An Open-Label Study to Investigate the Safety and Efficacy of Rotigotine Add-On Therapy With Low Doses of Pramipexole or Ropinirole in Patients With Advanced Parkinson's Disease Phase 3B

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Study | Finalised

Administrative details

EU PAS number

EUPAS4714

Study ID

6157

DARWIN EU® study

No

Study countries

Australia

Korea, Republic of

Malaysia

Singapore

Taiwan

Study description

This study is to investigate the safety and efficacy of Rotigotine add-on therapy with low doses of Pramipexole or Ropinirole in patients with advanced-stage Parkinson's Disease (PD) who have insufficient response to L-dopa and low doses dopamine receptor agonists.

Study status

Finalised

Research institutions and networks

Institutions

401, Sydney, Australia

402, Chatswood, New South Wales, Australia

404, Darlinghurst, New South Wales, Australia

403, Melbourne, Victoria, Australia

104, 112, 109, 111, Busan, Busan, Daegu, Gyeonggi-Do; Korea, Republic of

110, 101, 102, 103, 105, 107, 108, 106, Seoul; Korea, Republic of

202, 204, 201, Kuala Terengganu, Kuching

Sarawak, Pulau Pinang; Malaysia

501, 502, Singapore; Singapore

302, 303, 306, Taichung, Tainan, Taipei; Taiwan

Contact details

Study institution contact

Clinical Trial Registries and Results Disclosure UCB BIOSCIENCES GmbH clinicaltrials@ucb.com

Study contact

clinicaltrials@ucb.com

Primary lead investigator

Clinical Trial Registries and Results Disclosure UCB BIOSCIENCES GmbH

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/06/2012

Study start date

Actual: 19/10/2012

Date of final study report
Planned: 30/11/2013

Actual: 13/12/2013

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

UCB BIOSCIENCES GmbH, Otsuka Pharmaceutical Co., Ltd.

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Clinical trial

If ‘other’, further details on the scope of the study

Safety/Efficacy

Main study objective:

To investigate the safety and efficacy of rotigotine add-on therapy with low doses of pramipexole or ropinirole in patients with advanced-stage Parkinson’s disease (PD) who have insufficient response to L-dopa and low doses dopamine receptor agonists.

Study Design

Clinical trial regulatory scope

Pre-authorisation clinical trial

Clinical trial phase

Therapeutic confirmatory (Phase III)

Clinical trial types

Single-arm trial

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N04BC09) rotigotine

rotigotine

Additional medical condition(s)

Advanced Parkinson’s Disease

Population studied

Short description of the study population

Patients with advanced-stage Advanced Parkinson's Disease who have insufficient response to L-dopa and low doses dopamine receptor agonists

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Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with advanced-stage Parkinson’s Disease (PD)

Estimated number of subjects

90

Study design details

Outcomes

Clinical Global Impression Item 4 at the end of Treatment PeriodChange from Baseline to end of Treatment Period in the Unified Parkinson's Disease Rating Scale (UPDRS) Part III ("on" state) total scoreChange from Baseline to end of Treatment Period in the UPDRS Part II (average of "on" and "off" state) total scoreChange from Baseline to end of Treatment Period in absolute time spent "off", Change from Baseline to end of Treatment Period in time spent "on" without troublesome DyskinesiaChange from Baseline to end of Treatment Period in Parkinson's Disease Sleep Scale 2 (PDSS-2) total scoreChange from Baseline to end of Treatment Period in the Pittsburgh Sleep Quality Index (PSQI) global score

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Data analysis plan

Descriptive statistics to evaluate the safety of rotigotine add-on therapy with low doses of pramipexole or ropinirole.

Documents

Study results

pd0015-synopsis-28-feb-2014_Redacted.pdf (663.08 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency

but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No