**DIAGNOSIS AND OUTCOMES IN PATIENTS WITH ATYPICAL PATHOGENS IN A PHASE 3 COMMUNITY ACQUIRED BACTERIAL PNEUMONIA TRIAL COMPARING DELAFLOXACIN (DLX) TO MOXIFLOXACIN (MOX)**

Kara Keedy1, Amanda Sheets1, Ashley Nenninger1, Sandra McCurdy1, Laura Lawrence1, Megan Quintas1, Yang Li2, Sue Cammarata1

1 Melinta Therapeutics, Lincolnshire, IL, US. 2 Firma Clinical, Hunt Valley, MD, US.

**BACKGROUND AND PURPOSE**

- **Randomization**
  - Clinical and radiographic evidence of CABP

**STUDY POPULATION (Planned N=860)**

**VISIT SCHEDULE**

**SCR/BASE**

<table>
<thead>
<tr>
<th>Day 1</th>
<th>IV to Oral Delafloxacin (N=431)</th>
<th>300 mg IV (BID) for at least 6 doses then 400 mg tablet (BID)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomization</td>
<td>1:1</td>
<td></td>
</tr>
<tr>
<td>300 mg IV (QD)</td>
<td>for at least 3 active doses then 400 mg tablet (QD)</td>
<td></td>
</tr>
<tr>
<td>Total Duration of Therapy: 5-10 days</td>
<td>IV to IV Switch at Investigator Discretion</td>
<td></td>
</tr>
</tbody>
</table>

**IV to Oral Moxifloxacin (N=428)**

**EOT**

<table>
<thead>
<tr>
<th>96 h (±24) after first dose</th>
<th>Micro ITT (MITT-1) ITT patients with baseline pathogen</th>
</tr>
</thead>
<tbody>
<tr>
<td>24 h (±4) after last dose</td>
<td>Micro Evaluable (ME-1-TOC) CE patients at TOC with baseline pathogen</td>
</tr>
<tr>
<td>5-10 days after last dose</td>
<td>Clinically Evaluable (CE) Patients treated per protocol with in-window assessments</td>
</tr>
<tr>
<td>Day 28 (±2)</td>
<td>All randomized patients</td>
</tr>
</tbody>
</table>

**TOC/FU**

<table>
<thead>
<tr>
<th>Intent to Treat (ITT)</th>
<th>Micro ITT (MITT-1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All randomized patients</td>
<td></td>
</tr>
</tbody>
</table>

**Follow Up**

- Primary: ECR at 96 h (±24) after first dose in ITT population (N=860)
  - Monomicrobial atypical pathogens:
    - Legionella pneumophila:
    - Respiratory culture
    - Urinary antigen test (UAT)
    - Serology (acute versus convalescent titers; SCR vs TOC/FU)
  - Mycoplasma pneumoniae:
    - Oropharyngeal swab culture
    - Serology (acute versus convalescent titers; SCR vs TOC/FU)
  - Chlamydia pneumoniae:
    - Serology (acute versus convalescent titers; SCR vs TOC/FU)

**KEY ENDPOINTS**

- **Responder** = Improvement in ≥2 of the following: chest pain, frequency or severity of cough, sputum production, dyspnea, and no worsening of any.|)

**CONCLUSIONS AND CLINICAL IMPLICATIONS**

Atypical pathogens were frequently identified as CABP pathogens, including as monomicrobial infections.

DLX monotherapy was confirmed as efficacious for treatment of CABP.

DLX treatment provided comparable outcomes to MOX among patients with atypical pathogens.

DLX may be a useful treatment option in CABP when empirical coverage of atypical pathogens is desired.

Refer to full prescribing information at www.baxdela.com

**TABLE 1: DIAGNOSIS OF ATYPICAL PNEUMONIA (ITT)**

<table>
<thead>
<tr>
<th>Any Pathogen Detected, MITT-1 (% ITT)</th>
<th>Total N=859</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Atypical Pathogen, n (% MITT-1)</td>
<td>520 (60.5)</td>
</tr>
<tr>
<td>Any Pathogen, n (% MITT-1)</td>
<td>156 (30.0)</td>
</tr>
</tbody>
</table>

