ABILIFY® (aripiprazole) Supplemental New Drug Application For The Treatment Of Pediatric Patients With Bipolar I Disorder Accepted For Priority Review By The U.S. Food And Drug Administration

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- Otsuka-sponsored Study Evaluated Use of ABILIFY in Patients Ages 10 to 17 -

TOKYO & PRINCETON, N.J.--(BUSINESS WIRE)–Otsuka Pharmaceutical Co., Ltd. and Bristol-Myers Squibb Company (NYSE: BMY) announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing and granted a Priority Review to the supplemental New Drug Application (sNDA) of the atypical antipsychotic, ABILIFY® (aripiprazole) for the treatment of pediatric patients (10 to 17 years old) diagnosed with Bipolar I Disorder, manic or mixed episode with or without psychotic features.

Priority Review status for an application or supplement for a drug product is assigned if a product, if approved, could represent an improvement compared to marketed products, including non-drug products/therapies in the treatment, diagnosis or prevention of a disease. The FDA goal for reviewing a drug with Priority Review is six months.

This sNDA is based on data from a multicenter, randomized, double-blind, placebo-controlled study of two fixed oral doses of ABILIFY (10 mg/day or 30 mg/day). The efficacy and safety of ABILIFY were assessed in 296 ethnically diverse pediatric patients (ages 10 to 17) with Bipolar I Disorder over a 30-week treatment timeframe, which consisted of a four-week double-blind acute phase, followed by a 26-week double-blind continuation phase. This trial was sponsored by Otsuka Pharmaceutical Co., Ltd. and its U.S. subsidiary, Otsuka Pharmaceutical Development & Commercialization, Inc. (Princeton, NJ) and was conducted at 54 centers in the U.S.

About ABILIFY® (aripiprazole)

The first and only available dopamine partial agonist, ABILIFY is indicated for the treatment of acute manic or mixed episodes associated with Bipolar I Disorder in adults. ABILIFY is also indicated for the treatment of schizophrenia in adults and adolescents (13 to 17 years old). ABILIFY Injection is indicated for the treatment of adults with agitation associated with schizophrenia or Bipolar I Disorder, manic or mixed.

Initially approved in November 2002, over 12.5 million prescriptions have been written for ABILIFY in the U.S.1 through June 2007.

ABILIFY is available by prescription only. ABILIFY Tablets should be taken once daily with or without food and are available in 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg strengths. ABILIFY® DISCMELT™ (aripiprazole) Orally Disintegrating Tablets are available in 10 mg and 15 mg strengths. In addition, ABILIFY is available in a 1 mg/mL nonrefrigerated Oral Solution and as a single-dose ready-to-use solution for intramuscular injection 7.5 mg/mL. In adult patients, the recommended ABILIFY Oral target dose is 15 mg/day to 30 mg/day in Bipolar I Disorder and 10 mg/day to 15 mg/day in schizophrenia. In adolescent patients with schizophrenia, the recommended ABILIFY Oral target dose is 10 mg/day (with a starting dose of 2 mg/day which was titrated to 5 mg/day after 2 days and to the target dose of 10 mg/day after 2 additional days). The 30 mg/day dose was not shown to be more efficacious than the 10 mg/day dose. In adult patients with agitation associated with bipolar mania or schizophrenia, the ABILIFY® (aripiprazole) Injection initial dose is 9.75 mg/1.3 mL. If ongoing ABILIFY therapy is clinically indicated, oral ABILIFY in a range of 10 mg/day to 30 mg/day should replace ABILIFY Injection as soon as
possible. The safety of doses of ABILIFY Oral or ABILIFY Injection above 30 mg/day has not been evaluated in clinical trials.

IMPORTANT SAFETY INFORMATION and INDICATIONS for ABILIFY

INDICATIONS:

-- ABILIFY is indicated for acute and maintenance treatment of schizophrenia in adults

-- ABILIFY is indicated for the treatment of schizophrenia in adolescents 13 to 17 years of age

-- ABILIFY is indicated for acute and maintenance treatment of adults with manic or mixed episodes associated with Bipolar I Disorder with or without psychotic features

-- ABILIFY Injection is indicated for the treatment of adults with agitation associated with schizophrenia or Bipolar I Disorder, manic or mixed.

IMPORTANT SAFETY INFORMATION:

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. ABILIFY® (aripiprazole) is not approved for the treatment of patients with dementia-related psychosis (see Boxed WARNING).

