A Multicenter, Long-term Extension Study to Further Evaluate the Safety and Tolerability of Telotristat Etiprate (LX1606)

Published: 30-06-2014
Last updated: 21-04-2024

The primary objective of this study is to evaluate the long-term safety and tolerability of orally administered telotristat etiprate.The secondary objective is to evaluate changes in patients* quality of life (QOL) through week 84.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON44470

Source
ToetsingOnline

Brief title
LX1606-302 TELEPATH

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Carcinoid tumor; Carcinoid syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Lexicon Pharmaceuticals Inc.

Source(s) of monetary or material Support: Industry

Intervention

Keyword: LX1606-302, Phase 3, TELEPATH, Telotristat etiprate

Outcome measures

Primary outcome

The primary efficacy endpoint is to evaluate the long-term safety and tolerability of orally administered telotristat etiprate.

Safety

Safety assessments include monitoring of adverse events, clinical laboratory tests, vital signs measurements, 12-lead ECG, and physical examinations.

Efficacy

Efficacy assessments will include patient reported quality of life measures as captured in the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire QLQ-C30 and the module specific for gastrointestinal symptoms of carcinoid neuroendocrine tumors (GI.NET21) and subjective global assessment of symptoms associated with CS

Pharmacodynamics

Pharmacodynamic (PD) assessments include determination of 5-HIAA levels in plasma.

Secondary outcome

Secondary efficacy endpoint is to evaluate changes in patients* QOL over 84

weeks of therapy.

Study description

Background summary

Currently, the standard of care for patients with CS is symptom management using somatostatin analogs (SSA). As a result of the morbidity associated with SSAs and the associated tachyphylaxis, there is an unmet medical need to provide symptom management and modify the pathophysiology of patients with metastatic CS. Telotristat etiprate is being developed to manage GI symptoms and possibly other symptoms associated with CS. It could provide significant benefit as an additional treatment option.
This study will allow for continued access to telotristat etiprate after patients have completed the required study visits in ongoing Phase 2 and Phase 3 studies. Continuation of CS patients into this study will allow for the collection of additional long-term safety and efficacy data.

Study objective

The primary objective of this study is to evaluate the long-term safety and tolerability of orally administered telotristat etiprate.
The secondary objective is to evaluate changes in patients* quality of life (QOL) through week 84.

Study design

The study will be conducted as a multicenter, open-label, long-term extension study to further evaluate long-term safety and tolerability of telotristat etiprate.
Patients currently participating in any LX1606 Phase 2 carcinoid syndrome (CS) study may enter into this extension study upon institutional or local approval of the protocol. Patients participating in a Phase 3 CS study may enter into this extension study at the Week 48 visit. All patients who enter into this extension study will be exempt from any follow-up visit required by the original study and will not experience an interruption in study drug due to the transition from the original study to LX1060.1-302-CS.
Following confirmation of eligibility, patients will complete a series of visit assessments in order to establish Baseline symptoms. Patients will then continue on open-label study drug at the same dose level and regimen as identified in their original study.
Downward dose adjustment will be permitted during the study if evidence of intolerability emerges. Patients who experience intolerability at the 250 mg tid dose level must be discontinued from the study. Patients may return to the

previous dosing at the discretion of the Investigator and in consultation with the Medical Monitor.
Upon completion or early withdrawal from treatment, all patients will be required to complete a 14-day Follow-up Period, during which no study drug will be administered.
'All patients will participate in the Treatment Period until such time telotristat etiprate has received regulatory approval to be marketed and is available via prescription or 30 June 2018, whichever occurs first. Based upon the expected dates for eligible patients* entry into this study, overall duration of participation will last up to 235 weeks including the Treatment Period and Follow-up Period.

Intervention

Investigational product: Telotristat etiprate tablets

Doses: 250 mg (1 x 250 mg) tid or 500 mg (2 x 250 mg) tid

Mode of administration: oral

Study burden and risks

The patient population concerned in this study is patients with carcinoid syndrome who are no longer responding to standard Somatostatin Analog (SSA-currently approved hormone therapy). Telotristat etiprate has the potential to improve several signs and symptoms of CS. The Phase 2 clinical trial results indicated that treatment may lead to improvements in BM frequency, stool consistency, urgency, abdominal pain, diarrhea, flushing, and reductions in 5-HIAA. These potential benefits relate to a unique mechanism of action. Symptomatic improvement may lead to a better quality of life (QOL) for patients with few treatment options available, and a reduction in serotonin may help reduce the risk of carcinoid heart disease. Overall the benefit/risk profile of telotristat etiprate is expected to be favorable for participation in this clinical study.

Contacts

Public
Lexicon Pharmaceuticals Inc.

Technology Forest Place 8800
The Woodlands TX 77381
US
Scientific

Lexicon Pharmaceuticals Inc.

Technology Forest Place 8800
The Woodlands TX 77381
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients must meet all of the following criteria to be considered eligible to participate in the study:;1. Ongoing participation in a Phase 2 study (eg, LX1606.1-202-CS, LX1606.1-203-CS) or Phase 3 study (eg, LX1606.1-301-CS, LX1606.1-303-CS). ;2. Patients of childbearing potential must agree to use an adequate method of contraception (defined as having a failure rate of <1% per year) during the study and for 12 weeks after the Follow-up visit. Adequate methods of contraception for patients or partner include condoms with spermicide gel, diaphragm with spermicide gel, coil (intrauterine device), surgical sterilization, vasectomy, oral contraceptive pill, depot progesterone injections, progesterone implant, and abstinence during the study and for 12 weeks after the Follow-up Visit.;a. Childbearing potential is defined as those who have not undergone surgical sterilization, or those who are not considered postmenopausal. Postmenopause is defined as absence of menstruation for at least 2 years. If necessary, follicle-stimulating hormone (FSH) results >50 IU/L at Baseline day 1 are confirmatory in the absence of a clear postmenopausal history.;3. Ability and willingness to provide written informed consent prior to participation in any study-related procedure

Exclusion criteria

Patients who meet any of the following criteria will be excluded from participating in the study: ;1. Major protocol violations in regard to dosing compliance or telotristat etiprate tolerability concerns in a Phase 2 study (eg, LX1606.1-202-CS, LX1606.1-203-CS) or Phase 3

study (eg, LX1606.1-301-CS, LX1606.1-303-CS).;2. Positive pregnancy test;3. Presence of any clinically significant findings at entry for medical history, laboratory values, or physical examination (relative to patient population) that, in the Investigator*s or Medical Monitor*s opinion, would compromise patient safety or the outcome of the study;4. Patients who are currently committed to an institution by virtue of an order issued either by judicial or administrative authorities

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-05-2015
Enrollment:	9
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Telotristat etiprate
Generic name:	Telotristat etiprate

Ethics review

Approved WMO

Date:	30-06-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Approved WMO Date:	15-04-2015
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	09-06-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-06-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	16-12-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	17-12-2015
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	30-03-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	05-04-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	23-09-2016
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	14-06-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO	

Date:	23-06-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	12-09-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	24-09-2017
Application type:	Amendment
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2013-002596-18-NL
ClinicalTrials.gov	NCT02026063
CCMO	NL49418.015.14