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**ABILIFY® (aripiprazole) SUPPLEMENTAL NEW DRUG APPLICATION RECEIVES
PRIORITY REVIEW BY U.S. FOOD AND DRUG ADMINISTRATION FOR
ADJUNCTIVE TREATMENT IN ADULTS WITH MAJOR DEPRESSIVE DISORDER**

(PRINCETON, NJ and TOKYO, JAPAN, July 17, 2007) – Bristol-Myers Squibb Company [NYSE: BMY] and Otsuka Pharmaceutical Co., Ltd. announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing and granted a Priority Review for the supplemental New Drug Application (sNDA) of ABILIFY® (aripiprazole) for the treatment of adults with major depressive disorder as adjunctive to antidepressant therapy (ADT).

Priority Review status for an application or supplement for a drug product is assigned if a product, if approved, would be a significant 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 two six-week, double-blind, randomized, placebo-controlled, multi-center trials (n=743) evaluating the use of adjunctive ABILIFY in adult patients with a primary diagnosis of major depressive disorder who had an inadequate response to monotherapy with one or more ADTs.

About ABILIFY

The first and only available dopamine partial agonist, ABILIFY is 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. ABILIFY is also indicated for the 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. 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 bipolar disorder, manic or mixed or schizophrenia. According to the prescribing information if ongoing ABILIFY therapy is clinically indicated, oral ABILIFY in a range of 10 mg to 30 mg/day should replace ABILIFY Injection as soon as possible.

ABILIFY is available by prescription only. ABILIFY tablets are available in 2-, 5-, 10-, 15-, 20- and 30-mg strengths. ABILIFY DISCMELT™ Orally Disintegrating Tablets are available in 10- 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. The recommended dose is 10 or 15 mg/day for patients with schizophrenia, 15 or 30 mg/day for patients with Bipolar I Disorder and 9.75 mg/1.3mL for patients with agitation associated with schizophrenia or bipolar disorder, manic or mixed. ABILIFY is taken once daily with or without food. The safety of doses of ABILIFY Oral or ABILIFY Injection above 30 mg/day has not been evaluated in clinical trials. 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:

- 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*
- 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*

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

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

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® (aripiprazole) 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 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 Bristol-Myers Squibb and Otsuka Pharmaceutical Co., Ltd.

Bristol-Myers Squibb and Otsuka Pharmaceutical Co., Ltd. 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 US\$7.2 billion in 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 Bristol-Myers Squibb at: www.bms.com

Visit Otsuka Pharmaceutical Co., Ltd. at: www.otsuka-global.com

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