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HEALTH TECHNOLOGY BRIEFING
JUNE 2020

Abilify MyCite (aripiprazole with sensor) for bipolar disorder and schizophrenia

NIHRIO ID	24348	**NICE ID**	10351
Developer/Company	Otsuka Pharmaceutical Co. Ltd.	**UKPS ID**	Not available.

Licensing and market availability plans	Currently in Phase IV clinical trials.

SUMMARY

Abilify MyCite (aripiprazole with sensor) is in clinical development for the treatment of adults with Bipolar Disorder (BP1) and Schizophrenia (SCH). BP1 is a mental health condition that causes high and low mood swings that go on for longer periods of time, compared to usual fluctuations in mood. SCH can result in a person having relapses into episodes of psychosis, which can include losing touch with reality through hallucinations and hearing voices. Anyone can develop these mental health conditions throughout their lifetime, however they are more common in young adults.

Abilify MyCite is a drug-device combination comprising aripiprazole embedded with an Ingestible Event Marker (IEM) sensor. The aripiprazole attaches in the brain to receptors which help normalise the activity of the brain. The drug is packaged within an innovative system which helps patients (and healthcare workers) monitor when the medication is taken through integration with a sensor patch and app. Abilify MyCite is different to other ways of monitoring whether medication has been taken because it gives results of the actual medication taken, without need for blood or urine samples, as opposed to an estimate and if licensed, will offer an additional treatment option for patients with BP1 and SCH.

PROPOSED INDICATION

Treatment of adults with Bipolar Disorder 1 (BP1) and Schizophrenia (SCH).[1-4]

TECHNOLOGY

DESCRIPTION

Abilify MyCite (aripiprazole with sensor) is a drug-device combination product which consists of aripiprazole embedded with an ingestible event marker (IEM), a wearable sensor patch, smartphone app and web portal that accesses encrypted, cloud-based data. The active substance is aripiprazole attaches to the brain to neurotransmitters called dopamine and serotonin (5HT), which are believed to play a role in SCH and BP1. By attaching to these receptors, it is thought that aripiprazole helps normalise the activity of the brain, reducing psychotic or manic symptoms and preventing them from returning.[5] When the aripiprazole tablet enters the stomach the IEM sends a signal to the patch, which then shares this information with the app and subsequently the web-portal. The IEM is the size of a grain of sand and indigestible. The app is intended to be used by the patient to assist personal tracking of when the medication has been taken, as well as offering features to log health and wellbeing (e.g. self-reported mood). If the patient gives consent then healthcare providers and carers can use the web-portal to observe the patient's ingestion patterns.[6]

Abilify MyCite is currently in phase II and IV clinical development for the treatment of BP1 and SCH. The proposed treatment regimen is Abilify MyCite (aripiprazole dose 5mg, 10mg, 15mg and 30mg)[a] in a single daily dose.[1-4]

INNOVATION AND/OR ADVANTAGES

Patient non-adherence is a concern for healthcare providers because it can result in deterioration of a patient's wellbeing, increasing demand for resources to intervene with decline in health, and wasting medication.[7] Sudden withdrawal of antipsychotic medication can have adverse side-effects, such as (but not limited to) flu-like symptoms, insomnia, nausea and sensory disturbances.[8] Additionally, there can be a mental health relapse, that results in symptoms related to the treated condition, which can lead to reduced recovery, hospitalisation and suicide.[9,10]

Abilify MyCite would add to the methods used for patient adherence monitoring, which include pill counts, technology-assisted monitoring (through containers that electronically log when they have been accessed), pharmacy refill records and biological measurements (presence of a medication within samples such as saliva or urine).[11] The ability to identify when a patient has actually consumed medication, in a minimally invasive way, as opposed to an estimation, would give a more accurate indicator of patient adherence. Research is ongoing to investigate if the use of this technology has any impact on patient adherence.[4]

DEVELOPMENT STATUS AND/OR REGULATORY DESIGNATIONS

Abilify MyCite does not currently have Marketing Authorisation in the EU/UK for any indication. However, aripiprazole is already licensed in the UK for the schizophrenia and mania.[12]

Aripiprazole is in phase II and phase III clinical development for patients with autistic disorders, Tourette's Syndrome, alcohol use disorder and psychosis for stimulants.[13]

