Lefamulin Versus Moxifloxacin in Patients With Community-Acquired Bacterial Pneumonia at Risk for Poor Efficacy or Safety Outcomes: Pooled Subgroup Analyses From the Lefamulin Evaluation Against Pneumonia (LEAP) 1 and LEAP 2 Phase 3 Noninferiority Clinical Trials

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INTRODUCTION & PURPOSE

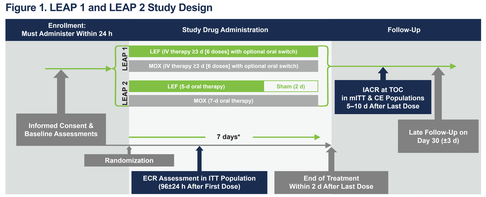
- In the United States, pneumonia is among the most common causes of hospitalization and a leading cause of infectious death[1,2]
- The management of community-acquired bacterial pneumonia (CABP) may be particularly challenging in certain subgroups of patients
  - The presence of chronic obstructive pulmonary disease (COPD) or diabetes mellitus (DM) increases the risk of severe CABP developing in patients, and these comorbidities may aggravate clinical symptoms and complicate management[3-5]
  - Underlying cardiac or liver disease increases the risk of potential cardiac or liver toxicities, respectively, associated with CABP antimicrobials[6,7]
  - The incidence and impact of CABP are greater in older vs younger individuals, and elderly patients with CABP may often present with challenges (eg, increased rates of resistance, polypharmacy/drug interactions) that can negatively affect treatment efficacy and safety[3,8,9]
- Lefamulin (LEF), a first-in-class pleuromutilin antibiotic approved for intravenous (IV) and oral use in adults with CABP,[10] selectively inhibits bacterial protein synthesis by binding to the 50S ribosomal subunit at the A- and P-sites in the peptidyl transferase center[11,12]
  - In patients with CABP, LEF demonstrated noninferiority to moxifloxacin (MOX) in the IV-to-oral switch Lefamulin Evaluation Against Pneumonia (LEAP) 1 phase 3 study[13] and in the LEAP 2 oral-only phase 3 study[14]
- We report pooled efficacy and safety outcomes in at-risk subgroups from the LEAP 1 and LEAP 2 trials, including patients with COPD/asthma, DM, underlying cardiac or liver disease, and the elderly

METHODS

Study Design and Patients

- Both studies were prospective, randomized, double-blind, double-dummy, phase 3 trials (**Figure 1**)[13,14]
  - In LEAP 1, patients with Pneumonia Outcomes Research Team (PORT) risk class III–V were randomized to receive IV LEF 150 mg every 12 hours (q12h) for 5–7 days or IV MOX 400 mg every 24 hours (q24h) for 7 days
    - Patients could switch to oral therapy (LEF 600 mg q12h or MOX 400 mg q24h) after 6 IV doses of study drug (~3 days) if predefined improvement criteria were met
  - In LEAP 2, patients with PORT risk class II–IV were randomized to receive oral LEF 600 mg q12h for 5 days or oral MOX 400 mg q24h for 7 days
- Key study exclusion criteria in LEAP 1 and LEAP 2 included the following (among others):
  - Evidence of significant hepatic disease (eg, known acute hepatitis, including active viral hepatitis; aspartate aminotransferase [AST] or alanine aminotransferase [ALT] >5× upper limit of normal [ULN]; total bilirubin >3× ULN [unless Gilbert's disease]; AST or ALT >3× ULN and total bilirubin >2× ULN; history of cirrhosis; manifestation of end-stage liver disease such as ascites and hepatic encephalopathy)
  - At risk of major cardiac events or dysfunction (eg, known QT prolongation or receipt of a medication within the previous 7 days with potential for QT prolongation; clinically significant hypokalemia not treated before randomization; clinically unstable cardiac disease; complete left bundle branch block)
  - Have a life expectancy of ≤3 months because of any disease other than the current episode of CABP (eg, current or impending respiratory failure, acute heart failure, shock, acute coronary syndrome, unstable arrhythmia, hypertensive emergency, clinically relevant gastrointestinal bleeding, profound metabolic abnormality, or acute cerebrovascular event)
  - Have known or suspected severe immunosuppression, defined as receipt of corticosteroid therapy (≥20 mg prednisone/day or equivalent for >4 weeks) within the previous 8 weeks; solid organ or bone marrow transplantation within the previous 12 months; currently receiving cytotoxic chemotherapy; current or anticipated neutropenia (<500 neutrophils/mm^3) or thrombocytopenia (<50,000 platelets/mm^3); or known HIV infection and a CD4 count <200/mm^3