Cerebrovascular adverse events (eg, stroke, transient ischemic attack), including fatalities, have been reported at an increased incidence in clinical trials of elderly patients with dementia-related psychosis treated with ABILIFY

Neuroleptic malignant syndrome (NMS)—As with all antipsychotic medications, a rare and potentially fatal condition known as NMS has been reported with ABILIFY. NMS can cause hyperpyrexia, muscle rigidity, diaphoresis, tachycardia, irregular pulse or blood pressure, cardiac dysrhythmia, and altered mental status. If signs and symptoms appear, immediate discontinuation is recommended

Tardive dyskinesia (TD)—The risk of developing TD and the potential for it to become irreversible may increase as the duration of treatment and the total cumulative dose increase. Prescribing should be consistent with the need to minimize TD. If signs and symptoms appear, discontinuation should be considered since TD may remit, partially or completely

Hyperglycemia and diabetes mellitus—Hyperglycemia, in some cases associated with ketoacidosis, coma, or death, has been reported in patients treated with atypical antipsychotics including ABILIFY. Patients with diabetes should be monitored for worsening of glucose control; those with risk factors for diabetes should undergo baseline and periodic fasting blood glucose testing. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. There have been few reports of hyperglycemia with ABILIFY

ABILIFY may be associated with orthostatic hypotension and should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

As with other antipsychotic drugs, ABILIFY should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

Like other antipsychotics, ABILIFY may have the potential to impair judgment, thinking, or motor skills. Patients should not drive or operate hazardous machinery until they are certain ABILIFY does not affect them adversely.

Disruption of the body’s ability to reduce core body temperature has been attributed to antipsychotics. Appropriate care is advised for patients who may exercise strenuously, be exposed to extreme heat, receive concomitant medication with anticholinergic activity, or be subject to dehydration.

Esophageal dysmotility and aspiration have been associated with antipsychotic drug use, including ABILIFY® (aripiprazole); use caution in patients at risk for aspiration pneumonia.

The possibility of a suicide attempt is inherent in psychotic illnesses and bipolar disorder, and close supervision of high-risk patients should accompany drug therapy.

Physicians should advise patients to avoid alcohol while taking ABILIFY.

Strong CYP3A4 or CYP2D6 inhibitors increase ABILIFY drug concentrations when used concomitantly.

CYP3A4 inducers decrease ABILIFY drug concentrations when used concomitantly.

Commonly observed adverse events (greater than or equal to 5 percent incidence and at least twice
the rate of placebo for ABILIFY vs placebo, respectively):

-- Adult patients with schizophrenia: akathisia (8 percent vs 4 percent)

-- Pediatric patients (13 to 17 years) with schizophrenia: extrapyramidal disorder (17 percent vs 5 percent), somnolence (16 percent vs 6 percent), and tremor (7 percent vs 2 percent)

-- Adult patients with bipolar mania: constipation (13 percent vs 6 percent), akathisia (15 percent vs 3 percent), sedation (8 percent vs 3 percent), tremor (7 percent vs 3 percent), restlessness (6 percent vs 3 percent), and extrapyramidal disorder (5 percent vs 2 percent)

-- Adult patients with agitation associated with schizophrenia or bipolar mania: nausea (9 percent vs 3 percent)

Please see FULL PRESCRIBING INFORMATION, including Boxed WARNING, for ABILIFY.

About Otsuka Pharmaceutical Co., Ltd. and Bristol-Myers Squibb

Otsuka Pharmaceutical Co., Ltd. and Bristol-Myers Squibb are collaborative partners in the development and commercialization of ABILIFY in the United States and major European countries.

ABILIFY was discovered by Otsuka Pharmaceutical Co., Ltd. Founded in 1964, Otsuka Pharmaceutical Co., Ltd. is a global healthcare company with the corporate philosophy: “Otsuka - people creating new products for better health worldwide.” Otsuka researches, develops, manufactures and markets innovative and original products, with a focus on pharmaceutical products for the treatment of diseases and consumer products for the maintenance of everyday health. Otsuka is committed to being a corporation that creates global value, adhering to the high ethical standards required of a company involved in human health and life, maintaining a dynamic corporate culture, and working in harmony with local communities and the natural environment. The Otsuka Pharmaceutical Group comprises 99 companies and employs approximately 31,000 people in 17 countries and regions worldwide. Otsuka and its consolidated subsidiaries earned U.S. $7.2 billion in annual revenues in fiscal 2006.

Bristol-Myers Squibb is a global pharmaceutical and related healthcare products company whose mission is to extend and enhance human life.

For more information and FULL PRESCRIBING INFORMATION, including Boxed WARNING, visit:
www.abilify.com
Visit Otsuka Pharmaceutical Co., Ltd. at: www.otsuka-global.com
Visit Bristol-Myers Squibb at: www.bms.com

REFERENCE:


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