# Clinical trial results:
# A Multi-Center, Open-Label Study Evaluating the Safety, Tolerability, and Efficacy of Pridopidine in Patients with Huntington's Disease (Open PRIDE-HD) (Open PRIdopidine Dose Evaluation in Huntington's Disease)

## Summary

| | |
|---|---|
| EudraCT number | 2015-000904-24 |
| Trial protocol | DE GB AT NL IT |
| Global end of trial date | 12 January 2018 |

**Results information**

| | |
|---|---|
| Result version number | v1 |
| This version publication date | 11 March 2021 |
| First version publication date | 11 March 2021 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | TV7820-CNS-20016 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02494778 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Prilenia Neurotherapeutics Ltd. |
| Sponsor organisation address | Hamenofim 10, Herzliya, Israel, 4672561 |
| Public contact | Michal Geva, Prilenia Neurotherapeutics Ltd., clinicaltrialseu@prilenia.com |
| Scientific contact | Michal Geva, Prilenia Neurotherapeutics Ltd., clinicaltrialseu@prilenia.com |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 10 July 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 12 January 2018 |
| Global end of trial reached? | Yes |
| Global end of trial date | 12 January 2018 |
| Was the trial ended prematurely? | Yes |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate safety and tolerability of pridopidine in patients with Huntington's Disease (HD).

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator:

No comparison drug was used in this open-label study.

| | |
|---|---|
| Actual start date of recruitment | 24 September 2015 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Netherlands: 9 |
| Country: Number of subjects enrolled | Poland: 28 |
| Country: Number of subjects enrolled | United Kingdom: 28 |
| Country: Number of subjects enrolled | Austria: 18 |
| Country: Number of subjects enrolled | France: 18 |
| Country: Number of subjects enrolled | Germany: 32 |
| Country: Number of subjects enrolled | Italy: 34 |
| Country: Number of subjects enrolled | Australia: 9 |
| Country: Number of subjects enrolled | Canada: 4 |
| Country: Number of subjects enrolled | Russian Federation: 34 |
| Country: Number of subjects enrolled | United States: 34 |
| Worldwide total number of subjects | 248 |
| EEA total number of subjects | 167 |

Notes:

### Subjects enrolled per age group

| | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |

| | |
|---|---|
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 215 |
| From 65 to 84 years | 33 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

248 patients, ≥21 years of age, with a body weight of ≥50 kg, with a diagnosis of HD who completed the double-blind, randomized phase in PRIDE-HD study, including the follow-up period, or who participated in the open-label ACR16C015 (Open-HART) extension study, were scheduled to be included in this study.

### Pre-assignment

Screening details:

The study consisted of a screening period/baseline visit of up to 2 weeks.

### Period 1

| | |
|---|---|
| Period 1 title | Overall trial (78 weeks) (overall period) |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Blinding implementation details:

This was an open-label study with no blinding.

### Arms

| | |
|---|---|
| **Arm title** | Pridopidine 45 mg bid |

Arm description:

Pridopidine (45 mg) was administered as oral capsules, taken twice daily (bid).

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Pridopidine |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule, hard |
| Routes of administration | Oral use |

Dosage and administration details:

Pridopidine (45 mg) was administered as oral capsules, taken twice a day (bid).

| **Number of subjects in period 1** | Pridopidine 45 mg bid |
|---|---|
| Started | 248 |
| Completed | 27 |
| Not completed | 221 |
| Consent withdrawn by subject | 20 |
| Adverse event, non-fatal | 18 |
| Death | 3 |
| Other | 173 |
| Noncompliance with study drug administration | 1 |
| Lost to follow-up | 2 |
| Lack of efficacy | 4 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Overall trial (78 weeks) |

Reporting group description: -

| Reporting group values | Overall trial (78 weeks) | Total | |
|---|---|---|---|
| Number of subjects | 248 | 248 | |
| Age categorical<br>Units: Subjects | | | |
| Adults (18-64 years) | 215 | 215 | |
| From 65-84 years | 33 | 33 | |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 50.6 | | |
| standard deviation | ± 11.61 | - | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 129 | 129 | |
| Male | 119 | 119 | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Pridopidine 45 mg bid |

Reporting group description:

Pridopidine (45 mg) was administered as oral capsules, taken twice daily (bid).

### Primary: Percentage of Participants With Adverse Events

| | |
|---|---|
| End point title | Percentage of Participants With Adverse Events[1] |

End point description:

| | |
|---|---|
| End point type | Primary |

End point timeframe:

78 weeks

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This was a single-arm, uncontrolled Trial, with safety defined as the primary objective. The primary endpoint was analysed using descriptive statistics only. No inferential testing was applied. A p-value was not defined.

| End point values | Pridopidine 45 mg bid | | | |
|---|---|---|---|---|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 248 | | | |
| Units: Patients | 193 | | | |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

| Adverse events information | |
|---|---|
| Timeframe for reporting adverse events: 78 weeks | |
| Assessment type | Non-systematic |

| Dictionary used | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 17.0 |

| Reporting groups | |
|---|---|
| Reporting group title | Pridopidine 45 mg bid |