Figure 1. LEAP 1 and LEAP 2 Study Design



CABP=community-acquired bacterial pneumonia; CE=clinically evaluable (patients who met predefined specified criteria related to protocol adherence); ECR=early clinical response (patient assessed as responder if alive, showed improvement in ≥2 CABP signs and symptoms; no worsening in any CABP sign or symptom; and no receipt of a concomitant nonstudy antibiotic for the current CABP episode); IACR=investigator assessment of clinical response (patients assessed as success if alive, with signs and symptoms of CABP resolved or improved such that no additional antibacterial therapy was administered for CABP); ITT=intent to treat (all randomized patients); IV=intravenous; LEAP=Lefamulin Evaluation Against Pneumonia; LEF=lefamulin; mITT=modified ITT (all randomized patients who received any amount of study drug); MOX=moxifloxacin; TOC=test of cure visit.

*In LEAP 1, the original protocol indicated a LEF treatment period of 5 days (but 10 days in patients with CABP due to *Legionella pneumophila* or methicillin-resistant *Staphylococcus aureus* [MRSA] or in patients with *Streptococcus pneumoniae* and bacteremia); however, this was later adjusted to 7 days (except in cases of confirmed MRSA, which continued to receive 10 days of treatment) to reduce medication errors and limit the burden on study sites.[13] If MRSA was suspected, linezolid or linezolid placebo was added to MOX or LEF therapy, respectively. A total of 14/275 (5.1%) patients randomized to MOX and 9/276 (3.3%) patients randomized to LEF received linezolid and linezolid placebo, respectively, because of suspected MRSA at baseline.

METHODS (continued)

Assessments

- The primary efficacy endpoint for the US Food and Drug Administration (FDA) was early clinical response (ECR) at 96±24 hours after the first dose of study drug in the intent-to-treat (ITT) population (see **Figure 1** footnote for study population definitions)
- The European Medicines Agency coprimary efficacy endpoints (FDA secondary endpoints) were investigator assessment of clinical response (IACR) at the test-of-cure (TOC) assessment 5–10 days after the last dose of study drug in the modified ITT (mITT) and clinically evaluable (CE) populations
- Safety assessments included treatment-emergent adverse events (TEAEs), laboratory tests, and electrocardiograms (ECGs) and were performed in the safety analysis set (all randomized and treated patients)
  - TEAEs and clinically significant abnormal laboratory test results were evaluated by the study investigator or a monitoring physician for relationship (not related, possibly related, probably related, or definitely related) to study drug
  - Hematology and clinical chemistry tests were performed at baseline, Day 4, Day 7 (if not end of treatment [EOT]), EOT, and TOC
  - For cardiac evaluations, triplicate 12-lead ECGs were performed within a 5-minute interval at screening and on Days 1 and 3 for LEAP 1 or Days 1 and 4 for LEAP 2 to capture changes at the estimated maximum observed plasma concentration of study drug

RESULTS

Demographics and Baseline Characteristics

- In the pooled ITT population, 1289 patients were randomized to LEF (*n*=646) or MOX (*n*=643)
- Patient demographics and baseline disease characteristics were generally well balanced between treatment groups and reflective of the general patient population with CABP[4,15] (**Table 1**)
  - 297 patients (23.0%) were aged 65–74 years, and 220 (17.1%) were aged ≥75 years
  - 232 patients (18.0%) had COPD/asthma, 168 (13.0%) had DM, 501 (38.9%) had hypertension, 73 (5.7%) had arrhythmia, and 263 (20.4%) had elevated transaminases

