

- Drug-resistant *S. pneumoniae* is Identified as a Serious Threat by the CDC
  - 1.2 million drug-resistant infections annually
  - 19,000 in excess hospitalizations
  - 7,000 deaths

---

Antimicrobial therapy decisions driven by antibiotic resistance and disease severity

**Previously Healthy**
- No antibiotics within 3 months
  - Macrolide
  - Doxycycline

**Comorbidities Or Antibiotics within 3 months**
- Respiratory
- Fluoroquinolone
- β-lactam + Macrolide

**Areas with S. pneumoniae macrolide –resistant ≥25%**
- β-lactam + Doxycycline
- Fluoroquinolones

---

**Risk of Clostridium difficile Infection**
- Crude incidence per 100,000 population and high mortality
  - 30 to 120 cases of community-associated infection
    - 13.5% mortality for first recurrence
  - 50 to 160 cases of healthcare-associated infection
    - 20.9% mortality for first recurrence
- Antimicrobial class risk: Clindamycin (OR 16.80), β-lactams (OR 5.50), FQ (OR 5.50), PNC (OR 2.71), TMP-S (OR 1.81) Tetracycline (OR 0.92)

---

**Fluoroquinolone Adverse Events**
- FDA Safety Communications for FQ antimicrobial Drugs May 2016: Label Box Warning for Tendinitis and Tendon Rupture
  - Risk in median 7 days of therapy
  - Risk increased 6.4 fold in patients 60-79 y
- Neurotoxicity
- Other Collagen Related AEs
  - Aortic dissection
  - Retinal detachment

---

Current Skin Infection IDSA Guidelines Present Limitations for ABSSSI Treatment Options

<table>
<thead>
<tr>
<th>Primary IV Options</th>
<th>IDSA Recommends a Targeted MRSA Antimicrobial Therapy¹</th>
</tr>
</thead>
</table>
| Vancomycin ±/– Piperacillin/Tazobactam | • NO bioequivalent Oral Option  
  • Monitoring Required  
  • Increased risk of nephrotoxicity  
  • Dosing 2 to 4 times/day |
| Linezolid ±/– Piperacillin/Tazobactam | • Drug to drug interactions (e.g., SSRIs, MAOI’s, and Pseudoephedrine)  
  • Warnings include myelosuppression |

<table>
<thead>
<tr>
<th>Primary Oral Options</th>
<th>Oral MRSA agents²</th>
</tr>
</thead>
</table>
| Clindamycin          | • Black box warning for Increased frequency of *C. diff* colitis  
  • Multiple daily doses  
  • Resistance |
| TMP-SMX              | • Sulphur allergy and hypersensitivity  
  • Multiple daily doses  
  • Concerns for safety and tolerability |
| Doxycycline          | • Photosensitivity  
  • Multiple daily doses  
  • Resistance |

1. Dennis L. Stevens, Alan Bisno, Henry F. Chambers et al. *Clin Infect Dis* First published online June 18, 2014,  
Omadacycline Benefits

- **Patient Outcomes**
  - Met FDA and EMA endpoints and requirements
  - Efficacy against common resistant CABP and ABSSSI pathogens
- **Patient Safety** (especially elderly patients who are most at risk)
  - Overall AEs and discontinuation rates similar to currently used ABs (linezolid & moxifloxacin)
  - Low propensity to induce *C. difficile*-associated diarrhea/colitis
  - Potential avoidance of fluoroquinolone collagen toxicities
  - Circumvents the mechanisms of tetracycline resistance
- **Streamlining care**
  - Early IV to PO switch
  - Provide appropriate broad spectrum treatment with a single agent allowing for early discharge from ER
  - Avoid complications associated with IV therapies & multiple antibiotics
Challenges in Community-Acquired Infections

Fredrick M. Abrahamian, DO, FACEP, FIDSA
Clinical Professor of Medicine
David Geffen School of Medicine at UCLA
Los Angeles, California
We have to think differently in the Emergency Department

- Treat primary disease plus complications
- Empiric therapy
- Limited diagnostic capability
- Gatekeeper; time pressure, quality metrics
Current Challenges Associated with Antibiotic Choice in the Emergency Department

• Rising therapy failure
  – Increasing virulence/resistance with increasing comorbidity burden, especially MRSA
  – More antibiotics being used for longer duration, per infective episode
  – *Clostridium difficile* disease burden is increasing

• Increasing hospitalization stay (Length of Stay-LOS)
  – IV antibiotic administration
  – Delay in patient discharge
  – Increase risk to hospital-onset infection:
    – Extending LOS by one day increases the probability new infection by 1.37%; then average LOS increased by 9.32 days¹

