Clinical trial results:
An Open-Label, Multicenter, Rollover, Long-term Study of Aripiprazole Intramuscular Depot in Patients with Schizophrenia

Summary

EudraCT number	2010-021143-41
Trial protocol	FI BG SK HU EE ES
Global end of trial date	06 December 2018

Results information

Result version number	v2 (current)
This version publication date	15 February 2020
First version publication date	02 December 2019
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	31-10-270

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01129882
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Otsuka Pharmaceutical Development & Commercialization, Inc.
Sponsor organisation address	2440 Research Boulevard, Rockville, Maryland, United States, 20850
Public contact	Global Clinical Development, Otsuka Pharmaceutical Development & Commercialization, Inc., 609 524-6788, clinicaltransparency@otsuka-us.com
Scientific contact	Global Clinical Development, Otsuka Pharmaceutical Development & Commercialization, Inc., 609 524-6788, clinicaltransparency@otsuka-us.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	04 February 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 December 2018
Global end of trial reached?	Yes
Global end of trial date	06 December 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the safety and tolerability of aripiprazole IM depot (400 mg or 300 mg) in participants with schizophrenia who completed the 52-week, open-label safety and tolerability Trial 31-08-248.

Protection of trial subjects:

This trial was conducted in accordance with International Council on Harmonisation (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which the trial was conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	24 June 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	8 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 15
Country: Number of subjects enrolled	Australia: 12
Country: Number of subjects enrolled	Bulgaria: 111
Country: Number of subjects enrolled	Chile: 43
Country: Number of subjects enrolled	Croatia: 22
Country: Number of subjects enrolled	Estonia: 22
Country: Number of subjects enrolled	Finland: 1
Country: Number of subjects enrolled	Hungary: 14
Country: Number of subjects enrolled	India: 41
Country: Number of subjects enrolled	Korea, Republic of: 18
Country: Number of subjects enrolled	Malaysia: 22
Country: Number of subjects enrolled	Mexico: 25
Country: Number of subjects enrolled	Philippines: 14
Country: Number of subjects enrolled	Poland: 43
Country: Number of subjects enrolled	Puerto Rico: 4
Country: Number of subjects enrolled	Romania: 26
Country: Number of subjects enrolled	Russian Federation: 65

Country: Number of subjects enrolled	Serbia: 16
Country: Number of subjects enrolled	Slovakia: 13
Country: Number of subjects enrolled	South Africa: 23
Country: Number of subjects enrolled	Spain: 9
Country: Number of subjects enrolled	Taiwan: 3
Country: Number of subjects enrolled	Thailand: 4
Country: Number of subjects enrolled	United States: 143
Worldwide total number of subjects	709
EEA total number of subjects	261

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)	709
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants with a current diagnosis of schizophrenia, as defined by Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR) criteria, who completed the open-label extension Study 31-08-248 (2008-002699-83) (completed Study 248 Study Completion visit, Week 52).

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Aripiprazole IM Depot

Arm description:

Monthly dose of 400 milligrams (mg) or 300 mg aripiprazole intramuscular (IM) depot to adult participants with schizophrenia who completed aripiprazole IM depot treatment in Study 31-08-248.

Arm type	Experimental
Investigational medicinal product name	Aripiprazole
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Aripiprazole IM depot treatment (400 mg or 300 mg)

Number of subjects in period 1	Aripiprazole IM Depot
Started	709
Received at Least 1 Dose of Study Drug	709
Completed	431
Not completed	278
Adverse event, serious fatal	6
Consent withdrawn by subject	160
Physician decision	27
Adverse event, non-fatal	39
Protocol Deviation	3
Withdrawal Criteria Met	19
Trial Termination By Sponsor	6
Lost to follow-up	13
Lack of efficacy	5

Baseline characteristics

Reporting groups	
Reporting group title	Aripiprazole IM Depot
Reporting group description:	
Monthly dose of 400 milligrams (mg) or 300 mg aripiprazole intramuscular (IM) depot to adult participants with schizophrenia who completed aripiprazole IM depot treatment in Study 31-08-248.	