**TABLE 2: SUSCEPTIBILITY OF ATYPICAL PATHOGENS AT BASELINE (MITT-1)**

<table>
<thead>
<tr>
<th>Delafloxacin MIC (mcg/mL)</th>
<th>Moxifloxacin MIC (mcg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>MIC50</td>
</tr>
<tr>
<td>M. pneumoniae</td>
<td>19</td>
</tr>
<tr>
<td>L. pneumophila</td>
<td>5</td>
</tr>
</tbody>
</table>

**FIGURE 1: ATYPICAL PATHOGENS BY DETECTION METHOD (MITT-1)**

**FIGURE 2: MONO/POLYMICROBIAL INFECTIONS (MITT-1)**

**FIGURE 3: CLINICAL SUCCESS AT TOC BY SELECTED POPULATION (ME-1-TOC)**

**FIGURE 4: CLINICAL SUCCESS AT TOC BY ATYPICAL PATHOGEN (ME-1-TOC)**

**TABLE 2: DIAGNOSIS OF ATYPICAL PNEUMONIA AT BASELINE (MITT-1)**

- **Clinical and radiographic evidence of CABP cover atypical pathogens.**

- Delafloxacin (DLX) is a novel fluoroquinolone (FQ), approved for IV oral treatment of serious skin infections, that is active against many FQ- or macrolide-resistant strains including MRSA. DLX has FQ class effect and no major drug-drug interactions.

- Clinical outcomes of patients with atypical pathogens are reported from a Phase 3 global, randomized, double-blind, active-controlled study of IV oral DLX vs. MOX in the treatment of CABP.

- IDSA/ATS Guidelines recommend that empirical treatment for CABP pathogens, including as monomicrobial infections.

- Delafloxacin (DLX) is a novel fluoroquinolone (FQ), approved for IV oral treatment of serious skin infections, that is active against many FQ- or macrolide-resistant strains including MRSA. DLX has FQ class effect and no major drug-drug interactions.

- Clinical outcomes of patients with atypical pathogens are reported from a Phase 3 global, randomized, double-blind, active-controlled study of IV oral DLX vs. MOX in the treatment of CABP.

- IDSA/ATS Guidelines recommend that empirical treatment for CABP pathogens, including as monomicrobial infections.

- Delafloxacin (DLX) is a novel fluoroquinolone (FQ), approved for IV oral treatment of serious skin infections, that is active against many FQ- or macrolide-resistant strains including MRSA. DLX has FQ class effect and no major drug-drug interactions.

- Clinical outcomes of patients with atypical pathogens are reported from a Phase 3 global, randomized, double-blind, active-controlled study of IV oral DLX vs. MOX in the treatment of CABP.

- IDSA/ATS Guidelines recommend that empirical treatment for CABP pathogens, including as monomicrobial infections.

- Delafloxacin (DLX) is a novel fluoroquinolone (FQ), approved for IV oral treatment of serious skin infections, that is active against many FQ- or macrolide-resistant strains including MRSA. DLX has FQ class effect and no major drug-drug interactions.

- Clinical outcomes of patients with atypical pathogens are reported from a Phase 3 global, randomized, double-blind, active-controlled study of IV oral DLX vs. MOX in the treatment of CABP.

- IDSA/ATS Guidelines recommend that empirical treatment for CABP pathogens, including as monomicrobial infections.

- Delafloxacin (DLX) is a novel fluoroquinolone (FQ), approved for IV oral treatment of serious skin infections, that is active against many FQ- or macrolide-resistant strains including MRSA. DLX has FQ class effect and no major drug-drug interactions.

- Clinical outcomes of patients with atypical pathogens are reported from a Phase 3 global, randomized, double-blind, active-controlled study of IV oral DLX vs. MOX in the treatment of CABP.

- IDSA/ATS Guidelines recommend that empirical treatment for CABP pathogens, including as monomicrobial infections.

- Delafloxacin (DLX) is a novel fluoroquinolone (FQ), approved for IV oral treatment of serious skin infections, that is active against many FQ- or macrolide-resistant strains including MRSA. DLX has FQ class effect and no major drug-drug interactions.

- Clinical outcomes of patients with atypical pathogens are reported from a Phase 3 global, randomized, double-blind, active-controlled study of IV oral DLX vs. MOX in the treatment of CABP.

- IDSA/ATS Guidelines recommend that empirical treatment for CABP pathogens, including as monomicrobial infections.