PATIENT GROUP

DISEASE BACKGROUND

Bipolar Disorder

Patients with BP1 experience changes in mood from one extreme to another; these episodes go between depression (having low mood and lethargy) and mania (being elated or agitated and overactive). BP1 mood swings can last extended periods of time (several weeks or longer). The exact cause of BP1 is unknown, but it is thought a number of physiological and environmental factors can trigger its development.[14]

Schizophrenia

Patients with SCH can experience various psychological symptoms including:[15]

- Hallucinations (hearing and seeing things)
- Delusions (unusual beliefs not based on reality)
- Losing interest in everyday activities
- Not caring about personal hygiene
- People avoidance, even those the patient is close to

While the exact cause of SCH is not known there is evidence to show that multiple factors can influence the chance of a person developing it. Family history of the condition, differences in brain development and environmental triggers, such as stress and drug abuse, can increase the risk of developing SCH.[15]

CLINICAL NEED AND BURDEN OF DISEASE

The estimated UK prevalence of mood disorders (including BP1) in 2010 was nearly four million cases (8.73% of the population).[16] Around 2% of the UK population experience bipolar disorder.[17-19] Hospital admissions data for England in 2018-2019 recorded 11,515 finished consulting episodes (FCE) for bipolar affective disorder (ICD-10 code F31), 388,000 FCE bed days and 7,584 hospital admissions.[20]

The chance of developing SCH is about 1 in 100 in the general population.[15,21] In England between 2018-19, the number of FCE for SCH (ICD-10 code F20) were 18,828, with the number of FCE bed days totalling 1,298,502 and the number of hospital admissions were 11,439.[20] Based on 2008 data, the total social and economic cost for schizophrenia and bipolar disorder was estimated to be £3.9 billion and £9.2 billion a year respectively.[17]

PATIENT TREATMENT PATHWAY

TREATMENT PATHWAY

Bipolar Disorder

Patients who display BP1 symptoms that have lasted four or more days should be referred for a specialist mental health assessment.[22] Once a diagnosis is received, treatments include mood stabilisers, medications to manage the symptoms, psychological interventions (e.g. cognitive behavioural therapy - CBT) and lifestyle advice.[14,22]

Identifying triggers, with the assistance of a mental health worker, is also useful so that the patient can identify when relapses are more likely to occur and seek appropriate help.[14] Patients and their carer(s) must be involved in treatment decisions so that they are educated about the benefits and risks of these interventions, in order to determine the best treatment to suit them.[22]

Schizophrenia

Patients with SCH that present to early intervention should receive urgent assessment with the appropriate psychosis services.[15,23] This is to provide a range of pharmacological, psychological, social, occupational or educational interventions in a timely manner. Guidance and support is given throughout treatment and management of the condition.[23]

SCH treatment decisions are guided by community mental health teams (CMHT) that are multidisciplinary and can include social workers, counsellors and psychiatrists. The patient will receive a key worker who is the first point of contact with the CMHT. If an episode is particularly severe then crisis resolution teams help treat the patient, as close to home as possible, to reduce the likelihood of hospitalisation. Treatments include psychological interventions (e.g. CBT) and antipsychotic medication.[15,23]

There is no cure for SCH, however patients can recover from these symptoms, but may have relapses. Treatment aims to manage the associated symptoms and reduce the possibility of relapses, so that a patient may continue with daily life.[15]

CURRENT TREATMENT OPTIONS

Bipolar Disorder

Patients who have developed mania, that are not taking an antipsychotic or mood stabiliser, may be offered one of the following:[24,25]

- Haloperidol
- Olanzapine
- Quetiapine
- Risperidone

Pharmacological options for further symptom management include:[14,24]

- Olanzapine (with or without the combination of fluoxetine)
- Quetiapine
- Lamotrigine (if the patient prefers or there is no response to fluoxetine with olanzapine, or quetiapine)

- Lithium (as a long-term treatment for BP1)
- Valproate

Schizophrenia

Patients with SCH may be treated with medication from one of two types of antipsychotics:[15,26]

- Typical ("older", first generation developed in the 1950s) such as chlorpromazine, flupentixol, haloperidol, levomepromazine, sulpiride and zuclopenthixol
- Atypical ("newer", second generation developed in the 1990s) such as amisulpride, aripiprazole, clozapine, olanzapine, quetiapine and risperidone

PLACE OF TECHNOLOGY

If licensed, Abilify MyCite will offer an additional therapy option for patients with BP1 and SCH.

