Poster C-1

Long-term Follow-up of Patients With Carcinoid Syndrome Diarrhea Treated With Telotristat Ethyl: A Pooled Analysis of Phase 2 and 3 Trials

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Lowell B. Anthony,[1] Matthew H. Kulke,[2] Martyn E. Caplin,[3] Emily Bergsland,[4] Kjell Öberg,[5] Marianne Pavel,[6,7] Dieter Hörsch,[8] Thomas M. O'Dorisio,[9] Joseph S. Dillon,[9] Pablo Lapuerta,[10] Kenneth Kassler-Taub,[10] Wenjun Jiang[10]

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Abstract

Background: Carcinoid syndrome (CS) secondary to metastatic neuroendocrine tumors (NETs) is associated with increased morbidity and mortality. Tumoral serotonin secretion in CS can be associated with debilitating diarrhea, resulting in significant health risk and decreased quality of life. Telotristat ethyl (TE), a tryptophan hydroxylase inhibitor, has been shown in studies to be effective and well tolerated in the treatment of CS diarrhea, which is particularly important in a disease with median overall survival (OS) measured in years.

Methods: The treatment-emergent adverse events (TEAEs) reported during 5 Phase 2 (n = 2) and Phase 3 (n = 3) clinical trials of TE in patients with CS were pooled. OS was estimated based on a review of long-term safety data, including causes of hospitalization and death.

Results: Across the trials, 239 patients with CS were treated with at least 1 dose of TE (250 mg or 500 mg [mostly 500 mg]). The mean time from diagnosis to enrollment was 6 to 8 years. As of January 2018, the mean duration of exposure was 1.6 years (1 week to ~ 6.4 years). Among these patients, at least 1 TEAE and at least 1 serious TEAE were reported in 98% (n = 234) and 49% (n = 118) of patients, respectively. Depression-related TEAEs were all mild or moderate in intensity and generally did not limit treatment. The leading causes of hospitalization were gastrointestinal disorders and progression of underlying NETs. Survival estimates at 1, 2, and 3 years were 93%, 89%, and 80% out of 125, 96, and 39 patients at risk, respectively (25 deaths in the first 3 years of follow-up). Nearly all deaths were due to progression or complication of underlying disease, with none attributable to TE.

Conclusions: The pooled long-term safety data of 5 Phase 2 and 3 clinical trials show safety and survival results that support treatment of CS diarrhea with TE.

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Background

- Patients with NETs are at risk of developing carcinoid syndrome (CS), caused by the tumoral secretion of serotonin and other bioactive molecules, resulting in diarrhea, flushing, abdominal pain, bronchial constriction, and carcinoid heart disease.[1,2]
- Somatostatin analogs (SSAs) are the standard treatment for patients with CS, but patients may develop recurrent symptoms.[3,4]
- Telotristat ethyl (TE), a small-molecule tryptophan hydroxylase inhibitor, is approved in the United States and Europe for the treatment of adults with CS diarrhea inadequately controlled by SSA therapy.[5,6]
- This study assessed the long-term safety of CS patients treated with TE from 5 clinical trials (2 Phase 2, 2 Phase 3, and 1 long-term extension).