Reporting group description: -

| Serious adverse events | Pridopidine 45 mg bid | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 31 / 248 (12.50%) | | |
| number of deaths (all causes) | 3 | | |
| number of deaths resulting from adverse events | 3 | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Malignant melanoma in situ | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Prostate cancer | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Squamous cell carcinoma | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Death | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 1 / 1 | | |
| Gait disturbance | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Pneumonia aspiration | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pulmonary embolism | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Psychiatric disorders | | | |
| Suicidal ideation | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 3 / 248 (1.21%) | | |
| occurrences causally related to treatment / all | 2 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Depression | | | |
| alternative assessment type: Systematic | | | |

| | | | | |
|---|---|---|---|---|
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Hallucination, auditory | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Paranoia | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Investigations | | | | |
| Weight decreased | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Injury, poisoning and procedural complications | | | | |
| Fall | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 4 / 248 (1.61%) | | | |
| occurrences causally related to treatment / all | 0 / 4 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subdural haematoma | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 2 / 248 (0.81%) | | | |
| occurrences causally related to treatment / all | 0 / 2 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Ankle fracture | | | | |
| alternative assessment type: Systematic | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Brain contusion | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Contusion | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Craniocerebral injury | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Extradural haematoma | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Facial bones fracture | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Head injury | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |

| | | | | |
|---|---|---|---|---|
| Skull fracture | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Skull fractured base | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Tibia fracture | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Toxicity to various agents | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Congenital, familial and genetic disorders | | | | |
| Huntington’s disease | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Nervous system disorders | | | | |
| Chorea | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 3 / 248 (1.21%) | | | |
| occurrences causally related to treatment / all | 0 / 3 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Dystonia | | | | |

| | | | | |
|---|---|---|---|---|
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Haemorrhage intracranial | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Peripheral nerve palsy | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Subarachnoid haemorrhage | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Syncope | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 1 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Transient ischaemic attack | | | | |
| alternative assessment type: Systematic | | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | | |
| occurrences causally related to treatment / all | 0 / 1 | | | |
| deaths causally related to treatment / all | 0 / 0 | | | |
| Blood and lymphatic system disorders | | | | |
| Anaemia | | | | |
| alternative assessment type: Systematic | | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 1 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |
| Gastrointestinal disorders | | | |
| Dysphagia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Gastrointestinal polyp haemorrhage | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Hepatobiliary disorders | | | |
| Drug-induced liver injury | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Musculoskeletal pain | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Pain in extremity | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Infections and infestations | | | |
| Pneumonia | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 2 / 248 (0.81%) | | |
| occurrences causally related to treatment / all | 0 / 3 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Diverticulitis | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urinary tract infection | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Urosepsis | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| Metabolism and nutrition disorders | | | |
| Cachexia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 1 / 248 (0.40%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |

Frequency threshold for reporting non-serious adverse events: 5 %

| **Non-serious adverse events** | Pridopidine 45 mg bid | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 191 / 248 (77.02%) | | |
| Investigations | | | |
| Weight decreased | | | |
| alternative assessment type: Systematic | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 13 / 248 (5.24%) | | |
| occurrences (all) | 13 | | |
| Injury, poisoning and procedural complications | | | |
| Fall | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 74 / 248 (29.84%) | | |
| occurrences (all) | 163 | | |
| Contusion | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 13 / 248 (5.24%) | | |
| occurrences (all) | 20 | | |
| Nervous system disorders | | | |
| Chorea | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 23 / 248 (9.27%) | | |
| occurrences (all) | 30 | | |
| Headache | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 14 / 248 (5.65%) | | |
| occurrences (all) | 19 | | |
| Psychiatric disorders | | | |
| Insomnia | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 20 / 248 (8.06%) | | |
| occurrences (all) | 27 | | |
| Anxiety | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 16 / 248 (6.45%) | | |
| occurrences (all) | 17 | | |
| Musculoskeletal and connective tissue disorders | | | |
| Back pain | | | |
| alternative assessment type: Systematic | | | |
| subjects affected / exposed | 14 / 248 (5.65%) | | |
| occurrences (all) | 15 | | |
| Infections and infestations | | | |

| | | | |
|---|---|---|---|
| Nasopharyngitis<br>alternative assessment type: Systematic<br>subjects affected / exposed<br>occurrences (all) | 29 / 248 (11.69%)<br>36 | | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 30 June 2015 | Amendment 1 to the protocol was issued before any patients were enrolled into the study. Following the voluntary harmonization procedure protocol assessment, the primary reasons for this amendment were to limit the duration of treatment with study drug to 52 weeks and to clarify the use of permitted medications and prohibited tricyclic antidepressants.<br>The following major procedural changes were made to the protocol:<br>• Treatment with study drug was limited to 52 weeks.<br>• Butriptyline and mianserin were removed from the list of allowed antidepressants, and trimipramine and mirtazapine were removed to clarify the use of the permitted medications and prohibited tricyclic and tetracyclic antidepressants.<br>• Clarification of the assessment time points following the limitation of the study drug treatment duration to 52 weeks. |
| 31 March 2016 | Amendment 2 to the protocol was issued after 94 patients were enrolled into the study. Changes to the protocol were considered to have no negative impact on the safety of patients already enrolled into the study. The primary reason for this global amendment was to implement the following major procedural changes made to the protocol:<br>• The 2 telephone calls for safety evaluation at weeks 18 and 38 were added, including C-SSRS and an abbreviated PBA-s assessment.<br>• The treatment duration in the study was extended by an additional period of 52 weeks (for a total of 104 weeks).<br>• Q-Motor assessments were added to the protocol as an efficacy measure.<br>• Suicidal thoughts and ideations were defined as protocol-defined adverse events for expedited reporting. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? Yes

| Date | Interruption | Restart date |
|---|---|---|
| 10 November 2017 | This was an open-label extension of study TV7820-CNS-20002. It was terminated on 10 Nov 2017, as it was considered by the sponsor to have served its purpose in providing long-term safety data. Study termination was not based on safety concerns. | - |

Notes:

## Limitations and caveats

None reported