CLINICAL TRIAL SUMMARY INFORMATION

Trial	NCT03568500; **A Multicentre, 8-week, Single-arm, Open-label, Pragmatic Trial to Explore Acceptance and Performance of Using a Digital Medicine System With Healthcare Professionals and Adult Subjects With Schizophrenia, Schizoaffective Disorder, or First Episode Psychosis on an Oral Atypical Antipsychotic (Aripiprazole, Olanzapine, Quetiapine, or Risperidone) Phase IV** **Location(s): United Kingdom**
Trial design	Non-randomised, open label, parallel assignment.
Population	n=44 (actual); adults aged 18 to 65; currently prescribed aripiprazole, olanzapine, quetiapine, or risperidone; possession of a smart phone and ability to download and use DMS app; skin on torso free from any dermatological problems.
Intervention(s)	A CoEncapsulated (CoE) antipsychotic, either aripiprazole, olanzapine, quetiapine or risperidone, a DMS patch and associated smartphone app. The oral tablet dosage were one of the following:[a] • Aripiprazole (5mg, 10mg or 15mg) • Olanzapine (5mg, 10mg or 15mg) • Quetiapine (50mg, 100mg or 200mg) • Risperidone (1mg, 2mg or 4mg)

[a] Information provided by Otsuka Pharmaceutical

	The prescription dose, regime and schedule was determined by health care providers and is independent from the protocol.
Comparator(s)	No comparator.
Outcome(s)	Good patch coverage [Time frame: Up to 8 weeks]: 80% patch data available or Ingestible Sensor Pills (MITs) detected within the 24-hour period for each day while subject is involved with the trial. See trial record for full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Trial	NCT03881449; **A Multicenter, 52-week, Provider-Randomized, Pragmatic Trial to Assess the Differences in ABILIFY MYCITE - a Digital Medicine System (DMS) Versus Treatment as Usual (TAU) for Adults With Schizophrenia, Bipolar I Disorder, or Major Depression (MDD) Currently Using Aripiprazole** **Phase IV** **Location(s): United States**
Trial design	Randomised, open label, parallel assignment.
Population	n=300 (planned); adults aged 18 and over; primary diagnosis of SCH, BP1 or MDD; patients have an active prescription for oral aripiprazole.
Intervention(s)	Combination of oral aripiprazole with IEM embedded, detector patch and smartphone app used for three months. All FDA approved doses were made available, which are the following: 2mg, 5mg, 10mg, 15mg, 20mg and 30mg. [b] After three months the patient, under instruction of their physician, may continue using the products for an additional nine months (total treatment period may not exceed 12 months). All treatment medication decisions will be made by the healthcare professionals (HCPs) and not by protocol.
Comparator(s)	Treatment as usual (TUA) patients taking aripiprazole according to current treatment plan as advised by their physician.
Outcome(s)	Aripiprazole refills [Time frame: 6 months]: Aripiprazole refill as operationalized as a continuous measure of the number of days covered over the baseline to 6-month period. See trial record for full list of other outcomes.

[b] Information provided by Otsuka Pharmaceutical

Results (efficacy)	-
Results (safety)	-

Trial	**NCT02219009; A Multicenter, 8-week, Open-label Study to Assess Usability of the Medical Information Device #1 (MIND1) System in Adult Subjects With Schizophrenia Who Are Treated With Oral Aripiprazole** **Phase II** **Location(s): United States**
Trial design	Multicentre, open label, single group assignment.
Population	n=67; adults aged 18 to 65; primary diagnosis of SCH; currently prescribed oral aripiprazole for SCH; must have the capacity to utilize technology interfaces; skin on torso free from any dermatological problems.
Intervention(s)	Oral aripiprazole, embedded with an IEM, on the following once-daily doses (10, 15, 20, or 30mg) during an eight-week period.
Comparator(s)	No comparator.
Outcome(s)	Proportion of participants who were able to pair and apply a patch independently (and successfully) by the end of the week-eight study visit (or early termination, if applicable), as defined by a score of 91 to 100 on the Subject Ability to Use System Scale – Healthcare Professional Version (SAUSS-HCP) [Time frame: baseline to week 8] See trial record for full list of other outcomes.
Results (efficacy)	By the end of week 8 or early termination, 82.1% (55/67) of patients had replaced the wearable sensor independently or with minimal assistance, based on HCP rating. The patients used the wearable sensor for a mean (SD) of 70.7% (24.7%) and a median of 77.8% of their time in the trial. The patients contacted a call centre most frequently at week 1. At the last visit, 78% (47/60) of patients were somewhat satisfied/satisfied/extremely satisfied with the DMS.[27]
Results (safety)	In general, all reported treatment-emergent adverse events (TEAEs) were consistent with the known safety profile of aripiprazole.[27]