Reporting group values	Aripiprazole IM Depot	Total	
Number of subjects	709	709	
Age categorical Units: Subjects			
<=18 years	0	0	
Between 18 and 65 years	709	709	
>=65 years	0	0	
Age continuous Units: Years			
arithmetic mean	41.9		
standard deviation	± 10.4	-	
Gender categorical Units: Subjects			
Female	295	295	
Male	414	414	
Race/Ethnicity, Customized Units: Subjects			
White	464	464	
Black or African American	78	78	
American Indian or Alaska Native	1	1	
Asian	107	107	
Native Hawaiian or Other Pacific Islander	1	1	
Other	58	58	

End points

End points reporting groups

Reporting group title	Aripiprazole IM Depot

Reporting group description:

Monthly dose of 400 milligrams (mg) or 300 mg aripiprazole intramuscular (IM) depot to adult participants with schizophrenia who completed aripiprazole IM depot treatment in Study 31-08-248.

Primary: Number Of Participants Reporting Severe Treatment-Emergent Adverse Events (TEAE)

End point title	Number Of Participants Reporting Severe Treatment-Emergent Adverse Events (TEAE)[1]

End point description:

A TEAE was defined as an AE that started after start of investigational medicinal product (IMP) treatment or if the event was continuous from baseline and was serious, IMP-related, or resulted in death, discontinuation, interruption, or reduction of IMP. A severe AE was one that caused inability to work or perform normal daily activity.

A summary of serious and all other non-serious adverse events, regardless of causality, is located in the Reported Adverse Events module.

End point type	Primary

End point timeframe:

Baseline to Month 97 (+/- 3 days)

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: Statistical analyses data were not calculated for adverse events per study protocol.

End point values	Aripiprazole IM Depot			
Subject group type	Reporting group			
Number of subjects analysed	709			
Units: participants				
number (not applicable)	50			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change In Clinical Global Impression-Severity (CGI-S) of Illness Scale Score From Baseline To Last Visit

End point title	Mean Change In Clinical Global Impression-Severity (CGI-S) of Illness Scale Score From Baseline To Last Visit

End point description:

The severity of illness for each participant was rated using the CGI-S scale. To assess CGI-S, the rater or investigator answered the following question: "Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?" Response choices included: 0 = not assessed; 1 = normal, not ill at all; 2 = borderline mentally ill; 3 = mildly ill; 4 = moderately ill; 5 = markedly ill; 6 = severely ill; and 7 = among the most extremely ill patients. The Last Visit was defined as the last available post-baseline evaluation. A decrease in the CGI-S score indicated disease stability or improvement.

End point type	Secondary

End point timeframe:

Baseline, Month 91

End point values	Aripiprazole IM Depot			
Subject group type	Reporting group			
Number of subjects analysed	703[2]			
Units: units on a scale				
arithmetic mean (standard deviation)	-0.14 (± 0.69)			

Notes:

[2] - Participants with baseline or at least 1 post-baseline assessment are included.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Baseline to Month 97 (+/- 3 days)

Adverse event reporting additional description:

The Safety Sample comprised all participants who received at least 1 dose of open-label aripiprazole IM depot.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups

Reporting group title	Aripiprazole IM Depot

Reporting group description:

Monthly dose of 400 milligrams (mg) or 300 mg aripiprazole intramuscular (IM) depot to adult participants with schizophrenia who completed aripiprazole IM depot treatment in Study 31-08-248.