• Drain on hospital resources, overall escalation in hospital costs

Aging population impacts the ED Decision Making Process in Patients with skin infection (ABSSSI)

- **Patients 65 years and older (i.e. Medicare) with skin infections had**
  - Higher prevalence of admission to the hospital (42.7% vs. 20.5%, p < 0.001)
  - 2.5x increased odds for failed initial ED treatment than for persons less than 65 years old
  - A greater proportion of elderly pts failed ED outpatient therapy upon follow up (25% vs. 11.7%)

- **Prevalence of chronic conditions increases with age**
  - 82% of aged Medicare beneficiaries have more than one chronic condition

- **Common comorbidities in hospitalized patients with ABSSSI**
  - Obesity 49.7%, Hypertension 48.9%, Diabetes mellitus 48.9%, Depression 12.4%

Aging population impacts the ED Decision Making Process in Patients with Community Acquired Pneumonia (CAP)

CAP incidence increases markedly with age, and age impacts number of episodes\(^1\)

- In the US the annual incidence of CAP requiring hospitalization was 24.8 cases per 10,000 adults in the Etiology of Pneumonia in the Community (EPIC) study published in 2014.
- The incidences of influenza and of \textit{S. pneumoniae} were almost 5 times as high among adults 65 years of age or older
- Common comorbidities are heart failure, COPD, coronary artery disease, and diabetes

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Allergies, AEs and resistance to antibiotics impacts medical decisions

- Antibiotic allergies and concerns for other AEs are common
- Multiple AE concerns with quinolones, especially in elderly
- Increasing *S. pneumoniae* resistance rates to macrolides and cephalosporins

<table>
<thead>
<tr>
<th>Antibiotic Allergy</th>
<th>Women</th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Penicillin</td>
<td>11%</td>
<td>6.5%</td>
</tr>
<tr>
<td>TMP-SMX</td>
<td>7.9%</td>
<td>2.4%</td>
</tr>
<tr>
<td>Macrolides</td>
<td>1.9%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Cephalosporin</td>
<td>1.7%</td>
<td>0.8%</td>
</tr>
<tr>
<td>Quinolones</td>
<td>0.8%</td>
<td>0.3%</td>
</tr>
</tbody>
</table>
Current tools do not meet ED needs

• What I have…
  • Most drugs are IV only
  • Many have safety limitations
  • Lack of efficacy or resistance issues

• What I need…
  • Efficacious monotherapy that has activity against important community pathogens
    - MRSA
    - DRSP
    - Gram negative potentially found in community acquired infections
  • Bioequivalent IV and oral formulations without safety limitations
  • Low potential for drug-drug interactions
  • Once daily administration
  • No dose adjustment for age, gender, and hepatic or renal impairment
Today’s Discussion

- CABP & ABSSSI Treatment Options Today
- Omadacycline Will Address Unmet Needs
- Omadacycline and the Path to Success
CABP & ABSSSI Treatment Options Today
Common Hospital Treatments for CABP Have Use-Limiting Formulations and Safety Considerations

Hospital Market Share
Total Number of Patients: 3.4M

- Fluoroquinolones 35.0%
- Beta-lactam + Macrolide 45.8%
- Penicillin, 14.2%
- Other Broad-Sp, 6.4%

Source: AMR, 2015 (reflects only hospital in-patients)
Current Hospital ABSSSI Options Have Use-Limiting Formulations or Safety Considerations

Source: AMR, 2015 (reflects only hospital in-patients)
Omadacycline Will Address Unmet Needs
Physicians Want to Simplify a Complicated Treatment Decision

1. How confident am I about the coverage for this patient?
   - Suspected resistance
   - gram +, gram -, atypical, or anaerobe
   - Potentially polymicrobial

2. Could the short-term benefit be outweighed by downstream issues?
   - Drug-drug interactions
   - *C. difficile* history
   - QTc, neurological, tendonitis
   - Renal impairment

3. Is the treatment affordable?
   - Cost to hospital
   - Cost to patient
Physicians Confirm Unmet Medical Needs
Omadacycline Provides an Important Solution

There are Unmet Needs that Omadacycline Will Address

- New Therapies to Overcome Drug Resistance
- More Oral Options
- Bioequivalent IV and Oral
- Confidence to Discharge Patient
- Alternative to Fluoroquinolones
- Reduce Usage of Multi-Drug Combinations
- High Efficacy in a Monotherapy
- Modernized Tetracycline
- Lack of Different Class Options
- Reduce Hospital Length of Stay
- Greater Safety
- Known Safety Profile
- Reduce Nursing Time
- Reduce Usage of Multi-Drug Combinations
- Modernized Tetracycline