Trial	**NCT02722967; A Multicenter, 8-week, Open-label, Single-Arm Exploratory Trial to Assess the Functionality of an Integrated Call Center for the Digital Medicine System (DMS) by Adult Subjects with Schizophrenia, Major Depressive Disorder, or Bipolar 1 Disorder Treated With Oral Aripiprazole** **Phase II** **Location(s): United States**
Trial design	Open label, single group assignment.
Population	n=49; adults aged 18 to 65; primary diagnosis of SCH, MDD, or BP1; must be able to swallow tablets; currently taking a stable daily dose of oral aripiprazole; must have the capacity to utilise the technology; skin in area of patch application must be free of any skin disorders or dermatological problems.
Intervention(s)	Oral aripiprazole (doses between 2mg to 30mg) with an IEM, in a single daily dose for the duration of the trial.
Comparator(s)	No comparator.
Outcome(s)	Assessment of the functionality of an integrated call centre for DMS by adult subjects with SCH, MDD, or BP1 who were treated with oral Aripiprazole [time frame: from baseline up to week 9]: measured by the number of patients in trial who made (inbound) or received (outbound) calls.
Results (efficacy)	All enrolled patients (n=49) used the DMS. For a duration of 8 weeks, 136 calls were made by patients, and a comparable 160 calls were made to patients, demonstrating interactive communication. The mean (SD) number of calls made by patients was 2.8 (3.5). Approximately half of the inbound calls made by patients occurred during the first 2 weeks and were software application- or patch-related. Mean ingestion adherence was 88.6%, and corresponding good patch wear occurred on 80.1% of study days.[28]
Results (safety)	No new safety signals beyond what has been previously reported.[28]

ESTIMATED COST

The cost of Abilify MyCite is not yet known.

Aripiprazole is already marketed in the UK (in 5mg- 30mg tablets). Twenty-eight tablets cost in the range of £1.12 to £192.08.[29]

RELEVANT GUIDANCE

NICE GUIDANCE

Bipolar Disorder

- NICE clinical guideline. Bipolar disorder: assessment and management (CG185). February 2020
- NICE quality standard. Bipolar disorder in adults (QS95). July 2015

Schizophrenia

- NICE technology appraisal. Guidance on the use of electroconvulsive therapy (TA59). October 2009
- NICE clinical guidance. Psychosis and schizophrenia in adults: prevention and management (CG178). February 2014
- NICE guideline in development. Rehabilitation in adults with complex psychosis and related severe mental health conditions. Expected publication date: TBC
- NICE quality standard. Psychosis and schizophrenia in adults (QS80). February 2015

NHS ENGLAND (POLICY/COMMISSIONING) GUIDANCE

- NHS England. Mental Health Implementation Plan 2019/20 - 2023/24. Publishing Approval Reference: 000830. July 2019
- NHS England. Implementing the Five Year Forward View for Mental Health. Gateway Reference: 05574. July 2016
- NHS England. Implementing the Early Intervention in Psychosis Access and Waiting Time Standard: Guidance. Gateway Reference: 04294. April 2016

OTHER GUIDANCE

ADDITIONAL INFORMATION

Otsuka Pharmaceutical Co. Ltd. did not enter information about this technology onto the UK PharmaScan database; the primary source of information for UK horizon scanning organisations on new medicines in development. As a result, the NIHR Innovation Observatory has had to obtain data from other sources. UK PharmaScan is an essential tool to support effective NHS forward planning; allowing more effective decision making and faster uptake of innovative new medicines for patients who could benefit. We urge pharmaceutical companies to use UK PharmaScan so that we can be assured of up-to-date, accurate and comprehensive information on new medicines.

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