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**ABILIFY[®] (aripiprazole) INJECTION FOR INTRAMUSCULAR USE
FOR ADULTS WITH AGITATION ASSOCIATED WITH
SCHIZOPHRENIA OR BIPOLAR MANIA NOW AVAILABLE**

- Provides Rapid Control of Agitation -

(PRINCETON, NEW JERSEY AND TOKYO, JAPAN, December 12, 2006) – Bristol-Myers Squibb Company (NYSE: BMY) and Otsuka Pharmaceutical Co., Ltd. today announced the launch of ABILIFY[®] (aripiprazole) Injection, an injectable form of ABILIFY, for intramuscular use. ABILIFY Injection provides rapid control of agitation in adults with schizophrenia or bipolar mania at primary endpoint (2 hours). The U.S. Food and Drug Administration (FDA) approved ABILIFY Injection on September 20, 2006.

The urgent nature of acute agitation requires immediate assessment and intervention. ABILIFY Injection 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.

“Acute agitation can be very serious, distressing and potentially dangerous for patients, healthcare professionals and caregivers,” said Michael H. Allen, MD, Director, Emergency Psychiatry, Associate Professor, University of Colorado at Denver and Health Sciences Center’s School of Medicine. “ABILIFY Injection controls agitation independent of sedation.”

Acute Agitation

Acute agitation is a common cause of psychiatric emergencies characterized by a range of behaviors that includes excessive motor and/or verbal activity, irritability, uncooperativeness, verbal outburst or abuse and threatening behavior or language.

Smooth Transition from Injection to Oral Long-Term Therapy

The Prescribing Information for ABILIFY[®] (aripiprazole) Injection instructs that if ongoing ABILIFY therapy is clinically indicated, ABILIFY Oral should replace ABILIFY Injection as soon as possible.

Many physicians state that they would prefer to start with an injectable agent in the acute setting and then transition to the oral formulation of the same agent for long-term disease management. ABILIFY Injection now provides healthcare professionals with the ability to start and stay with ABILIFY in the treatment of schizophrenia or Bipolar I Disorder (manic or mixed). Physicians who elect to use ABILIFY for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual patient.

Clinical Studies

The efficacy of ABILIFY Injection in controlling acute agitation was evaluated in three short-term (24-hour), randomized, double-blind, placebo-controlled studies in patients with schizophrenia (two studies) and bipolar disorder (one study), manic or mixed, involving a total of 1,086 patients. The effectiveness of ABILIFY Injection to control agitation was measured in these studies using several scales, including the Positive and Negative Syndrome Scale Excited Component (PANSS EC) and Clinical Global Impression of Improvement (CGI-I) scale. The primary efficacy measure used for assessing signs and symptoms of agitation was the change from baseline in the PANSS EC at two hours post-injection. PANSS EC includes five items: poor impulse control, tension, hostility, uncooperativeness and excitement.

ABILIFY Injection was statistically superior to placebo (p-value less than 0.05) in all three studies as measured using the PANSS EC. On the primary efficacy measure PANSS EC, the recommended dosage of 9.75 mg of ABILIFY Injection was shown to be effective in controlling agitation.

In two studies in agitated patients with schizophrenia, ABILIFY[®] (aripiprazole) Injection and Haldol[®] (haloperidol) intramuscular, a common conventional antipsychotic frequently used for acutely agitated patients, were compared to placebo. These studies demonstrated that ABILIFY was superior to placebo. Haldol intramuscular, the active comparator, was superior to placebo.

Clinical trial data also have shown that for agitated patients with schizophrenia who transitioned from ABILIFY Injection to ABILIFY 15 mg tablets, improvement was maintained.

ABILIFY Injection and Ativan[®] (lorazepam) Injection, an antianxiety and sedative medication commonly used for the treatment of agitation, were compared to placebo in the study involving agitated patients with Bipolar I Disorder (manic or mixed). In this study, ABILIFY Injection was superior to placebo. Ativan Injection, the active comparator, was superior to placebo.

The most frequently reported adverse events occurring in at least 5% of patients and greater than placebo with ABILIFY Injection were headache (ABILIFY 12% vs placebo 7%), nausea (ABILIFY 9% vs placebo 3%), dizziness (ABILIFY 8% vs placebo 5%), somnolence (ABILIFY 7% vs placebo 4%). In the three ABILIFY Injection trials, the safety profile was comparable to placebo regarding the incidence of Extrapyramidal symptoms (EPS), akathisia or dystonia. Non-akathisia related EPS adverse events were similar for the ABILIFY Injection and placebo groups (2% and 2%, respectively). The incidence of akathisia-related adverse events with ABILIFY Injection was 2% compared to 0% for placebo, while the incidence of dystonia with ABILIFY Injection was less than 1% compared to 0% for placebo. In addition, the incidence of QTc prolongation was also comparable between ABILIFY Injection and placebo.

ABILIFY Injection is intended for intramuscular use only and is available in single-dose ready-to-use vials as a 9.75 mg/1.3 mL (7.5 mg/mL), clear, colorless, sterile, aqueous solution. The recommended dose of ABILIFY Injection is 9.75 mg.

ABILIFY now has one of the broadest ranges of formulations (tablets, non-refrigerated oral solution, orally disintegrating tablets and intramuscular injection) among antipsychotics to help support the individual needs of patients and their healthcare professionals.

About ABILIFY

The first and only available dopamine partial agonist, ABILIFY® (aripiprazole) is 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. 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 for extended periods should periodically re-evaluate the long-term usefulness of the drug for the individual. Initially approved in November 2002, ABILIFY is the fastest-growing atypical antipsychotic in the United States with over nine million prescriptions written through May 2006.

ABILIFY is available by prescription only. ABILIFY tablets are available in 2-, 5-, 10-, 15-, 20- 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 nonrefrigerated oral solution. The safety of doses of ABILIFY above 30 mg/day has 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 for ABILIFY:

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® (aripiprazole)
- **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 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® (aripiprazole).

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 4-6-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, include 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

Treatment-emergent adverse events reported with ABILIFY Injection in short-term (24-hour) trials at an incidence greater than or equal to 5% and greater than placebo, respectively, include headache (12% vs 7%), nausea (9% vs 3%), dizziness (8% vs 5%), and somnolence (7% vs 4%).

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[®] (aripiprazole) in the United States and major European countries.

ABILIFY was discovered by Otsuka Pharmaceutical Co., Ltd. The brand name ABILIFY is registered to 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 87 companies and employs approximately 27,000 people in 17 countries and regions worldwide. Otsuka and its consolidated subsidiaries earned US \$6.8 billion in consolidated annual revenues in fiscal 2005.

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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