Source: Paratek sponsored market research
Omadacycline and the Path to Success
Success Begins in the Hospital with Specialists

Launch and Beyond
- IDs
- ER Doctors
- Hospitalists
- Pulmonologists
- Pharm. D IDs

Year 2 and Beyond
- Internal Medicine
- Primary Care Provider
- NPs, PAs
- Urgent Care

CABP and ABSSSI Patients Suffer Annually
- ~6.7M\(^1\)

CABP and ABSSSI Omadacycline Addressable Market
- ~900K

CABP and ABSSSI Omadacycline’s Addressable Market
- ~2.1M\(^1\)

CABP and ABSSSI Prescriptions Annually
- ~23.7M\(^1\)

- ~1.2M

Source 1. AMR, 20% est failures (based on hospital patterns) of first line MRSA treatment projected for 2028
Focus of Launch Efforts
Awareness & Education Lead to Access & Use

- Advocacy
- Formulary Access
- Utilization

Awareness & Education + Access = Behavior Change

- Scientific Exchange
- Unbranded Disease State Education Programs
- Publications

- HEOR Publications
- Payer Discussions
- Guidelines

- Trial
- Usage
- Adoption
Omadacycline: U.S. Timeline
Launch January 2019

- Complete Submission (NDA Filing)
- NDA Acceptance
- Anticipated NDA Action
- OPDP Review of Marketing Materials

2017
Aug  | Sept  | Oct  | Nov  | Dec
2018
Jan  | Feb  | Mar  | Apr  | May  | Jun  | Jul  | Aug  | Sep  | Oct  | Nov  | Dec
2019
Jan  | Feb  | Mar

Commercial Readiness Completed Actions:
- Commercial Team Hired
- Payer Team Hired
- Advisory Boards
- Market Research
- Disease State Education
- Initial Payer Research

- Account Teams Hired
- Hire MSLs
- Payer Reimbursement and Trade Discussions
- Finalize Pricing
- KPI Dashboard
- Sales Teams Hired
- Launch
- Product Supply

Budget Impact Model and Health Economic Analysis and Publications

Scientific Exchange

Publications/News Flow Continues
Disease State Education Efforts Continue

**Antibiotic Rise Up Campaign**

- Designed to raise awareness of Paratek and educate target HCPs about the need for new effective and safe IV/oral antibiotics
- Over 9,000\(^1\) Infectious Disease specialists and Hospital Pharmacists have been reached through targeted digital media – 60% open rate\(^1\)

Source 1: Antibiotic Rise Up Campaign Metrics
Multiple indications at launch
  • Greater utility

IV and Oral dosing/once day
  • Confidence transitioning patient home

Compelling value proposition
  • GO HOME, STAY HOME™

No branded competing products
  • First new once-daily Oral and IV CABP in over 10 years
Payers do not anticipate restricting use

**Acute vs. Chronic Condition**
- No annuity of cost

**Mortality Issue With CABP**
- Poor outcome with delayed therapy

**IV to Oral = hospital minimization**
- Cost savings

**Specialist prescriptions maintained upon discharge**
- Cost savings

**Access Expectations:**
- **First 3 months of approval:** Three major payers representing approximately one third of the covered lives
- **First 12 months of approval:** Six major payers representing approximately two thirds of the lives within the first year of approval

Source: Campbell Alliance, Omadacycline Payer Research, 2015, Paratek Payer Advisory Board August, 2017
Focus Where It Counts
~80% of Hospital IV Initiation and Utilization

Call Universe

Hospital Reps
- Education & Awareness Efforts
- Reimbursement Information

Inside Sales
- Education
- Reimbursement Information
- Reimbursement & Coding Guide
- Educational Programs

Field-Based Medical
- Clinical Information
- Scientific Exchange
- Publications
- IIR

Key Account Managers
- Health Outcomes Information
- Budget Impact Model
- Reimbursement & Coding Guide
- Contract Negotiation

Commercial Payer Team
- Health Outcomes Information
- Budget Impact Model
- AMCP Monograph
- Contract Negotiation

Source 1: IMS, 2016 (top 6 deciles hospital reps + inside sales)
THE PARATEK DIFFERENCE™

- A Proven Record of Excellence in Execution
- Right Product for the Right Patient at the Right Time
- A Thorough Understanding of Market Dynamics
- A Practical Plan for Delivering Success
Thank you

Questions and Answers