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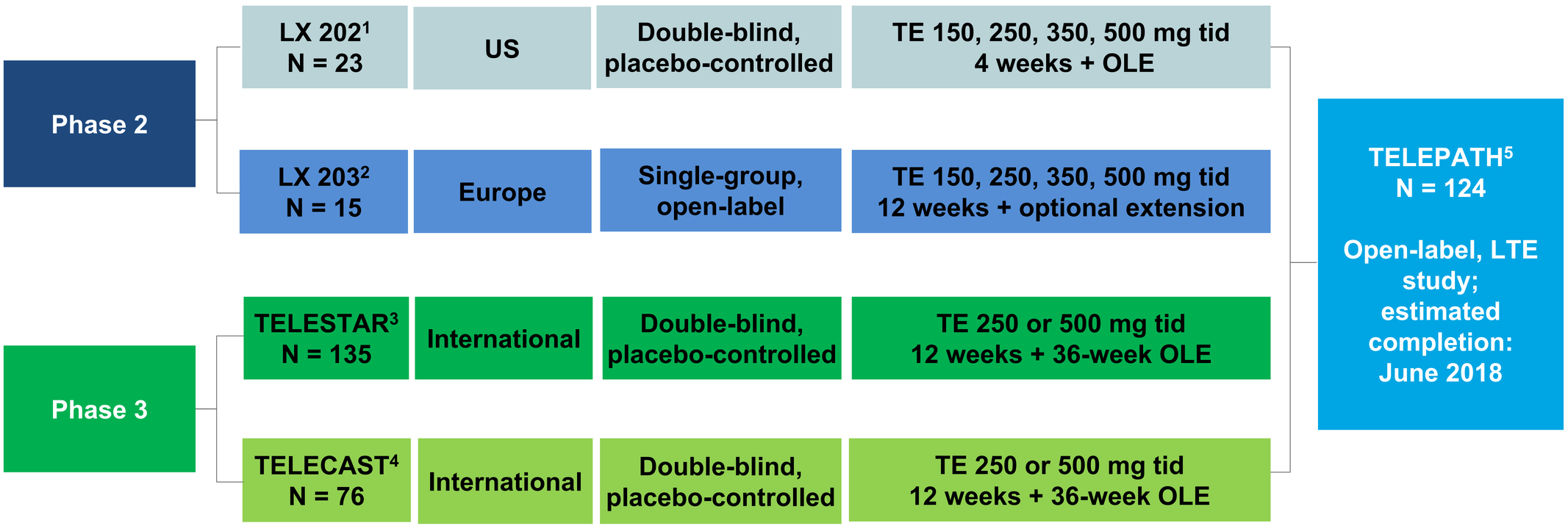
Abstract
Background
Methods
Results
Summary & Conclusions
Acknowledgments & Disclosures

Methods: Study Overview



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Abbreviations: TE, telotristat ethyl

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Abstract
Background
Methods
Results
Summary & Conclusions
Acknowledgments & Disclosures

Methods: Summary of Key Inclusion and Exclusion Criteria

Trial	Inclusion criteria	Exclusion criteria
LX 202[1]	• ≥4 BM/day	• KPS ≤70% • Previous use of TPH inhibitor
LX 203[2]	• ≥4 BM/day	• KPS ≤70%
TELESTAR[3]	• ≥4 BM/day • Receiving stable-dose SSAs	• KPS ≤60% • Previous treatment with TE
TELECAST[4]	• <4 BM/day if on SSAs • If not on SSAs, ≥1 sign or symptom of CS	• KPS ≤60%
TELEPATH[5]	• Ongoing participation in LX 202, LX 203, TELESTAR, or TELECAST	• Major protocol violation or safety concern from LX 202, LX 203, TELESTAR, or TELECAST

1. Clinicaltrials.gov. NCT00853047. Available at: https://clinicaltrials.gov/ct2/show/NCT00853047. Accessed July 31, 2018. 2. Clinicaltrials.gov. NCT01104415. Available at: https://clinicaltrials.gov/ct2/show/NCT01104415. Accessed July 31, 2018. 3. Clinicaltrials.gov. NCT01677910. Available at: https://clinicaltrials.gov/ct2/show/NCT01677910. Accessed July 31, 2018. 4. Clinicaltrials.gov. NCT02063659. Available at: https://clinicaltrials.gov/ct2/show/NCT02063659. Accessed July 31, 2018. 5. Clinicaltrials.gov. NCT02026063. Available at: https://clinicaltrials.gov/ct2/show/NCT02026063. Accessed July 31, 2018.