Serious adverse events	Aripiprazole IM Depot		
Total subjects affected by serious adverse events			
subjects affected / exposed	62 / 709 (8.74%)		
number of deaths (all causes)	6		
number of deaths resulting from adverse events	5		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Pancreatic Carcinoma Metastatic			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Breast Cancer			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebellar Tumour			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung Adenocarcinoma			

subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metastases to Liver			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Pleomorphic Adenoma			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Social circumstances			
Poor Personal Hygiene			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Cystocele			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metrorrhagia			

subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ovarian Cyst				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Pulmonary Embolism				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary Hypertension				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Psychotic Disorder				
subjects affected / exposed	9 / 709 (1.27%)			
occurrences causally related to treatment / all	0 / 9			
deaths causally related to treatment / all	0 / 0			
Suicide Attempt				
subjects affected / exposed	2 / 709 (0.28%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Suicidal Behaviour				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Schizophrenia				
subjects affected / exposed	14 / 709 (1.97%)			
occurrences causally related to treatment / all	3 / 14			
deaths causally related to treatment / all	0 / 0			

Insomnia			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Aggression			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Delusion			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Acute Stress Disorder			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicidal Ideation			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Impulse-Control Disorder			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Hepatic Enzyme Increased			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Accidental Overdose			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Gun Shot Wound				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Foot Fracture				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Road Traffic Accident				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Vitello-Intestinal Duct Remnant				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Supraventricular Tachycardia				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Acute Myocardial Infarction				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Arteriospasm Coronary				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Myocardial Ischaemia				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Cardio-Respiratory Arrest			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Nervous system disorders			
Presyncope			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cerebrovascular Accident			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Thrombotic Cerebral Infarction			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	2 / 709 (0.28%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Loss of Consciousness			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Anaemia			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Hepatobiliary disorders			
Hepatic Failure			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Autoimmune Hepatitis			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatic Cirrhosis			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Skin Ulcer			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dermatitis Allergic			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Still's Disease			
subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia Bacterial			

subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	3 / 709 (0.42%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Oesophageal Candidiasis				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary Tract Infection				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary Tuberculosis				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infection				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Erysipelas				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abscess Jaw				

subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal Abscess				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Abdominal Infection				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dengue Fever				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Type 2 Diabetes Mellitus				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Diabetes Mellitus				
subjects affected / exposed	1 / 709 (0.14%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Haemosiderosis				

subjects affected / exposed	1 / 709 (0.14%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Aripiprazole IM Depot		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	515 / 709 (72.64%)		
Investigations			
Weight Increased			
subjects affected / exposed	81 / 709 (11.42%)		
occurrences (all)	81		
Nervous system disorders			
Headache			
subjects affected / exposed	77 / 709 (10.86%)		
occurrences (all)	77		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	37 / 709 (5.22%)		
occurrences (all)	37		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	44 / 709 (6.21%)		
occurrences (all)	44		
Insomnia			
subjects affected / exposed	70 / 709 (9.87%)		
occurrences (all)	70		
Musculoskeletal and connective tissue disorders			
Back Pain			
subjects affected / exposed	42 / 709 (5.92%)		
occurrences (all)	42		
Infections and infestations			
Influenza			
subjects affected / exposed	48 / 709 (6.77%)		
occurrences (all)	48		
Nasopharyngitis			

subjects affected / exposed	87 / 709 (12.27%)		
occurrences (all)	87		
Upper Respiratory Tract Infection			
subjects affected / exposed	54 / 709 (7.62%)		
occurrences (all)	54		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 November 2010	Included the assessments of AIMS, SAS, and BARS to assess EPS at least every 6 months and clarified the definition of trial completers.
08 April 2013	Changed the 6-Month Follow-up phone call to a 30-day Follow-up phone call after it was determined that the participant would no longer participate in the trial.
11 April 2013	Changed the participant enrollment number from 400 participants to approximately 500 to 800 subjects from Trial 31-08-248.
08 July 2015	The number and types of assessments obtained during the trial were reduced to decrease the burden on participants. Participants being treated with aripiprazole IM depot in Trial 31-10-270 could continue treatment until the trial ended as described in the protocol. However, if the sponsor terminated the trial prior to 31 Dec 2018 for any reason other than commercial availability, investigators in some countries where the sponsor had limited or delayed commercialization plans, or where no commercialization activity was anticipated, may have been eligible to participate in a managed access program until aripiprazole IM depot was commercially available in their country or until 31 Dec 2018.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Not specified

Notes: