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ABILIFY[®] (aripiprazole) SUPPLEMENTAL NEW DRUG APPLICATION FOR PEDIATRIC PATIENTS WITH SCHIZOPHRENIA ACCEPTED FOR PRIORITY REVIEW BY THE U.S. FOOD AND DRUG ADMINISTRATION

- Otsuka-sponsored Study Evaluated Use of ABILIFY in Patients Ages 13-17 -

(TOKYO, JAPAN and PRINCETON, NJ, JUNE 5, 2007) – 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 priority (six month review target) review the supplemental New Drug Application (sNDA) of the atypical antipsychotic ABILIFY[®] (aripiprazole) for the treatment of pediatric patients (13-17 years old) with schizophrenia. This sNDA is based on data from a six-week, double-blind, randomized, placebo-controlled study, sponsored by Otsuka Pharmaceutical Co., Ltd., and its U.S. subsidiary, Otsuka Pharmaceutical Development & Commercialization, Inc. (Princeton, NJ) evaluating the use of ABILIFY in 302 ethnically diverse pediatric patients (ages 13-17) and was conducted at 101 centers in 13 countries.

About ABILIFY[®] (aripiprazole)

The first and only available dopamine partial agonist, ABILIFY is indicated for the short- and long-term treatment of schizophrenia including maintaining stability in adults who had been symptomatically stable on other antipsychotic medications for periods of three months or longer and observed for relapse during a period of up to 26 weeks. ABILIFY is also indicated for the treatment of acute manic and mixed episodes associated with Bipolar I Disorder, and for maintaining efficacy in adults with Bipolar I Disorder with a recent manic or mixed episode who

had been stabilized and then maintained for at least six (6) weeks. Physicians who elect to use ABILIFY® (aripiprazole) for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual. ABILIFY Injection is indicated for the treatment of agitation associated with schizophrenia or bipolar disorder, manic or mixed.

Initially approved in November 2002, over 10 million prescriptions have been written for ABILIFY in the U.S.¹ through January 2007.

ABILIFY is available by prescription only. ABILIFY tablets are available in 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths. The effective dose range is 10-30 mg/day for schizophrenia patients, and 15 or 30 mg/day for Bipolar I Disorder patients. ABILIFY DISCMELT™ (orally disintegrating tablets) are available in 10 mg and 15 mg strengths. In addition, ABILIFY is available in a 1 mg/mL non-refrigerated Oral Solution. ABILIFY Injection, an injectable form of ABILIFY for intramuscular use, provides healthcare professionals with the first ready-to-use single dose vial (9.75 mg/1.3 mL) of an atypical antipsychotic to calm the agitated patient. The safety of doses of ABILIFY above 30 mg/day have not been evaluated in clinical trials.

ABILIFY is taken once daily with or without food. It is important to talk to a healthcare professional for more information about ABILIFY.

IMPORTANT SAFETY INFORMATION and INDICATIONS for ABILIFY

INDICATIONS:

ABILIFY is indicated for the treatment of:

- Schizophrenia, including maintaining stability in patients who had been symptomatically stable on other antipsychotic medications for periods of 3 months or longer and observed for relapse during a period of up to 26 weeks*
- Acute manic and mixed episodes associated with Bipolar I Disorder
- Maintaining efficacy in patients with Bipolar I Disorder with a recent manic or mixed episode who had been stabilized and then maintained for at least 6 weeks*

ABILIFY Injection is indicated for the treatment of agitation associated with schizophrenia or bipolar disorder, manic or mixed.

*Physicians who elect to use ABILIFY® (aripiprazole) for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

IMPORTANT SAFETY INFORMATION:

Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk (1.6 to 1.7 times) of death compared to placebo (4.5% vs 2.6%, respectively). ABILIFY is not approved for the treatment of patients with dementia-related psychosis (see Boxed WARNING).

- **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
- **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
- **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.

As antipsychotics have been associated with **esophageal dysmotility and aspiration**, ABILIFY® (aripiprazole) should be used cautiously in patients at risk for aspiration pneumonia.

As the possibility of a **suicide** attempt is inherent in psychotic illness and bipolar disorder, close supervision of high-risk patients should accompany drug therapy. Prescriptions for ABILIFY should be written for the smallest quantity consistent with good patient management to reduce the risk of overdose.

Physicians should determine if a patient is **pregnant** or intends to become pregnant while taking ABILIFY. Patients should be advised not to breast-feed while taking ABILIFY.

Physicians should advise patients to avoid alcohol while taking ABILIFY.

Both CYP3A4 and CYP2D6 are responsible for ABILIFY metabolism. Agents that induce CYP3A4 (eg, carbamazepine) could cause an increase in ABILIFY clearance and lower blood levels. Inhibitors of CYP3A4 (eg, ketoconazole) or CYP2D6 (eg, quinidine, fluoxetine, or paroxetine) can inhibit ABILIFY elimination and cause increased blood levels.

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

ABILIFY Oral

In 3-week bipolar mania trials the following were reported: akathisia (15% vs 3%), constipation (13% vs 6%), sedation (8% vs 3%), tremor (7% vs 3%), restlessness (6% vs 3%), and extrapyramidal disorder (5% vs 2%).

In 4- to 6-week schizophrenia trials the following was reported: akathisia (8% vs 4%).

A similar adverse event profile was observed in a 26-week trial in schizophrenia except for a higher incidence of tremor (ABILIFY 8% vs placebo 2%).

ABILIFY Injection

In short-term (24 hour) trials in patients with agitation associated with schizophrenia or bipolar mania the following was reported: nausea (9% vs 3%).

Treatment-emergent adverse events reported with:

ABILIFY Oral

In short-term trials of patients with schizophrenia (up to 6 weeks) or bipolar disorder (up to 3 weeks), the following were reported at an incidence greater than or equal to 10% and greater than placebo, respectively: headache (30% vs 25%), anxiety (20% vs 17%),

insomnia (19% vs 14%), nausea (16% vs 12%), vomiting (12% vs 6%), dizziness (11% vs 8%), constipation (11% vs 7%), dyspepsia (10% vs 8%), and akathisia (10% vs 4%).

ABILIFY[®] (aripiprazole) Injection

In short-term (24 hour) trials, the following were reported at an incidence greater than or equal to 5% and greater than placebo, respectively: headache (12% vs 7%), nausea (9% vs 3%), dizziness (8% vs 5%), and somnolence (7% vs 4%).

Please see accompanying FULL PRESCRIBING INFORMATION, including **Boxed WARNING**, for ABILIFY (aripiprazole).

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 healthcare company with the mission statement: "Otsuka - people creating new products for better health worldwide." Otsuka researches, develops, manufactures and markets innovative, original products, focusing its core businesses on pharmaceutical products for the treatment of disease and consumer products for the maintenance of everyday health. 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 US \$7.2 billion in consolidated annual revenues in fiscal 2006.

Bristol-Myers Squibb is a global pharmaceutical and related health care 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

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¹ IMS Auditrac NGPS: Abilify total monthly retail prescriptions: Data accessed 11/2006.