ABILIFY for the Adolescent Bipoloar I Mania Indication of Tool Effectiveness Evaluation Strategy

First published: 19/03/2014

Last updated: 31/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6083

Study ID

23794

DARWIN EU® study

No

Study countries

- Austria
- Cyprus
- Denmark
- Germany

Ireland
Italy
Norway
Portugal
Slovenia
Spain
Sweden
United Kingdom

Study description

ABILIFY® (aripiprazole) is a drug indicated for the treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older. It was approved by the European Commission on January 24th 2013. For reasons of conciseness, the indication throughout this protocol is termed adolescent bipolar I mania.As part of marketing authorisation approval, the ABILIFY® risk management plan (RMP) requires distribution of two Risk Minimisation (RM) communication tools, additional to the SmPC, to Healthcare Providers (HCPs) prescribing ABILIFY® for the adolescent bipolar I mania indication.These tools are a Healthcare Provider Frequently Asked Questions Brochure (HCP FAQ) and a Patient / Caregiver Information Brochure (PCIB). The purpose of the HCP FAQ is to clearly explain to prescribers or other HCPs involved in patient treatment the need to carefully consider the indicated age range, dose, and duration of treatment before prescribing ABILIFY® for the adolescent bipolar I mania indication. Furthermore, vigilance is urged in the on-going evaluation of weight gain, EPS, and ADRs related to somnolence and fatigue. A PCIB is available for physicians to give to their patients (and their caregivers) to help them better understand and recognise specific ADRs. The EU-RMP committed Otsuka Pharmaceutical Europe Ltd., as the marketing authorisation holder (MAH), to evaluate the effectiveness of these additional RM activities (i.e. the RM tools and their distribution) for the adolescent bipolar I

mania indication.

Study status

Finalised

Research institutions and networks

Institutions

Drug safety, Risk management & regulatory Practice, Pope Woodhead & Associates (PWA)

United Kingdom

First published: 22/03/2010

Last updated: 07/03/2024

Institution | **Educational Institution** | **Non-Pharmaceutical company** | **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Landsberg Wally

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 21/10/2013

Actual: 21/10/2013

Study start date
Planned: 30/07/2014

Actual: 11/11/2014

Data analysis start date
Planned: 04/01/2016

Actual: 04/01/2016

Date of final study report
Planned: 30/12/2016

Actual: 23/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

OTSUKA PHARMACEUTICALS EUROPE LIMITED/LUNDBECK

Study protocol

protocol for submission.pdf (363.83 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

1. To determine the proportion of HCPs, patients and caregivers that are aware of the RM tools and how these tools are accessed2. To determine when, how and by whom the tools are used 3. To determine the level of knowledge and comprehension of key risks

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N05AX12) aripiprazole

aripiprazole

Population studied

Short description of the study population

Healthcare Providers (HCPs), patients and caregivers in markets where ABILIFY® has been used for the adolescent bipolar I mania indication for more than six months.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Patients with bipolar I mania

Estimated number of subjects

300

Study design details

Data analysis plan

Descriptive statistics for discontinuous data will be used to examine the key research questions of interest. The data for the overall population will be examined by users and non-users, general psychiatrists, child / adolescent psychiatrists, nurses, pharmacists, patients and caregivers, and individual countries. The data will be presented with responses' frequency distributions and 95% confidence intervals

Documents

Study results

Encepp summary PASS study 31-13-300 Final.pdf (111.46 KB)

Study publications

Landsberg W, Al-Dakkak I, Coppin-Renz A, Geis U, Peters-Strickland T, van Heume…

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

Unknown