Table 1. Demographics and Baseline Disease Characteristics (Pooled ITT Population)

Parameter	LEF (*n*=646)	MOX (*n*=643)	Overall (*N*=1289)
Age, y, mean (SD)	58.9 (16.5)	58.5 (15.7)	58.7 (16.1)
Age group, y, *n* (%)			
18–64	378 (58.5)	394 (61.3)	772 (59.9)
65–74	152 (23.5)	145 (22.6)	297 (23.0)
≥75	116 (18.0)	104 (16.2)	220 (17.1)
Male, *n* (%)	377 (58.4)	340 (52.9)	717 (55.6)
White, *n* (%)	513 (79.4)	509 (79.2)	1022 (79.3)
BMI, kg/m^2, mean (SD)	26.5 (5.8)	26.4 (6.0)	26.5 (5.9)
Smoking history, *n* (%)	284 (44.0)	242 (37.6)	526 (40.8)
PORT risk class,* *n* (%)			
I/II	184 (28.5)	192 (29.9)	376 (29.2)
III	341 (52.8)	334 (51.9)	675 (52.4)
IV/V	121 (18.7)	117 (18.2)	238 (18.5)
History of DM, *n* (%)	80 (12.4)	88 (13.7)	168 (13.0)
History of COPD/asthma, *n* (%)	119 (18.4)	113 (17.6)	232 (18.0)
History of hypertension, *n* (%)	248 (38.4)	253 (39.3)	501 (38.9)
History of arrhythmia, *n* (%)	43 (6.7)	30 (4.7)	73 (5.7)
Baseline liver enzyme elevation (AST or ALT >ULN), *n* (%)	119 (18.4)	144 (22.4)	263 (20.4)

ALT=alanine aminotransferase; AST=aspartate aminotransferase; BMI=body mass index; COPD=chronic obstructive pulmonary disease; DM=diabetes mellitus; eCRF=electronic case report form; ITT=intent to treat; LEF=lefamulin; MOX=moxifloxacin; PORT=Pneumonia Outcomes Research Team; ULN=upper limit of normal.
*PORT risk class was calculated programmatically using data obtained at the site and reported in the eCRF and was not always consistent with the site-reported PORT risk class used for enrollment/stratification; as a result, 3 PORT risk class I patients (LEF, *n*=1; MOX, *n*=2) were enrolled in the LEAP 2 study; 1 PORT risk class II patient (MOX) was enrolled in the LEAP 1 study; and 3 PORT risk class V patients (LEF, *n*=1; MOX, *n*=2) were enrolled in the LEAP 2 study.

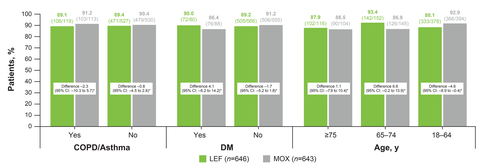
Efficacy in At-Risk Patients

- ECR rates in the ITT population were high and similar across the LEF and MOX treatment groups within the subgroups of patients with COPD/asthma, DM, and advanced age (**Figure 2A**)
  - Results in these subgroups were consistent with those seen in the overall pooled ITT population (LEF 89.3% [577/646] vs MOX 90.5% [582/643]; difference, –1.1; 95% CI, –4.4 to 2.2)
- IACR success rates at TOC in the mITT and CE populations were also high and similar across the LEF and MOX treatment groups within the subgroups of patients with COPD/asthma, DM, and advanced age (**Figure 2B and 2C**)

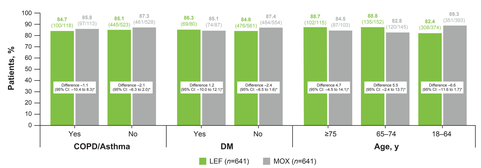
RESULTS (continued)

Figure 2. Pooled At-Risk Patients Meeting Criteria for Early Clinical Response (A) and Investigator Assessment of Clinical Response Rates (B–C)

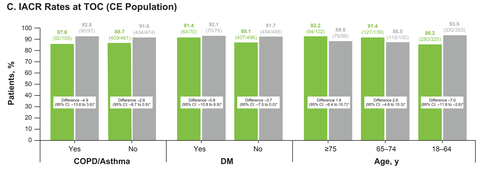
A. ECR Rates (ITT Population)



B. IACR Rates at TOC (mITT Population)



C. IACR Rates at TOC (CE Population)



CE=clinically evaluable; COPD=chronic obstructive pulmonary disease; DM=diabetes mellitus; ECR=early clinical response; IACR=investigator assessment of clinical response; ITT=intent to treat; LEF=lefamulin; mITT=modified ITT; MOX=moxifloxacin; TOC=test of cure.
*Weighted treatment difference and CI were computed using the method of Miettinen and Nurminen and adjusted for study, with the inverse variance of effect size as stratum weights.

Safety in At-Risk Patients

- Regardless of treatment group, the percentage of patients with severe TEAEs, serious TEAEs, and TEAEs leading to death increased with advancing age (**Table 2**)
- The most frequently reported TEAEs (≥2% in either treatment group) by age group were as follows:
  - 18–64 years: diarrhea (LEF, 8.8%; MOX, 4.6%), nausea (5.3%; 1.8%), vomiting (2.9%; 0.5%), headache (1.9%; 2.5%), and increased ALT (1.9%; 2.0%)
  - 65–74 years: diarrhea (LEF, 5.9%; MOX, 2.1%), nausea (2.0%; 3.4%), pneumonia (2.0%; 0.7%), hypertension (0.7%; 2.8%), and hypokalemia (0%; 2.1%)
  - ≥75 years: diarrhea (LEF, 4.3%; MOX, 3.9%), nausea (3.5%; 1.0%), vomiting (3.5%; 0%), urinary tract infection (2.6%; 4.9%), hypertension (2.6%; 1.9%), and insomnia (2.6%; 1.0%)
- In patients with a history of hypertension or arrhythmia and in patients aged ≥65 years, TEAEs in the system organ class (SOC) of cardiac disorders were reported at a similar and low incidence in both treatment groups (**Table 3**)
  - In each of the same subgroups, the percentages of patients who experienced an increase from baseline in the QT interval corrected according to Fridericia (QTcF) >60 msec or a QTcF value >500 msec were low and greater with MOX vs LEF
- In patients with baseline liver enzyme elevation and in patients aged ≥65 years, TEAEs in the SOC of hepatobiliary disorders were reported at a similar and low incidence in both treatment groups (**Table 4**)
  - In each subgroup, the percentages of patients who experienced liver enzyme elevations were low and similar with LEF and MOX treatment and resolved upon treatment discontinuation

Table 2. Summary of TEAEs by Age Group (Safety Analysis Set)

Patients, *n* (%)	LEF 18–64 y (*n*=374)	LEF 65–74 y (*n*=152)	LEF ≥75 y (*n*=115)	MOX 18–64 y (*n*=393)	MOX 65–74 y (*n*=145)	MOX ≥75 y (*n*=103)
All TEAEs*	143 (38.2)	34 (22.4)	47 (40.9)	115 (29.3)	46 (31.7)	34 (33.0)
Related TEAEs†	63 (16.8)	17 (11.2)	19 (16.5)	39 (9.9)	18 (12.4)	11 (10.7)
TEAEs by severity						
Mild	79 (21.1)	15 (9.9)	25 (21.7)	73 (18.6)	26 (17.9)	18 (17.5)
Moderate	53 (14.2)	13 (8.6)	12 (10.4)	32 (8.1)	16 (11.0)	7 (6.8)
Severe	11 (2.9)	6 (3.9)	10 (8.7)	10 (2.5)	4 (2.8)	9 (8.7)
Serious TEAEs	15 (4.0)	8 (5.3)	13 (11.3)	16 (4.1)	5 (3.4)	10 (9.7)
TEAEs leading to death	2 (0.5)	4 (2.6)	5 (4.3)	3 (0.8)	2 (1.4)	3 (2.9)