Abbreviations: TE, telotristat ethyl; TPH, tryptophan hydroxylase

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Poster C-1

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Abstract
Background
Methods
Results
Summary & Conclusions
Acknowledgments & Disclosures

Results : Summary of Patient Demographics and Selected CS-related Medical History

Patient characteristics	N = 239
Mean age, years (SD)	63.0 (9.9)
Median age, years (range)	64 (35 – 88)
Male, n (%)	126 (52.7)
Medical history, n (%)[a]	
Carcinoid heart disease[b]	65 (27)
Anemia	36 (15)
Fatigue	70 (29)
Weight decreased	27 (11)
Ascites	8 (3)
Cachexia	5 (2)
Dehydration	4 (2)
Malnutrition	3 (1)
Total[c]	126 (53)

[a]Terms as reported by investigators. [b]Includes the preferred terms tricuspid valve incompetence, mitral valve incompetence, carcinoid heart disease, tricuspid valve replacement, carcinoid syndrome, aortic valve incompetence, pulmonary valve incompetence, pulmonary valve replacement, heart valve incompetence, heart valve replacement, tricuspid valve disease, cardiac valve disease, aortic valve disease, aortic valve stenosis, tricuspid valve stenosis, and mitral valve repair. [c]Some patients had > 1 of the conditions listed.

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Abstract
Background
Methods
Results
Summary & Conclusions
Acknowledgments & Disclosures

Results: Serious[a] Treatment Emergent Adverse Events Experienced by ≥5% of Patients by System Organ Class in the Pooled Analysis

System organ class, preferred term, n (%)	US study n = 22	European study n = 15	TELESTAR n = 128	TELECAST n = 74	Total N = 239[b]
At least 1 serious TEAE	9 (40.9)	8 (53.3)	68 (53.1)	33 (44.6)	**118 (49.4)**
Gastrointestinal disorders	3 (13.6)	5 (33.3)	27 (21.1)	13 (17.6)	**48 (20.1)**
Abdominal pain	0	1 (6.7)	12 (9.4)	2 (2.7)	**15 (6.3)**
Neoplasms benign, malignant, and unspecified (including cysts and polyps)[c]	3 (13.6)	1 (6.7)	14 (10.9)	9 (12.2)	**27 (11.3)**
General disorders and administration site conditions[d]	1 (4.5)	1 (6.7)	15 (11.7)	8 (10.8)	**25 (10.5)**
Disease progression	1 (4.5)	0	10 (7.8)	1 (1.4)	**12 (5.0)**
Infections and infestations	0	2 (13.3)	12 (9.4)	6 (8.1)	**20 (8.4)**
Nervous system disorders	1 (4.5)	2 (13.3)	10 (7.8)	7 (9.5)	**20 (8.4)**
Surgical and medical procedures[e]	2 (9.1)	2 (13.3)	8 (6.3)	6 (8.1)	**18 (7.5)**
Investigations[f]	0	2 (13.3)	10 (7.8)	3 (4.1)	**15 (6.3)**
Cardiac disorders	2 (9.1)	1 (6.7)	7 (5.5)	2 (2.7)	**12 (5.0)**

[a]Leading to hospitalization and/or death. [b]Safety population. [c]Includes preferred terms related to tumor progression. [d]Includes the preferred terms disease progression, general physical health deterioration, pyrexia, death, asthenia, complication of device insertion, fatigue, multi-organ failure, and pain. [e]Includes the preferred terms related to planned antitumor therapies. [f]Includes the preferred terms investigation, blood creatinine increased, blood potassium decreased, cholangiogram, diagnostic procedure, general physical condition.

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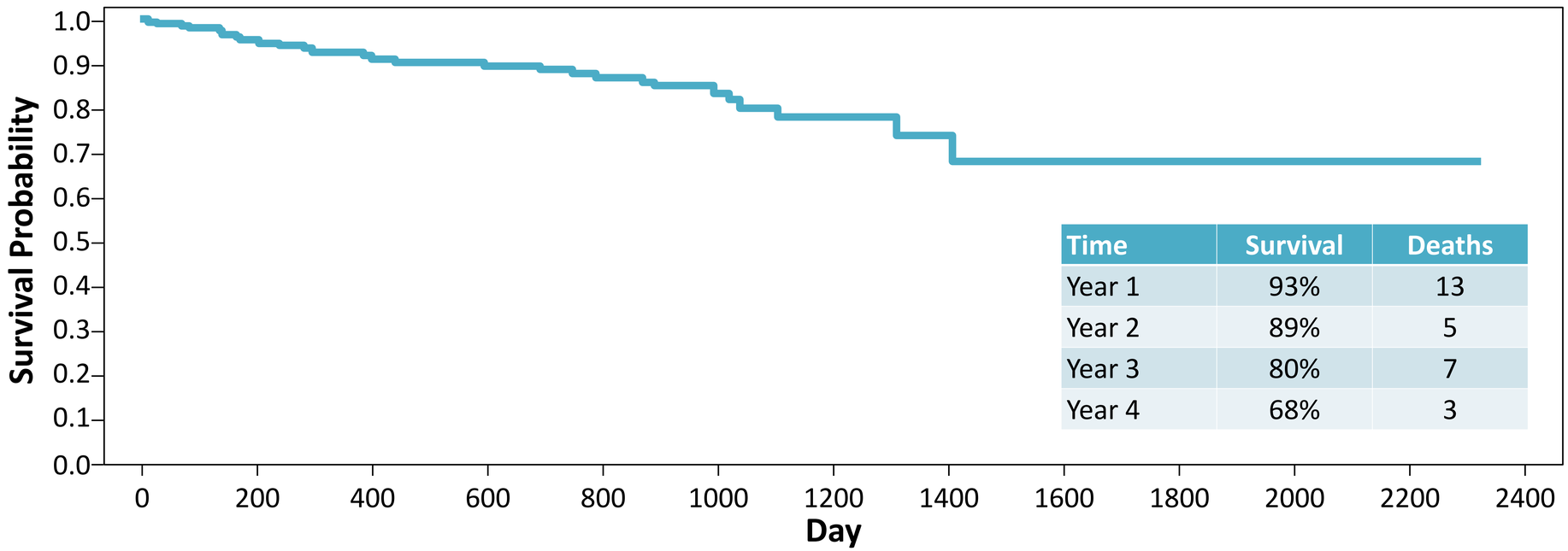
Results: Kaplan-Meier Survival Curve for Patients Treated With TE in 5 Clinical Studies



Time	Survival	Deaths
Year 1	93%	13
Year 2	89%	5
Year 3	80%	7
Year 4	68%	3

[a]Number at risk includes only patients who received treatment with telotristat ethyl, shown according to duration of treatment.

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Abstract
Background
Methods
Results
Summary & Conclusions
Acknowledgments & Disclosures

Summary and Conclusions

- Review of long-term safety data shows that the safety profile of TE supports treatment of CS diarrhea with TE.
- Total exposure is over 385 patient-years and supports the long-term administration of TE in patients with CS in combination with SSAs.
- The number of and types of deaths observed were consistent with expectations for this patient population with metastatic NETs.
  - Nearly all deaths were attributable to progression of or complications related to the underlying tumor and associated CS symptoms.
- TPH inhibition with TE combined with SSA therapy represents a suitable treatment approach for patients with CS diarrhea.

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Abstract
Background
Methods
Results
Summary & Conclusions
Acknowledgments & Disclosures

Acknowledgments and Disclosures

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Disclosures

LBA: Lexicon Pharmaceuticals, Inc. (RF, H)

MHK: Lexicon Pharmaceuticals, Inc. (C/A), Ipsen Pharmaceuticals (C/A), Novartis Pharmaceuticals (C/A)

MEC: Lexicon Pharmaceuticals, Inc. (C/A, RF, H), Novartis Pharmaceuticals (C/A, RF, H), Ipsen Pharmaceuticals (C/A, RF, H)

EB: UpToDate (IP), Novartis Pharmaceuticals (RF), Lexicon Pharmaceuticals, Inc. (C/A), Ipsen Pharmaceuticals (C/A)

KO: Novartis Pharmaceuticals (RF), Ipsen Pharmaceuticals (H)

MP: Novartis Pharmaceuticals (RF, H), Ipsen Pharmaceuticals (RF, H), Lexicon Pharmaceuticals, Inc. (H), Pfizer, Inc (H)

DH: Lexicon Pharmaceuticals, Inc. (C/A), Ipsen Pharmaceuticals (RF, C/A)

TMO: none

JSD: Lexicon Pharmaceuticals, Inc. (RF)

PL, KK-T, and WJ: employees of Lexicon Pharmaceuticals, Inc.

Abbreviations: C/A, consultancy agreement; IP, intellectual property rights/inventor/patent holder; H, honoraria received; RF, research funding.

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