An Uncontrolled, Open-Label Extension Study to Evaluate the Long-Term Safety, Tolerability, and Maintenance of Effect of BIIB074 in Subjects WithNeuropathic Pain From Lumbosacral Radiculopathy

Published: 07-12-2016
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The primary objective of the study is to evaluate the long-term safety and tolerability of BIIB074 in subjects with neuropathic PLSR.

Ethical review	Not approved
Status	Will not start
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON42982

Source
ToetsingOnline

Brief title
Open-Label study to evaluate long-term effects of BIIB074 from PLSR

Condition

- Spinal cord and nerve root disorders

Synonym
Hernia, Pain From Lumbosacral Radiculopathy (PLSR)

Research involving
Human

Sponsors and support

Primary sponsor: Convergence Pharmaceuticals Ltd., a Biogen company
Source(s) of monetary or material Support: Convergence Pharmaceuticals Ltd (een Biogen dochter) is sponsor van het onderzoek

Intervention

Keyword: Leg pain NRS, Lumbosacral radiculopathy, Neuropathic pain, Sodium channel blocker

Outcome measures

Primary outcome

The primary endpoints that relate to this objective are as follows:

* Adverse events and serious adverse events

* Vital signs

* Electrocardiogram parameters

* Laboratory safety tests

* Columbia-Suicide Severity Rating Scale

Secondary outcome

Secondary objectives and endpoints are as follows:

To investigate the maintenance of effect during long-term treatment with

BIIB074 in subjects with neuropathic PLSR.

For all efficacy assessments, Baseline will be the 1-week period prior to

randomization (at Day 15, Week 2) into Study 1014802-203.

* Efficacy endpoints in neuropathic pain:

* Change from Baseline to Week 52 in the weekly average of the daily

neuropathicpain* score on the 11-point Pain IntensityNumerical Rating Scale; subjects will be asked every evening to rate their overall neuropathic pain for the last 24-hour period.

*Neuropathic pain will be evaluated in the worse affected leg, as identified on Day 1 of Study 1014802-203

* 50% neuropathic pain reduction response (yes/no) at Week 52, where a response is defined as a *50% reduction in the weekly average of the daily neuropathic pain score from Baseline to Week 52

* 30% neuropathic pain reduction response (yes/no) at Week 52, where a response is defined as a *30% reduction in the weeklyaverage of the daily neuropathic pain score from Baseline to Week 52

* Changes from Baseline in the weekly average of the daily neuropathic pain score at each visit

* Efficacy endpoint in low back pain:

* Change from Baseline to Week 52 in the weekly average of the daily pain score for low back pain; subjects will be asked everyevening to rate their overall low back pain for the last 24-hour period

To evaluate the impact of treatment with BIIB074 on quality of life

* Patient Global Impression of Change responder (yes/no) at Week 52, where a responder is defined as either *much improved* or *very much improved*

* Change from Baseline to Week 52 on the Oswestry Disability Index

* Change from Baseline to Week 52 in the weekly average of the daily sleep

score; subjects will be asked every morning to rate on the 11-point

Sleep Numerical Rating Scale how leg pain interfered with their sleep quality

* Change from Baseline to Week 52 in the Brief Pain Inventory (BPI) *

Interference index

* Change from Baseline (Week 2) to Week 52 inthe BPI * Pain index

* Change from Baseline to Week 52 on theEuroQoL 5-Dimension 5-Level

Questionnairehealth index

* Change from Baseline to Week 52 in the Short Form 36 Questionnaire

Study description

Background summary

BIIB074 is a potent, state-dependent, sodium channel blocker with selectivity for the voltage-gated sodium 1.7 subtype, and based on nonclinical and clinical data, it is hypothesized to be an effective treatment for neuropathicpain, with a potentially better tolerability profile and a wider therapeutic index than currently available treatments. This study will evaluate the long-term safety and tolerability, and the maintenance of effect of BIIB074 in subjects with PLSR who have completed Study 1014802-203; PLSR is an area of high unmet medical need, with no treatments currently indicated specifically for this type of neuropathic pain and with other pain medications, including opiates, being used with limited efficacy and poor tolerability.

Study objective

The primary objective of the study is to evaluate the long-term safety and tolerability of BIIB074 in subjects with neuropathic PLSR.

Study design

Uncontrolled, open-label extension study

Intervention

Subjects will receive an initial dose regimen of 350 mg twice daily (BID) of BIIB074, which may be reduced to 200 mg BID based on tolerability.

Study burden and risks

Based on clinical and nonclinical data, dose regimens of 200 and 350 mg BID are expected to not pose an unacceptable safety risk to subjects with PLSR.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Is able to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use confidential health information in accordance with national and local subject privacy regulations.
2. Has completed Study 1014802-203 through the Week 14 (Day 99) visit. Subjects who discontinued double-blind study treatment but continued to return for study visits through Week 14 (Day 99) and document their pain scores are eligible unless there are safety concerns.

Exclusion criteria

1. Had a major protocol deviation regarding inclusion or exclusion criteria for the doubleblind Phase 2b study (Study 1014802-203).
2. Had a treatment-related AE or SAE that would pose an increased risk for continued treatment with BIIB074, or discontinued study treatment in the double-blind Phase 2b study (Study 1014802-203) due to an AE or SAE.
3. Did not return for study visits through Week 14 (Day 99) after discontinuing treatment in the double-blind phase of the Phase 2b study.
4. Is unable to enroll in the 1014802-204 Study on the 1014802-203 Week 14 (Day 99) visit.
5. Other unspecified reasons that, in the opinion of the Investigator or Convergence Pharmaceuticals, make the subject unsuitable for enrollment.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	28
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	nog niet bepaald
Generic name:	Raxatrigine (voorgesteld)

Ethics review

Approved WMO Date:	07-12-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Not approved Date:	10-04-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2015-004796-68-NL
CCMO	NL59147.091.16