LEF=lefamulin; MOX=moxifloxacin; TEAE=treatment-emergent adverse event.
*A TEAE was defined as an adverse event that started or worsened at or during the time of or after the first study drug administration. An event with an unknown start date or partial date was categorized as a TEAE. Adverse events were coded according to the Medical Dictionary for Regulatory Activities, version 20.0.
†Defined as TEAEs that were considered "definitely," "probably," or "possibly" related to study drug by the investigator. TEAEs for which a relationship was missing were considered "related." Patients with multiple events in each category were counted only once in that category.

Table 3. Cardiac TEAEs and Postbaseline ECG Changes in Patients at Risk of Cardiac Safety Concerns

Patients with history of hypertension, *n* (%)	LEF (*n*=246)	MOX (*n*=252)
TEAEs in cardiac SOC*	8 (3.3)	8 (3.2)
TE-AESIs in QT prolongation category†	1 (0.4)	4 (1.6)
Patients with both baseline and postbaseline values of QTcF	(*n*=244)	(*n*=251)
Increase in QTcF	215 (88.1)	223 (88.8)
Increase >30 msec in QTcF	45 (18.4)	57 (22.7)
Increase >60 msec in QTcF	4 (1.6)	8 (3.2)
Value QTcF >480 msec	10 (4.1)	9 (3.6)
Value QTcF >500 msec	1 (0.4)	2 (0.8)
Baseline QTcF ≤480 msec and postbaseline QTcF >480 msec	9 (3.7)	7 (2.8)
Baseline QTcF ≤500 msec and postbaseline QTcF >500 msec	1 (0.4)	1 (0.4)
Patients with history of arrhythmia, *n* (%)	**LEF (*n*=42)**	**MOX (*n*=30)**
TEAEs in cardiac SOC‡	4 (9.5)	3 (10.0)
TE-AESIs in QT prolongation category†	2 (4.8)	1 (3.3)
Patients with both baseline and postbaseline values of QTcF	(*n*=42)	(*n*=30)
Increase in QTcF	36 (85.7)	22 (73.3)
Increase >30 msec in QTcF	10 (23.8)	8 (26.7)
Increase >60 msec in QTcF	1 (2.4)	3 (10.0)
Value QTcF >480 msec	2 (4.8)	3 (10.0)
Value QTcF >500 msec	0	1 (3.3)
Baseline QTcF ≤480 msec and postbaseline QTcF >480 msec	2 (4.8)	2 (6.7)
Baseline QTcF ≤500 msec and postbaseline QTcF >500 msec	0	0
Patients aged ≥65 y, *n* (%)	**LEF (*n*=267)**	**MOX (*n*=248)**
TEAEs in cardiac SOC§	3 (1.1)	3 (1.2)
Patients with both baseline and postbaseline values of QTcF	(*n*=266)	(*n*=247)
Increase in QTcF	234 (88.0)	218 (88.3)
Increase >30 msec in QTcF	52 (19.5)	49 (19.8)
Increase >60 msec in QTcF	4 (1.5)	7 (2.8)
Value QTcF >480 msec	11 (4.1)	14 (5.7)
Value QTcF >500 msec	1 (0.4)	6 (2.4)
Baseline QTcF ≤480 msec and postbaseline QTcF >480 msec	10 (3.8)	10 (4.0)
Baseline QTcF ≤500 msec and postbaseline QTcF >500 msec	1 (0.4)	4 (1.6)

ECG=electrocardiogram; LEF=lefamulin; MOX=moxifloxacin; QTcF=QT interval corrected according to Fridericia; SMQ=Standardized Medical Dictionary for Regulatory Activities query; SOC=system organ class; TEAE=treatment-emergent adverse event; TE-AESI=treatment-emergent adverse event of special interest.
*Specific preferred terms that occurred in >1 patient were myocardial infarction (LEF, *n*=2), acute myocardial infarction (MOX, *n*=2), and atrial fibrillation (MOX, *n*=3); all other cardiac TEAEs occurred in ≤1 patient per treatment group.
†Included broad SMQ search for "Torsades des Pointes/QT Prolongation."
‡Specific preferred term that occurred in >1 patient was atrial fibrillation (LEF, *n*=2); all other cardiac TEAEs occurred in ≤1 patient per treatment group.
§All cardiac TEAEs occurred in ≤1 patient per treatment group.

Table 4. Hepatobiliary TEAEs and Postbaseline Liver Enzyme Changes in Patients at Risk of Hepatic Safety Concerns

Patients with baseline liver enzyme elevation (AST or ALT >ULN)	LEF (*n*=119)	MOX (*n*=144)
TEAEs in hepatobiliary SOC,* *n* (%)	4 (3.4)	3 (2.1)
TE-AESIs in liver safety† *n* (%)	2 (1.7)	9 (6.3)
Any postbaseline value, *n/N* (%)		
ALT >3× ULN	2/36 (5.6)	5/34 (14.7)
ALT >5× ULN	1/36 (2.8)	1/34 (2.9)
ALT >10× ULN	0/36	0/34
AST >3× ULN	0/23	0/39
AST >5× ULN	0/23	0/39
AST >10× ULN	0/23	0/39
Total bilirubin value >2× ULN	1/102 (1.0)	1/124 (0.8)
ALT or AST >3× ULN and total bilirubin value >2× ULN	0/55	1/64 (1.6)
Patients aged ≥65 y	**LEF (*n*=267)**	**MOX (*n*=248)**
TEAEs in hepatobiliary SOC,* *n* (%)	2 (0.7)	1 (0.4)
Any postbaseline value, *n/N* (%)		
ALT >3× ULN	11/262 (4.2)	8/242 (3.3)
ALT >5× ULN	3/262 (1.1)	4/242 (1.7)
ALT >10× ULN	1/262 (0.4)	0/242
AST >3× ULN	6/262 (2.3)	4/242 (1.7)
AST >5× ULN	2/262 (0.8)	2/242 (0.8)
AST >10× ULN	1/262 (0.4)	0/242
Total bilirubin value >2× ULN	0/262	1/242 (0.4)
ALT or AST >3× ULN and total bilirubin value >2× ULN	0/262	1/242 (0.4)

ALT=alanine aminotransferase; AST=aspartate aminotransferase; LEF=lefamulin; MOX=moxifloxacin; SMQ=Standardized Medical Dictionary for Regulatory Activities query; SOC=system organ class; TEAE=treatment-emergent adverse event; TE-AESI=treatment-emergent adverse event of special interest; ULN=upper limit of normal.
*All hepatobiliary TEAEs occurred in ≤1 patient per treatment group.
†TE-AESIs in the liver safety SMQ included broad searches for "liver-related investigations, signs, symptoms" and "biliary-related investigations, signs, symptoms."

Other Findings From LEAP 1 and LEAP 2 Pooled Analyses

- Please refer to Posters 684 and 699 for cardiac and hepatobiliary safety results, respectively

CONCLUSIONS

- In pooled LEAP 1 and LEAP 2 analyses, patients at risk for poor efficacy outcomes due to age or comorbidity were well represented and efficacy with LEF was high and similar to that with MOX
- Likewise, high-risk patients are potentially at greater risk of adverse safety outcomes, but this pooled analysis suggests that the safety profile in these patients was comparable to that of the overall population
- LEF showed a favorable safety profile with a low frequency of transient transaminase elevations (similar to that seen with MOX) and fewer increases in QTcF >60 msec or QTcF values >500 msec than seen with MOX
- LEF is a promising new IV/oral monotherapy option for CABP in patients at risk of poor outcomes due to CABP or CABP antimicrobial therapy

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